



# Corporate Presentation

March 2024



# Forward Looking Statements

This presentation is for informational purposes only and shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities of Beyond Air, Inc. (the “Company”) nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such jurisdiction. The Company files annual, quarterly and other reports with the Securities and Exchange Commission (the “SEC”) including its Annual Report on Form 10-K for the year ended March 31, 2023 (the “Form 10-K”) which was filed on June 22, 2023. You may get these documents for free by visiting EDGAR on the SEC’s website at [www.sec.gov](http://www.sec.gov). For a more complete discussion of the risk factors affecting our business, please refer to the Form 10-K.

Our public communications, including this presentation, and SEC filings, may contain statements related to future, not past, events. These forward-looking statements are based upon current beliefs and expectations of Beyond Air’s management and are subject to significant risks and uncertainties. These forward-looking statements often, but not always, may be identified by the use of words such as “believes,” “estimates,” “anticipates,” “targets,” “expects,” “plans,” “projects,” “intends,” “predicts,” “may,” “could,” “might,” “will,” “should,” “approximately,” “potential” or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

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.

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 or not at all. Although we believe that we have a reasonable basis for each forward-looking statement contained in this 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 this presentation.

# Nitric Oxide: A Simple, Yet Complex Molecule

## We are the Nitric Oxide Company



nitric oxide

- Nitric Oxide (NO) is the combination of nitrogen and oxygen in a specific manner
- NO is a free radical gas that the human body synthesizes from L-arginine via the enzyme nitric oxide synthase (NOS)
- Modulation of NO in the human body can have significant benefits
- Endogenous and exogenous NO are 100% structurally identical and physiologically indistinguishable in the human body
- In nature a lightning strike forms NO

Nitric oxide synthase (NOS) exists in 3 isoforms in the human body and has multiple functions.

Type	Location	Mechanism	Therapeutic Target
<b>Endothelial (eNOS)</b>	Vascular endothelial cells	Vasodilation Vasoprotection Atherosclerosis prevention	Hypoxic respiratory failure: Right ventricular dysfunction
<b>Inducible (iNOS)</b>	Macrophages	Non-specific immune defense Mediation of inflammation Septic shock	Respiratory infection; Solid tumors
<b>Neuronal (nNOS)</b>	Neuronal tissue	Neuronal function	Autism

# Our Mission: Harness the Power of Nitric Oxide

We are developing the ability to transition between the **ICU**, whole **hospital** and the untapped **home** market



**Beyond Air's robust active pipeline of products targets the following conditions:**

- ✓ Hypoxic respiratory failure
- ✓ Right ventricular dysfunction
- ✓ Respiratory infection
- ✓ Cancer
- ✓ Autism spectrum disorder

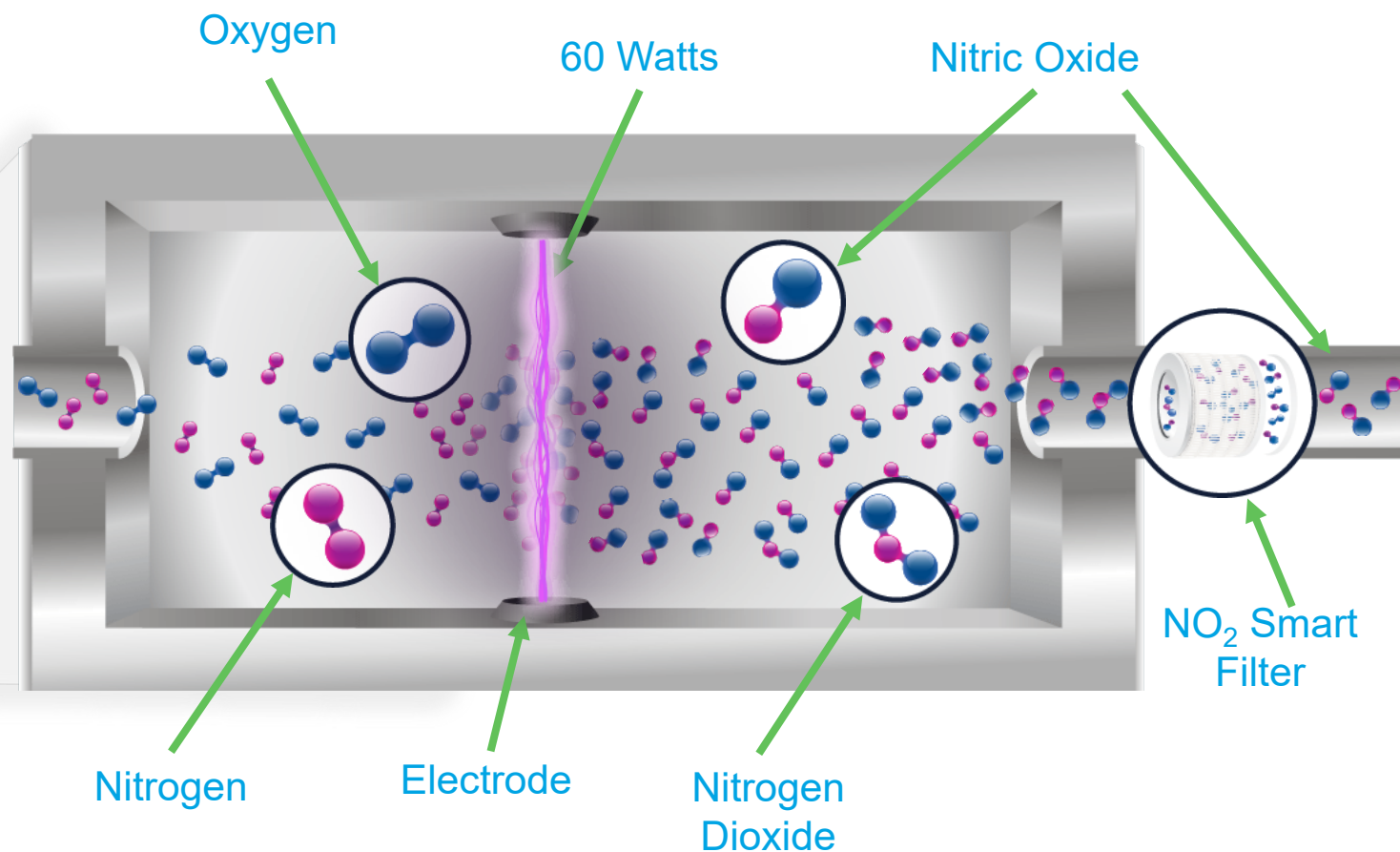
**Beyond Air Is The World's Leading Nitric Oxide Company**

# Introducing the LungFit PH with our Patented Ionizer™ Technology

The LungFit® PH is the first and only FDA approved system with patented **ionizer technology** that generates nitric oxide using room air, enabling the delivery of **unlimited, on-demand nitric oxide** regardless of dose or flow.



Main and Backup Ionizers



For illustrative purposes.

# Innovative LungFit® Platform Elicits Paradigm Shift for Nitric Oxide Therapy

Our revolutionary LungFit® technology platform generates nitric oxide (NO) on-demand from ambient air and safely delivers it to patients to treat a variety of lung diseases

The LungFit® Systems are designed by the same inventors who developed the first nitric oxide delivery system and other systems in use worldwide



**LungFit® PRO**

### Hospital Setting

High concentration nitric oxide to treat viral community acquired pneumonia (including COVID-19) and bronchiolitis+



**LungFit® PH**

### Hospital NICU Setting

Low concentration nitric oxide for the treatment of term and near-term neonates with hypoxic respiratory failure\*



**LungFit® GO**

### At-Home Treatment

High concentration nitric oxide for the treatment of NTM and lung infections in patients with underlying COPD+

\*Commonly referred to as persistent pulmonary hypertension of the newborn or PPHN.

+Caution: LungFit® PRO and LungFit® GO are investigational devices, limited by federal (or United States) law to investigational use. High concentration iNO is defined as >80 ppm to <400 ppm. Low concentration is ≤80 ppm.

# Robust, Active LungFit<sup>®</sup> Pipeline





Device	Therapeutic Area	Preclinical	Pilot	Pivotal	PMA	Commercial	Next Milestone*	Partners <sup>1</sup>
<b>LungFit<sup>®</sup> PH</b> Hospital NICU Setting Low-concentration iNO ( $\leq 80$ ppm) for pulmonary treatments	Persistent pulmonary hypertension of the newborn (PPHN)	[Progress bar: Preclinical to Commercial]					US FDA approved CE Mark – 1H 2024	
	Cardiac surgery	[Progress bar: Preclinical to PMA]					PMA approval 2H 2024	
<b>LungFit<sup>®</sup> PRO</b> Hospital Setting High-concentration iNO (150 to 400 ppm) for antimicrobial treatments	Viral Community-Acquired Pneumonia (VCAP) including COVID-19; Bronchiolitis	[Progress bar: Preclinical to Pilot]					US VCAP pilot study ongoing with pivotal study planned for 2025/2026 winter	
<b>LungFit<sup>®</sup> GO</b> At-Home Treatment High-concentration iNO (80 to 400 ppm) for antimicrobial treatments	Nontuberculous mycobacteria (NTM) lung infection; Severe exacerbations due to lung infections in COPD patients	[Progress bar: Preclinical to Pilot]					Discuss pivotal trial design w/ FDA in 2024	
						COPD pilot TBD based on strategic priorities		

(\*) All dates are calendar year, and based on projections and appropriate financing, anticipated first launch on a global basis pending appropriate regulatory approvals

(1) Getz Healthcare is our commercial partner in 10 Asian countries (not including Japan) and is recognized as the leading distributor of medical equipment, devices, and consumables, in Asia Pacific





The Cystic Fibrosis Foundation provided us with a grant of up to \$2.17 million to help fund the completed trial of LungFit GO to treat NTM pulmonary disease in Australia

# Drug NO Candidates

	Drug Therapeutic Area	Preclinical   Ph 1   Ph 2   Ph 3   NDA   Commercial   Next Milestone <sup>(*)</sup>
<b>nNOS Inhibitor</b> (neuronal nitric oxide synthase inhibitor)	Autism spectrum disorder (ASD)	 First-in-human data anticipated in 2025
	Other nNOS related neurological disorders	



Ultrahigh concentration NO >10,000 ppm to treat multiple types of solid tumors.  
For more information, visit [beyondcancer.com](https://beyondcancer.com)

Monotherapy	Drug Therapeutic Area	Preclinical   Ph 1   Ph 2   Ph 3   NDA   Commercial   Next Milestone <sup>(*)</sup>
UNO	Cutaneous/ near cutaneous tumors	 Phase 1a full dataset mid 2024
UNO	Multiple solid tumors	
Combination Therapy		
UNO + anti-PD-1	Multiple solid tumors	
UNO + anti-CTLA-4	Multiple solid tumors	



# Large Market Opportunities

## PPHN Opportunity:

7.5k cases in US<sup>1</sup>  
ex-US Includes PPHN & Cardiac Patients

LungFit<sup>®</sup> PH

>\$350M

>\$700M

## Annual Viral Pneumonia Hospitalizations:

350k US<sup>2</sup>  
16M ex-US<sup>3</sup>

LungFit<sup>®</sup> PRO

>\$1.5B

>\$3B

## Annual Bronchiolitis Hospitalizations:

120K US<sup>4</sup>  
3.2M ex-US<sup>4,5</sup>

LungFit<sup>®</sup> GO

>\$500M

>\$1.2B

## Total Refractory NTM Patient Populations:

15K US<sup>6</sup>  
4k EU<sup>5,7</sup>  
15k Japan<sup>8</sup>

Programs not using LungFit >>>

<< US\$ Sales Potential

<< WW\$ Sales Potential

BEYOND  
CANCER<sup>™</sup>  
Next Level ImmuNO-oncology

Solid Tumor Program

>\$37 Billion Global Checkpoint Inhibitor Market in 2022 and Growing<sup>10</sup>

The cost of caring for Americans with ASD is expected to be >\$460b by 2025<sup>11</sup>

Autism Spectrum Disorder (ASD)

- 1) Lakshminrusimha et al. Neoreviews. 2015;16(12):e680–92.
- 2) NCHS, National Hospital Ambulatory Medical Care Survey, 2017. CDC.
- 3) Rudan et al. WHO Child Health Epidemiology Reference Group. Bull World Health Organ. 2004 Dec;82(12):895-903.
- 4) Hall et al. . N Engl J Med. 2009;360(6):588–598.
- 5) UNICEF
- 6) Winthrop et al. Ann Am Thorac Soc, 17 (2020), pp. 178-185
- 7) Ringshausen et al. . Emerg Infect Dis. 2016;22(6):1102-1105. doi:10.3201/eid2206.151642
- 8) Izumi et al. Ann Am Thorac Soc. 2019 Mar;16(3):341-347. doi: 10.1513/AnnalsATS.201806-366OC. PMID: 30339468.
- 9) Jinjuvadia, Chetna et al. . COPD. 2017;14(1):72-79.
- 10) Company Presentations and Regulatory Filings from Bristol-Myers Squibb , Merck , Roche, AstraZeneca, Pfizer, Regeneron ; Sanofi 2011-2020.
- 11) Leigh JP et al., J. Autism Dev. Disord., 2015

# Financial and Patent Information

## Financial Overview

Ticker	XAIR
Exchange	NASDAQ
Share Price	\$1.87 (as of Feb. 9, 2024)
Shares Outstanding	36 million

## As of December 31, 2023

Cash, Cash Equivalents & Restricted Cash	\$31.3 million
Debt	\$17.5 million
Expected quarterly burn approximately	\$10M

Revenue Guidance for fiscal year 2025  
**\$12 - \$16 million**

>15 issued patents expiring through 2040  
>10 pending patent applications, if issued, may extend expiration through **2044**

Patent portfolio is strong and broad, including but not limited to.....

- The NO generator
- The breathing circuit
- NO delivery system
- NO<sub>2</sub> filter (utility and design)
- NO concentration
- NO action in the body
- NO dosing





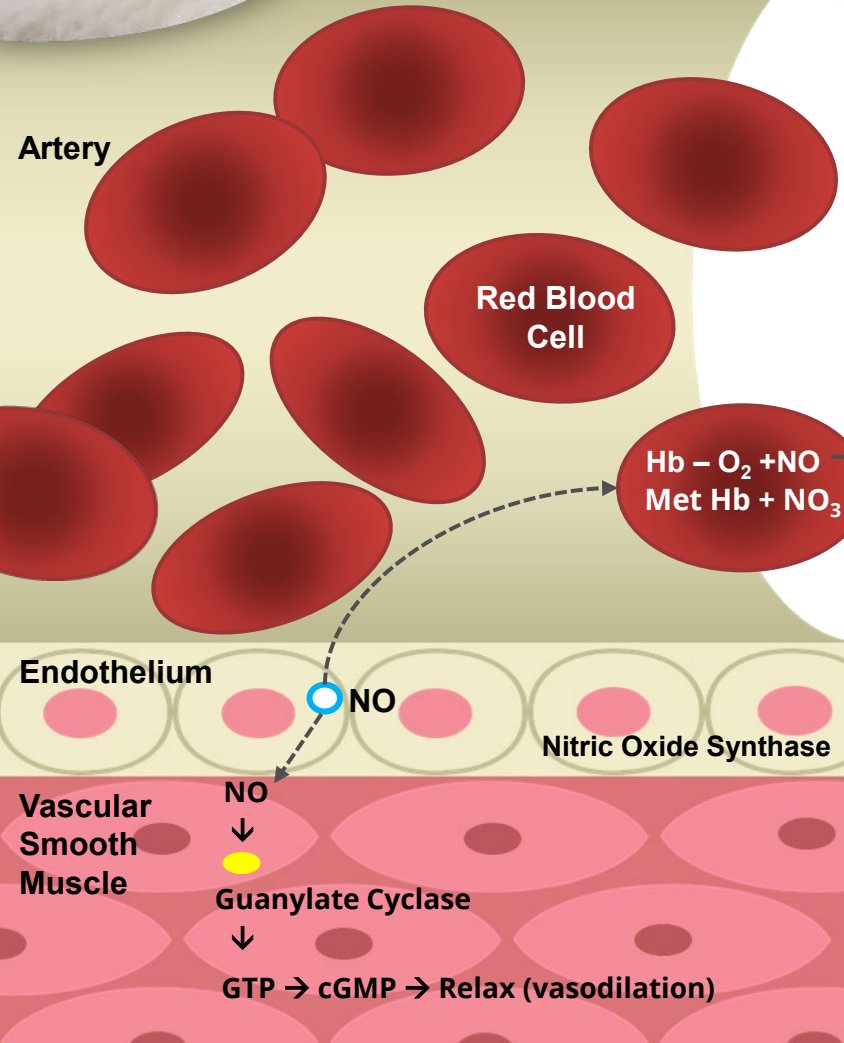
# Persistent Pulmonary Hypertension of the Newborn (PPHN)\*

LungFit® PH offers significant advantages to hospitals

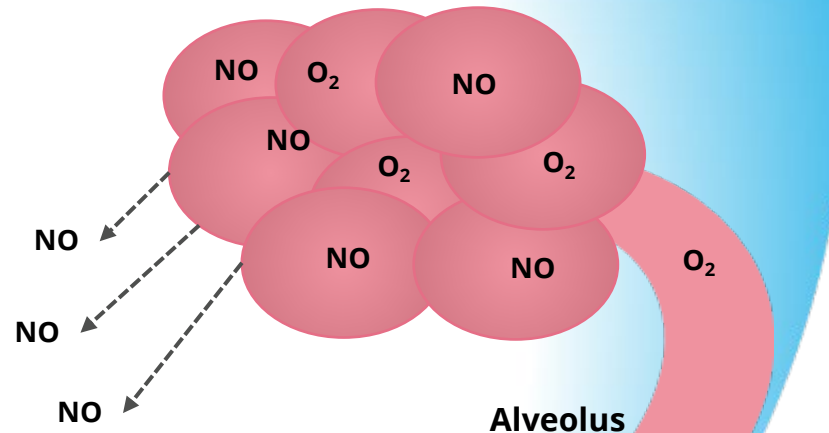
**LungFit® PH**

\*PPHN is commonly used to refer to the condition treated with NO. The actual labelled indication is to improve oxygenation and reduce the need for extracorporeal membrane oxygenation in term and near-term (>34 weeks gestation) neonates with hypoxic respiratory failure associated with clinical or echocardiographic evidence of pulmonary hypertension in conjunction with ventilatory support and other appropriate agents.

# 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>

In PPHN NO reversal of pulmonary hypertension decreases right-to-left shunt through patent foramen ovale (PFO) and patent ductus arteriosus (PDA), dramatically improving oxygenation



## Cardiac Surgery<sup>3</sup>

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

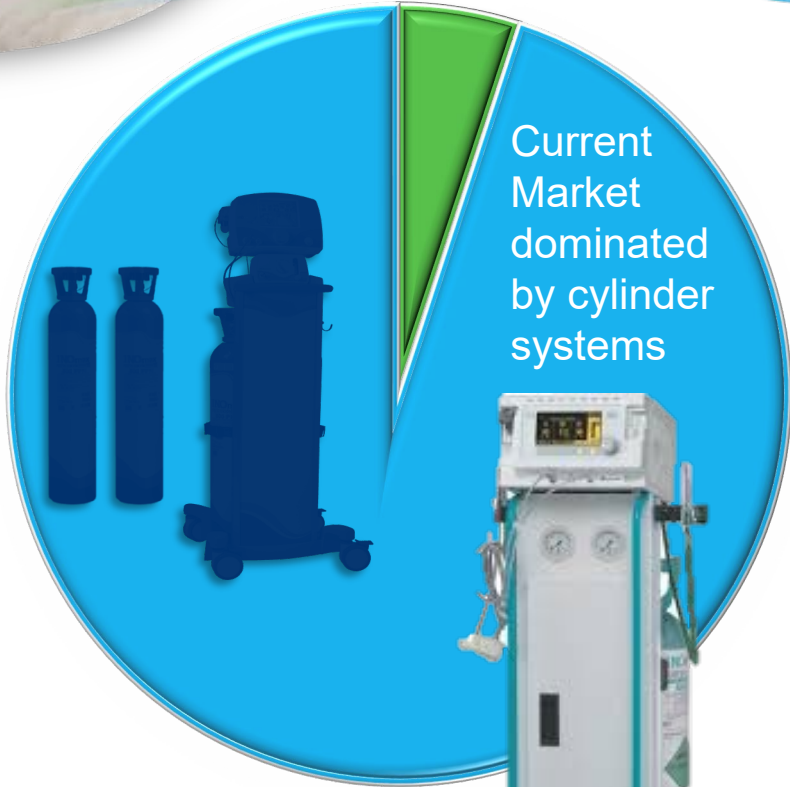


*\*not on label in the US*

1) Inhaled Medical Gases: More to Breathe Than Oxygen, Michael A Gentile, Respiratory Care September 2011, 56 (9) 1341-1359  
 2) Persistent Pulmonary Hypertension of the Newborn, Satyan Lakshminrusimha and Martin Keszler, NeoReviews December 2015, 16 (12) e680-e692;  
 3) Left ventricular heart failure and pulmonary hypertension, October 2015, European Heart Journal 37(12)



# Nitric Oxide U.S. Market Dynamics



LungFit<sup>®</sup> PH is the FDA PMA approved state of the art system transforming NO use in the hospital



1999



2018



2019



2022

*All You Need Is Air<sup>™</sup>*

Images sourced from company websites.



# LungFit® PH: The Power to Transform iNO Care

LungFit® PH is the first and only FDA approved system to generate and deliver **unlimited, on-demand, nitric oxide using room air**



*All You Need Is Air™*



## Fast, Precise, Simple

Power on, generate, and deliver iNO within 1 minute.



## No Cylinders.

No handling and storing bulky 42 lb cylinders.



## Simple Pre-use

No pressure Testing, manual purging or potential NO<sub>2</sub> exposure due to leaks.



## iNO on Demand

Unlimited generation of nitric oxide from room air, regardless of dose or flow.





# Beyond Air Smart Filter vs. Cylinder

## LungFit® PH: Revolutionary, Smart Design

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

Filters are a fraction of the cylinder size

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

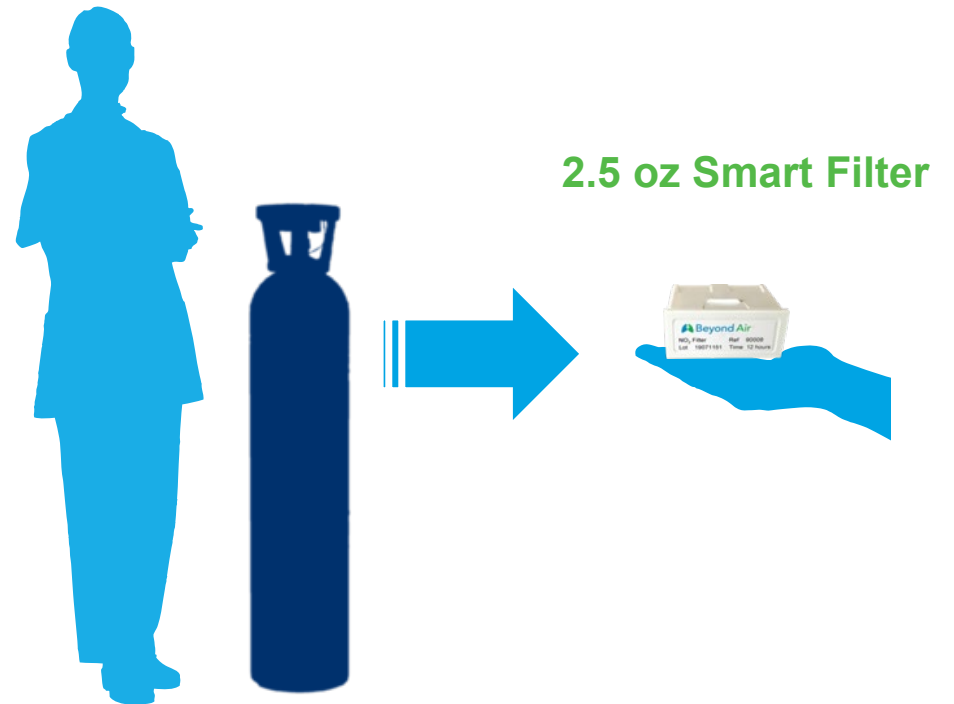
Smart filter (with RFID chip)

- Measures time until filter change required
- Recognition – LungFit® will not function without smart filter
  - 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 hospital only charged for what is used

- Each filter lasts 12 hours regardless of dose or flow

Standard 42-pound  
Cylinder



\*not displayed to scale



# Our Innovation Provides Significant Advantages to Hospitals

## Improved Operating Economics for the Hospital

### Save Time

Reduced training time due to simplicity of LungFit PH and elimination of tanks

Inventory management dramatically simplified with elimination of cylinders

### Safety

Lower risk of physical injury as vent connections conveniently located and weight vastly reduced

Risk of NO<sub>2</sub> exposure decreased via Smart Filter and auto-purging

### Save Space

No need for special storage conditions

Physical storage footprint nearly extinguished



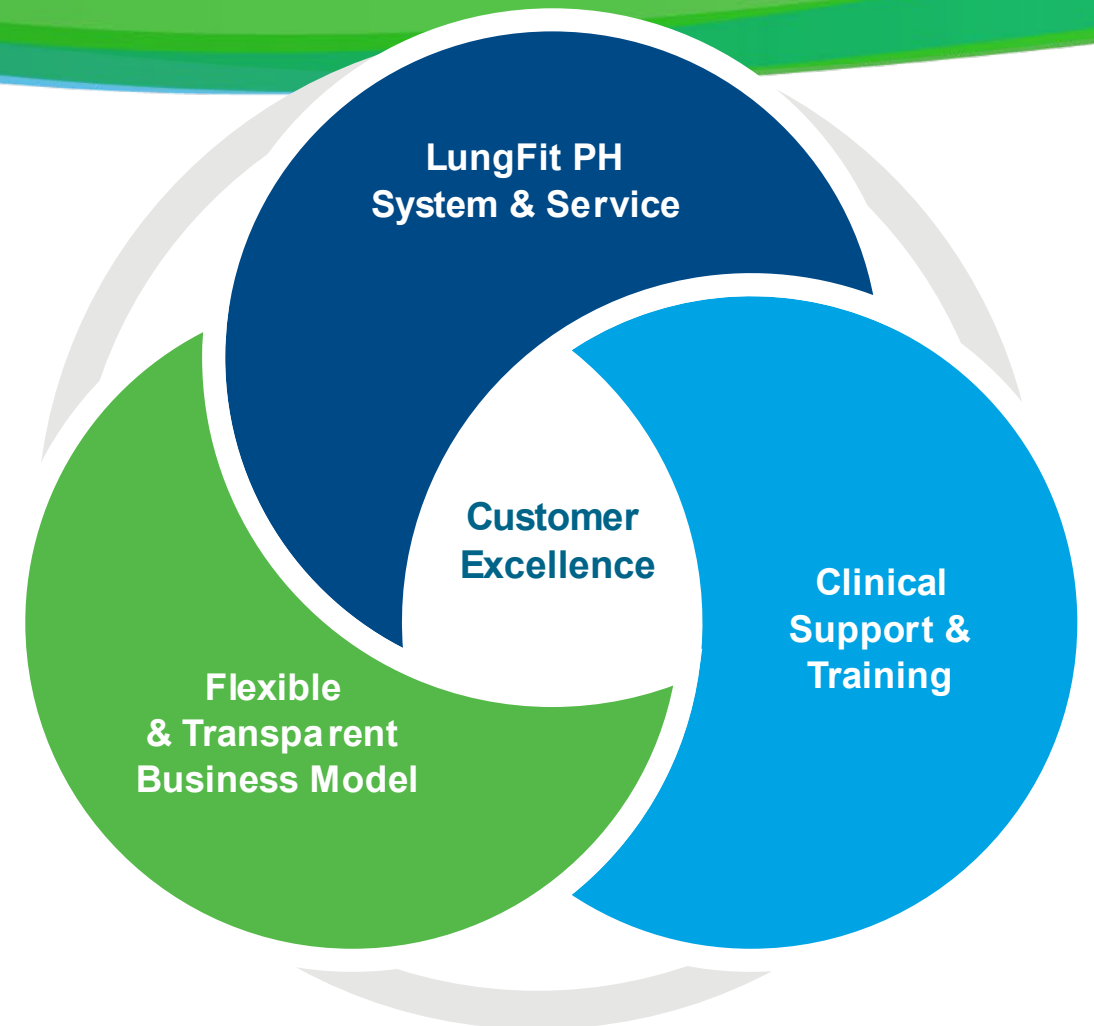
# An All-Inclusive Partnership

**LungFlex™**

24/7 Partnership & Support

## Exceeding your expectations with:

- ✓ All-inclusive contract—LungFit® PH Systems, backup systems, and accessories, creating budget certainty
- ✓ 24/7 live customer service and support (technical, clinical, commercial)
- ✓ **LungFlex Rapid Replacement Program**—Emergency deliveries within 6 hours\*
- ✓ Convenient ordering for all components with first priority overnight deliveries
- ✓ On-demand, on-site clinical expertise and support
- ✓ Comprehensive live on-demand training customized to the hospital's needs



**LungFlex 24/7 Service and Support Line**  
1-855-LUNG-FLX or 1-855-586-4359

LungFit® PH

\*LungFlex Rapid Replacement Program response times are based on hospital locations. While every effort is made to accommodate emergency deliveries within 6 hours of request, some hospital locations may take longer.



# LungFit PH Awarded Vizient Innovative Technology Contract

***Vizient Innovative Technology contracts are only awarded for products that bring improvement to the health care industry***

- It signifies to Vizient members that the ***LungFit PH has unique qualities*** that may enhance:
  - ✓ Clinical care
  - ✓ Patient safety
  - ✓ Health care worker safety
  - ✓ Improve business operations
- A product with this Innovative Technology designation may be awarded a contract outside of the competitive bid cycle

***VIZIENT is the nation's largest member-driven health care performance improvement company***

- ✓ Services approximately 60% of the nation's acute care hospitals
- ✓ Serves approximately 97% of the nation's academic medical centers
- ✓ > \$100 billion in annual member purchase volume, the industry's largest

# Harnessing the Power of Nitric Oxide



Built on a Legacy of Innovation

# LungFit® For Treating Lung Infections

## Simple, safe and convenient

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

## Easy to Use

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

## Portable

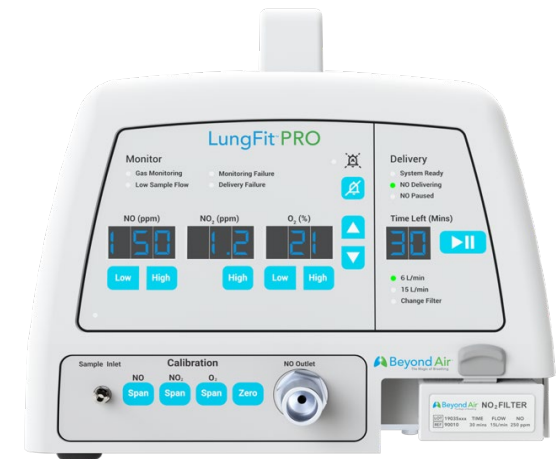
- Only 20 lbs (home version may be lighter)

## One system can treat multiple patients

- Easy to change breathing circuit
- One circuit per patient
- One filter per treatment

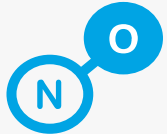
## One Respiratory Therapist (RT) can operate multiple systems

- Insert filter and press “GO”
- Alarms monitor performance



# High Concentration NO – Beyond Air Demonstrated Safety in Humans

**5,000+**



Treatments  
Administered

**170+**



Patients  
Treated

**12**



Different  
Clinical Settings

**0**

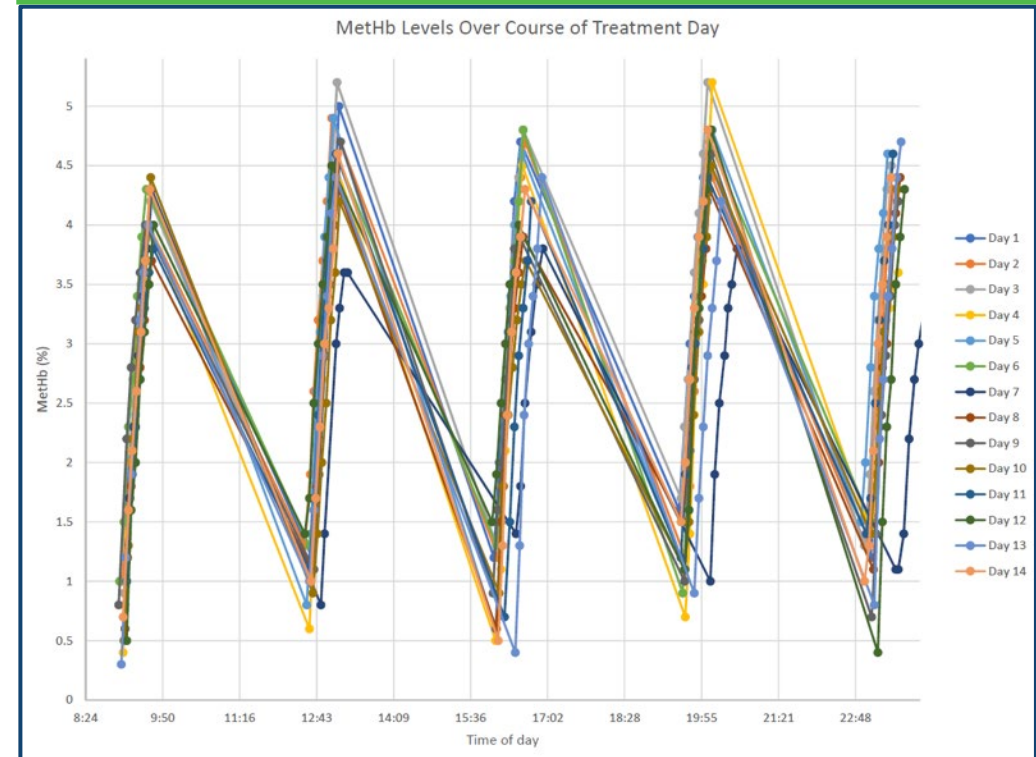
Serious Adverse  
Events Related to NO

- Beyond Air has 10+ 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
- Multiple animal studies in 2 species show intermittent dosing up to 400 ppm NO to be safe with no macroscopic or microscopic findings

# Intermittent Dosing Key to Safe Administration of High Concentration NO

- Methemoglobin (MetHb) is a well-known biomarker for safety of NO; with the acceptable safety threshold <10%
- Methemoglobinemia is a condition where higher-than-normal levels of MetHb are found in the blood, causing too little oxygen to be delivered to the cells of the body
- An intermittent dosing regimen allows for high concentration NO to be administered without negative side effects, specifically addressing concerns of methemoglobinemia
- In the clinical study, MetHb levels followed a predictable pattern, rising during NO administration and falling back to normal, baseline levels shortly after the administration was stopped

## NTM Compassionate Use – 160 PPM NO



MetHb levels of 5 NO administrations (160 ppm every 4 hours) in 1 subject for 14 days



# Viral Community- Acquired Pneumonia in Hospitalized Patients

Nitric oxide has demonstrated antiviral and broad-spectrum antimicrobial activity

LungFit<sup>®</sup> PRO

# Viral Lung Disease Overview



Vaccines are not available for all causes of pneumonia

## Viral Community-Acquired Pneumonia (VCAP)

- Influenza virus is the most common cause of viral pneumonia in adults<sup>1</sup>
- Other viruses that cause viral pneumonia include<sup>1</sup>: varicella-zoster virus, respiratory syncytial virus (RSV), human metapneumovirus, adenoviruses, picornaviruses, and coronaviruses
- Antibiotics are used for the bacterial causes of pneumonia, but are ineffective for viral causes<sup>2</sup>

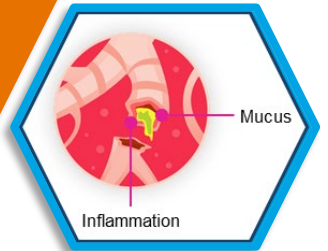
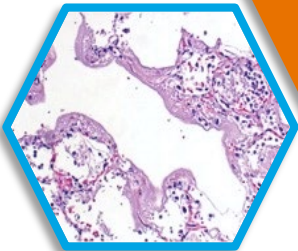
## Benefits of Nitric Oxide

- Nitric Oxide has broad-spectrum activity
  - Preclinical studies show high dose NO has antibacterial and antiviral properties<sup>3-4</sup>
  - Four prior human pneumonia studies completed by Beyond Air and shown on later slides
- Pulmonary vasodilatory properties
  - FDA/EMA approved for ~20 years

## Bronchiolitis

- RSV is the most common cause of bronchiolitis in children<sup>5</sup>
- Usually affects children <2 years, with a peak in infants aged 3-6 months<sup>6</sup>
- Leading cause of infant hospitalizations, accounting for >120,000 hospitalizations with a direct cost of at least \$550 million each year<sup>6</sup>

Leading cause of childhood mortality



1) Cesario T., Viruses Associated With Pneumonia in Adults, Clinical Infectious Diseases, V. 55, I. 1, 1 July 2012, Pgs 107–113  
2) American Thoracic Society- Top 20 Pneumonia Facts 2019 ([here](#))  
3) Saura, M., et al., An antiviral mechanism of nitric oxide: inhibition of a viral protease. Immunity, 1999. 10(1): p. 21-8  
4) Wink DA et al., Chemical biology of nitric oxide..” Free Rad Biol Med 1998; (4-5): 434-56.  
5) Piedimonte G, et al. Respiratory syncytial virus infection and bronchiolitis. Pediatr Rev. 2014; 35(12):519-30  
6) Hasegawa et al. Trends in bronchiolitis hospitalizations in the United States, 2000-2009. Pediatrics 2013, 132(1):28-36.





# Viral Community-Acquired Pneumonia (VCAP) US Pilot Study Design

## Pilot Clinical Trial in the United States (FDA IDE approved)

- Multicenter, randomized, double blind, placebo controlled study of adult patients hospitalized with VCAP, including COVID-19
- Primary Endpoint is Safety
- Exploratory efficacy endpoints include:
  - Mortality, Progression to non-invasive ventilation or intubation, Oxygen free hours, Improvement of signs and symptoms
- 1:1 randomization of up to 50 patients
  - Nitric oxide provided by LungFit PRO plus standard supportive therapy (SST) vs placebo plus SST

## Pilot Study May Extend Over 2 Seasons

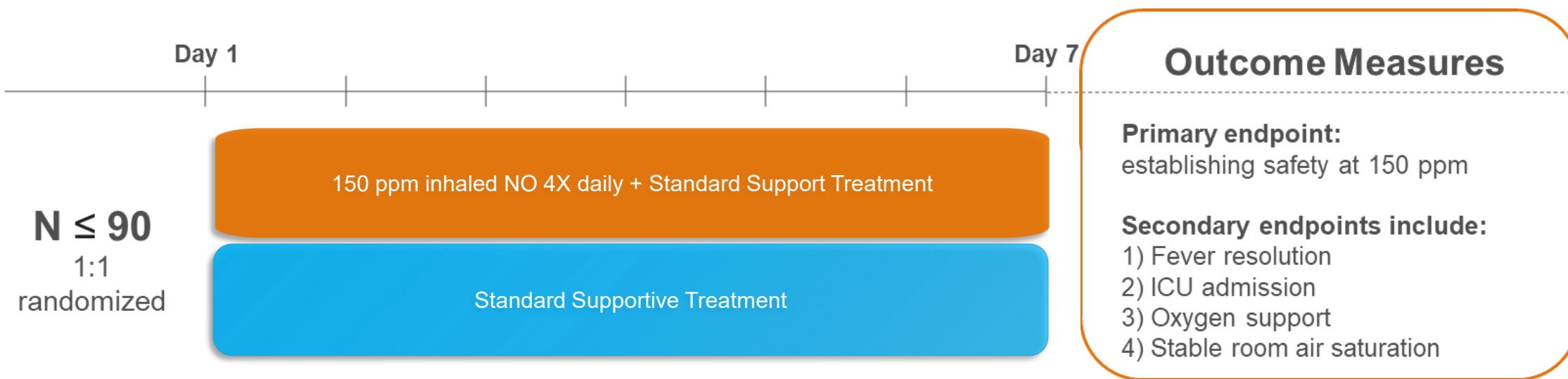
**Registration Study Targeted for 2025/2026 Season**

*The following slides illustrate our strong efficacy and safety profile from four previous studies*

# Viral Community-Acquired Pneumonia (VCAP) Pilot Study Design

## Pilot Clinical Trial in Israel

- ✓ Commenced enrollment in November 2020
- ✓ Interim data presented at ATS 2021
- ✓ Additional data presented at ECCMID 2022
- Multicenter open label study of adult patients hospitalized with VCAP, including COVID-19
- Objective: establish 150 ppm NO is safe and tolerable in target patient population



# 150 PPM NO Evaluated in VCAP (including COVID-19) Pilot Study

Results Presented at the European Congress of Clinical Microbiology & Infectious Diseases in 2022

Intent to Treat Population: 35 subjects (16 iNO + SST vs 19 SST)

Adverse Events	SST	LungFit- 150 ppm NO+SST
Any AE	9 (47%)	13 (81%)
Any AE drug/device related*	0	0
Any SAE	0	2 (13%)
Any SAE drug/device related*	0	0
Any AE (moderate or severe)	3 (16%)	3 (19%)
Any AE (moderate or severe) drug/device related*	0	0

\*including possibly and probably related

## iNO treatment with LungFit<sup>®</sup> PRO was well tolerated

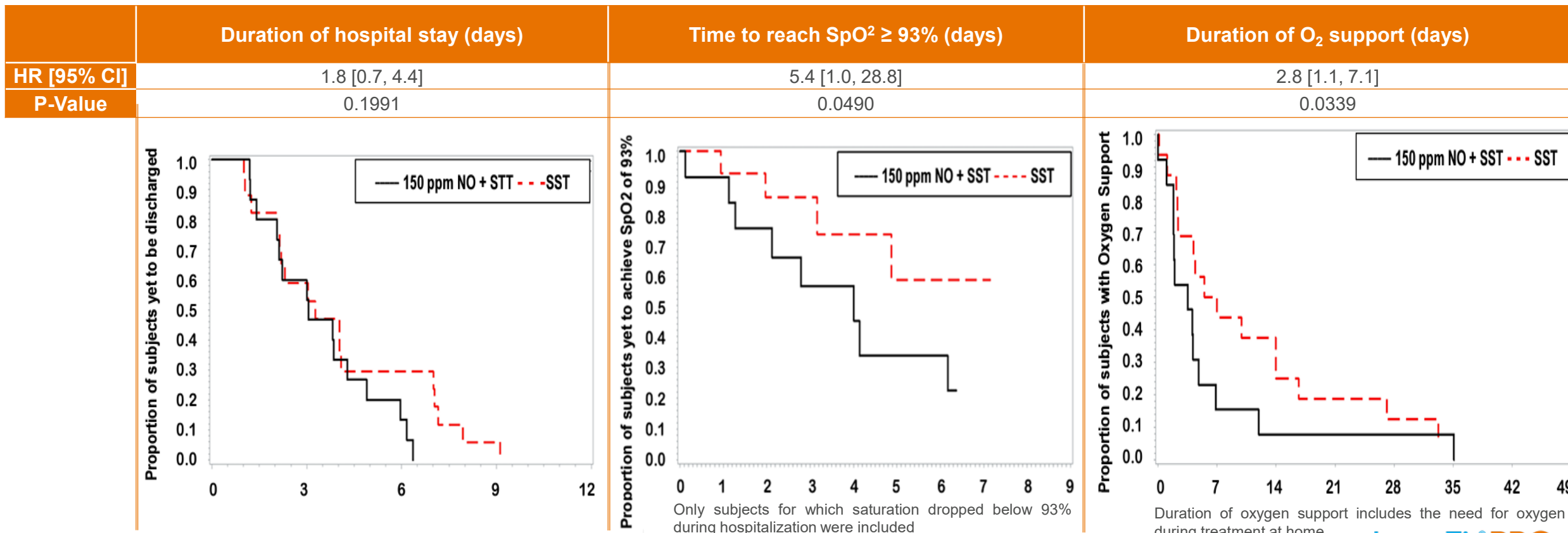
- *No treatment was discontinued due to AE or discomfort*
- No clinically significant differences were noted in respiratory rate, heart rate or blood pressure when compared between pre and end of inhalation
- MetHb levels were below 6.8% at all times (10% limit)
- NO<sub>2</sub> levels were below 4.4 ppm at all times (5 ppm limit)

Baseline Characteristics	SST	LungFit- 150 ppm NO+SST
O2 required %	68.4	62.5
Cardiac disorders %	10.5	12.5
Metabolic disorders %	47.4	43.8
Respiratory disorders %	21.1	12.5
Vascular disorders %	21.1	50.0

# VCAP (including Covid-19) Efficacy Data

Efficacy Data show Strong Trends in Favor of NO (97% of subjects were Covid-19)

Intent to Treat Population: 35 subjects (16 iNO + SST vs 19 SST)



# NO Safe & Well Tolerated in Bronchiolitis Studies

Pooled Safety Results Presented at American Thoracic Society International Conference 2021

	SST (N=82)		85 ppm NO + SST (N=32)		150 ppm NO + SST (N=29)		160 ppm NO + SST (N=55)		All (N=198)	
	N	%	N	%	N	%	N	%	N	%
<b>Any AE</b>	45	54.9%	20	62.5%	18	62.1%	25	45.5%	108	54.5%
<b>Any SAE</b>	10	12.2%	1	3.1%	3	10.3%	11	20.0%	25	12.6%

150 – 160 PPM NO treatment administered intermittently was generally safe and well tolerated across the three pilot trials, with the adverse event rates similar among treatment groups

# Long-Term Safety Data Supports High Concentration NO

## Long-Term Safety Results Presented at Pediatric Academic Societies 2022 Meeting

### Subjects re-hospitalized for bronchiolitis related outcomes

Treatment/ Control Group	Subjects Re-hospitalized (N)	Total Subjects (N)	Incidence Rate (95% CI)%	Patient Exposure Years*	Rate per 100 PEY (95% CI)
SST	6	39	15.39 (5.86 to 30.53)	143.0	<b>4.20</b> (1.60 to 8.33)
85 PPM iNO + SST	1	24	4.17	38.0	<b>2.63</b>
150 PPM iNO + SST	1	20	5.00	32.4	<b>3.09</b>
160 PPM iNO +SST	2	18	11.11 (1.38 to 34.71)	90.6	<b>2.21</b> (0.27 to 6.90)

\*PEY=Patient Exposure Years, It is anticipated that the follow-up time when subjects completed the original studies to this current study will be different for different subjects. It is, therefore, necessary to calculate the patient year (PEY) which is the summation of the time (in years) from original study completion date to date of participation in the current study

- The multi-center study for longitudinal data collection was designed to evaluate the long-term effect of inhaled NO treatment in infants who participated in three pilot studies conducted between 2012-2020 and were given 85 – 160 PPM inhaled NO intermittently
- A total of 198 infants participated in the 3 studies, with 101 infants participating in long-term follow-up study
- Study concludes that the treatment of hospitalized infants with acute bronchiolitis by intermittent high dose NO show a favorable long-term safety profile and support further development of high concentration NO in this population

# 150 PPM NO is Minimum Therapeutic Dose for Patients Hospitalized due to Viral Infection

Data Presented at CHEST 2020 – Statistical Significance on both the Primary & Secondary Endpoint at 150 PPM

## Third Bronchiolitis Pilot Study Results

	150 ppm vs. 85 ppm	150 ppm vs. SST	85 ppm vs. SST
<b>Primary endpoint: 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
<b>Secondary Endpoint: 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



# Nontuberculous Mycobacteria

Expanding Nitric Oxide into the  
Home Market for Lung Infections

LungFit® GO

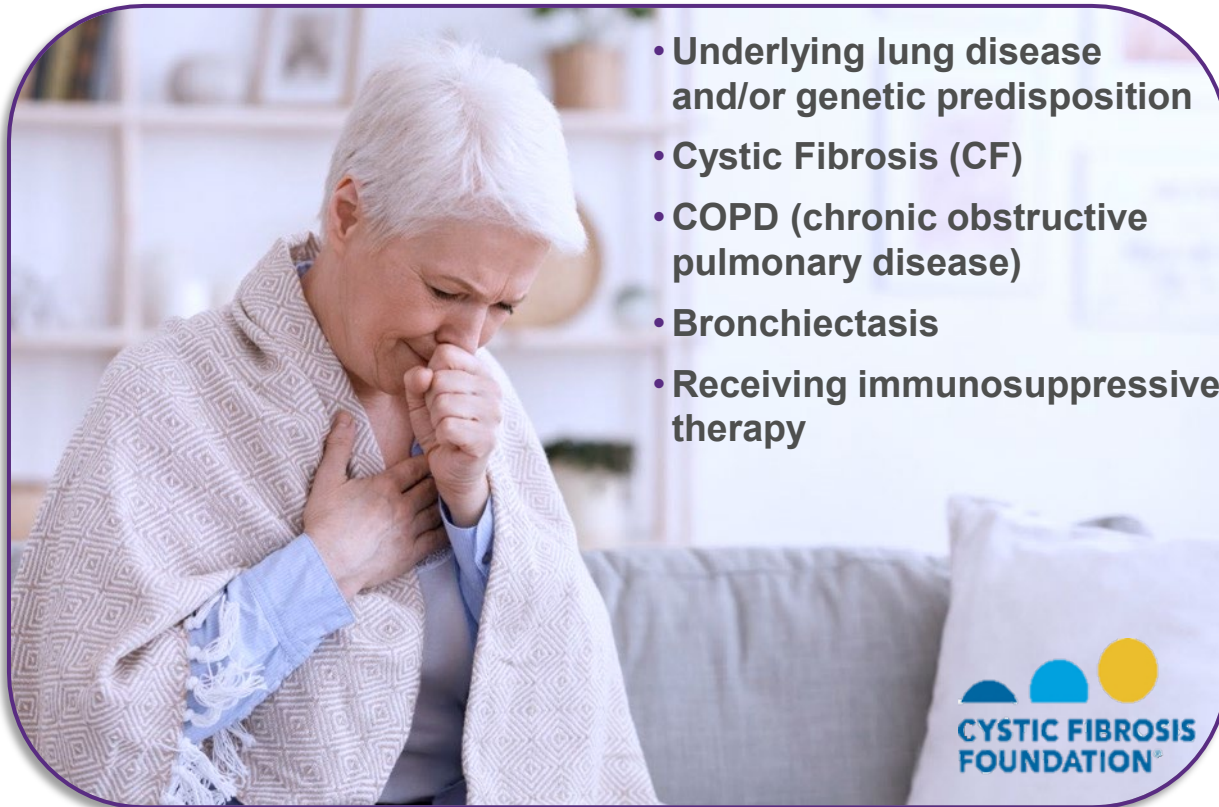


# Nontuberculous Mycobacteria (NTM) Overview

## • Who is at risk?

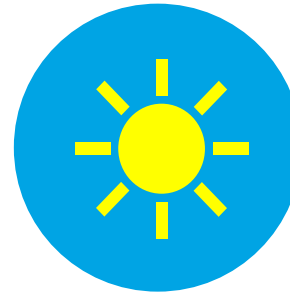
Immunocompromised people are at a greater risk for NTM

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

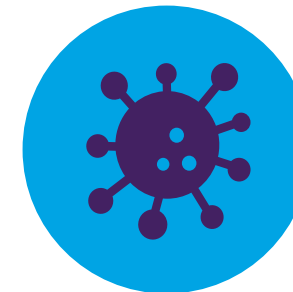


## How is NTM acquired?

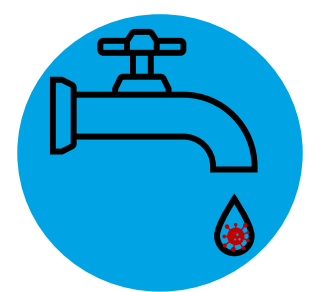
NTM is commonly found in water sources, with warmer climates having higher infection rates



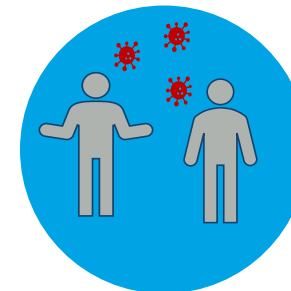
Gulf States account for 70% of annual NTM cases in the United States<sup>1</sup>



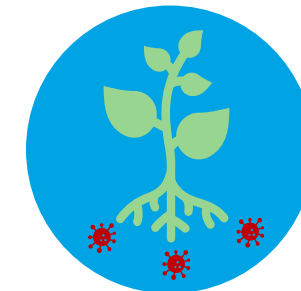
NTM is caused by 120+ species of bacteria



US study across 25 states showed that NTM bacteria were found in nearly 8 out of 10 water samples<sup>1</sup>



Patient to patient transmission is possible



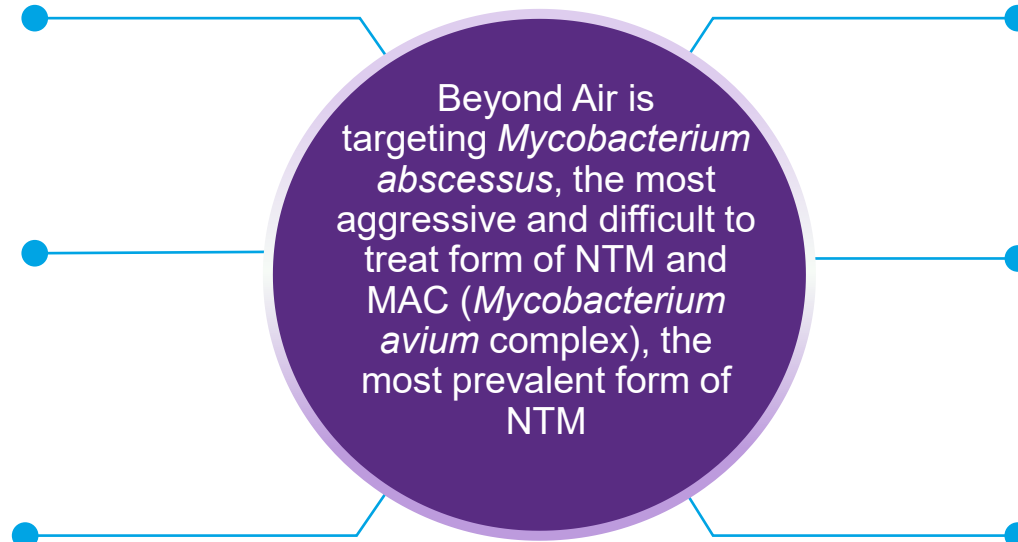
Bacteria live in soil from parks, gardens, and environment

# Home Market: NTM Market Dynamics

There are a limited number of players in NTM

Median survival for MAC is 13 years while for non-MAC NTM it is 4.6 years<sup>1</sup>

Patients with COPD and NTM experienced a 1.43x increased risk of all-cause mortality vs patients with COPD alone<sup>3</sup>



Significant undiagnosed NTM patient population

NTM costs estimated at \$1.7 Billion<sup>2</sup> with *M. abscessus* costs > 2x MAC costs

37% of NTM confirmed Cystic Fibrosis patients in the US are *M. abscessus*<sup>4</sup>

1) Kotilainen, H. et al. "Clinical Findings in Relation to Mortality in Non-Tuberculous Mycobacterial Infections..."European Journal of Clinical Microbiology & Infectious Diseases 34.9 (2015)

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

3) Pyarali FF, Schweitzer M, Bagley V, et al. Increasing non-tuberculous mycobacteria infections in veterans with COPD and association with increased risk of mortality. Front Med (Lausanne). 2018;5:311.

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

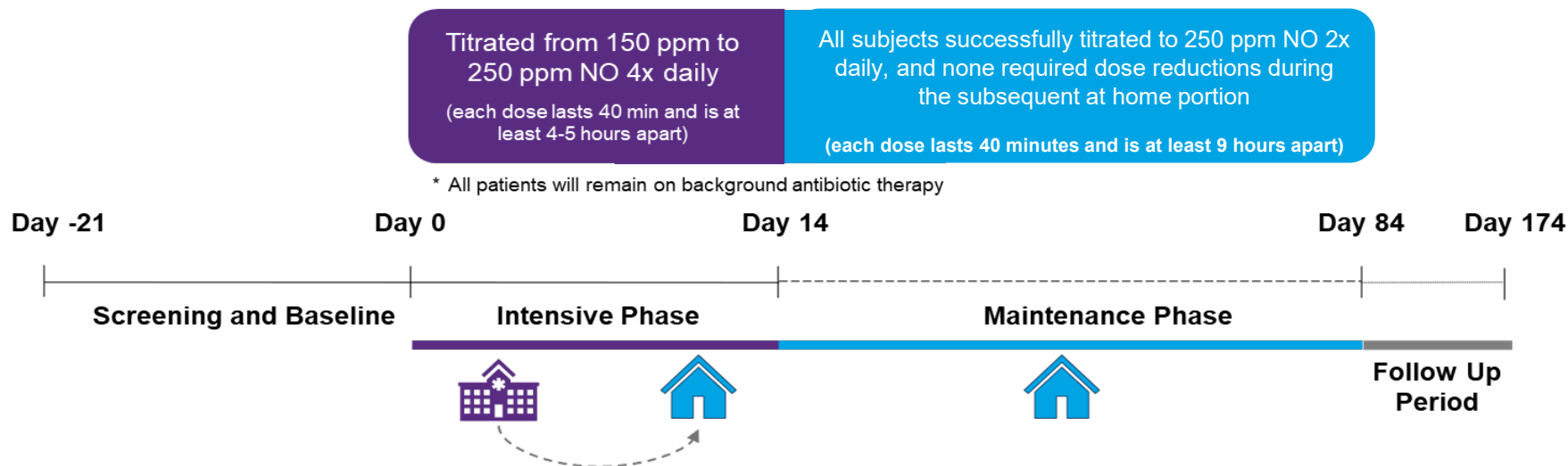
# Pilot LungFit<sup>®</sup> NTM Study Protocol Summary



## Pilot Clinical Trial In Australia

- ✓ Received grant for up to \$2.17 million from the Cystic Fibrosis Foundation to help fund pilot study
- ✓ Data presented at the CHEST Conference on October 17, 2022
  - 12-week, single-arm, multicenter study of 15 adult Cystic Fibrosis (CF) or non-CF bronchiectasis patients with refractory NTM lung infections including *Mycobacterium avium* complex (MAC) and *Mycobacterium abscessus* complex (MABSC)

Baseline Demographics		
	<b>N</b>	<b>15</b>
Age (yrs.)	Mean	62.1 (15)
Gender	Male	3
NTM species	MABSC	4
	MAC	9
	Other	2



**Outcome Measures**

**Primary endpoint:**  
establishing safety at 250 ppm

**Secondary endpoints include:**

- 1) Culture conversion/bacterial load
- 2) Quality of Life
- 3) Respiratory function
- 4) Physical function (activity tracker, 6MWT, etc.)

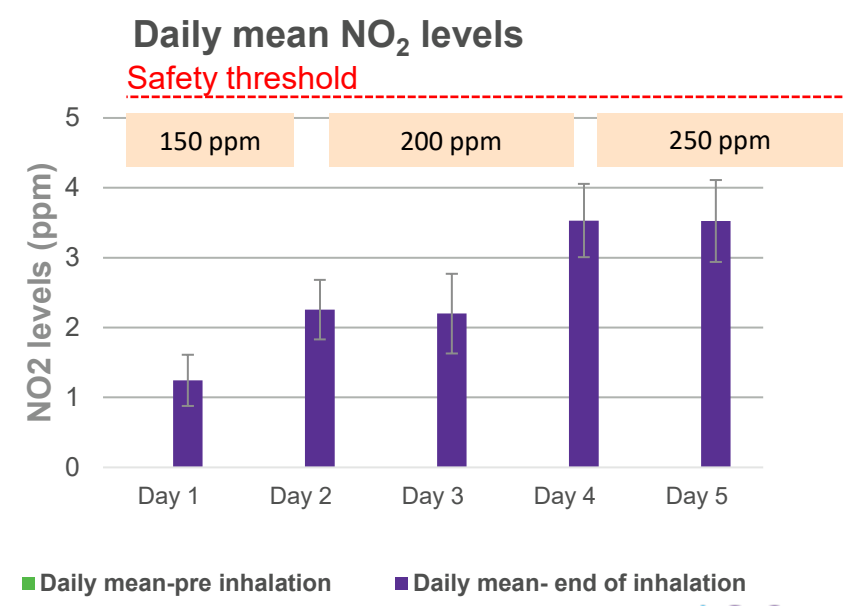
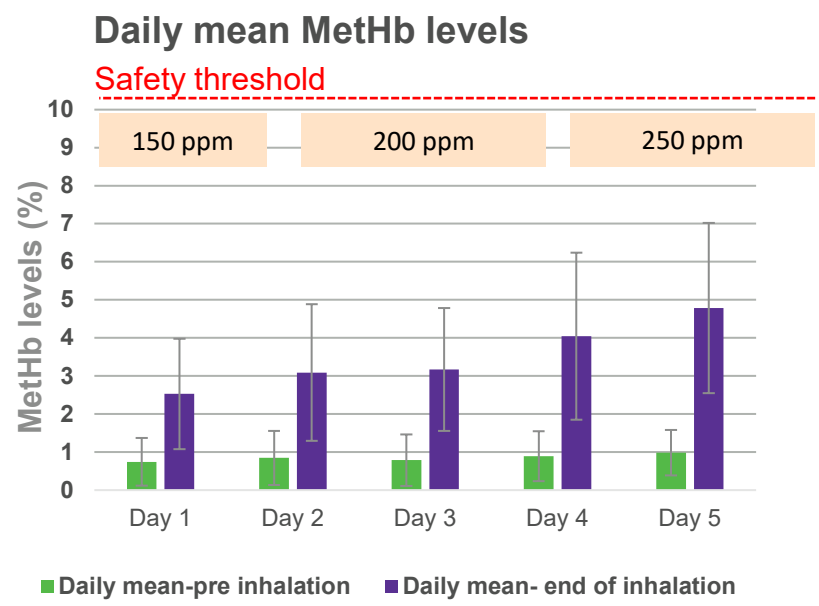
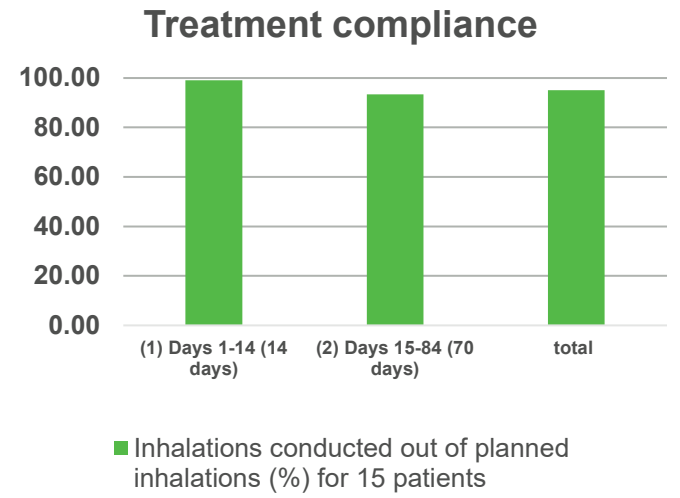


# High Compliance Rate with No SAEs that led to Discontinuation of Treatment

Total N (Intent-to-treat Population) = 15	N	%
Any AE	15	100
Any AE related to study treatment *	9	60.0
Any AE related to study treatment classified as Severe *	0	0
Any Serious Adverse Event (SAE)	6	40.0
Any SAE occurring during treatment period	3	20
Any SAE related to study treatment *	1	6.7

- Related AEs included: Hemoptysis (SAE), vomiting, balance difficulty, dry mouth, fatigue, headache, paresthesia and hypotension
- Methemoglobin and NO<sub>2</sub> elevation are both associated with iNO exposure; therefore these two parameters were monitored during treatments in hospitalization period, with safety thresholds set to 10% and 5 ppm respectively

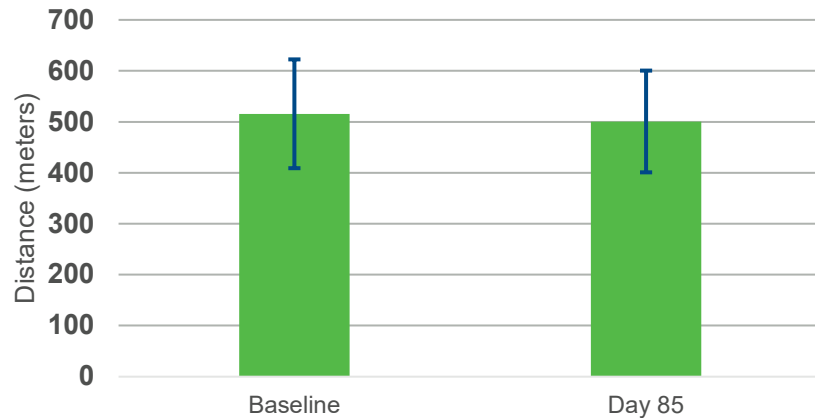
\*including possibly, probably and definitely related



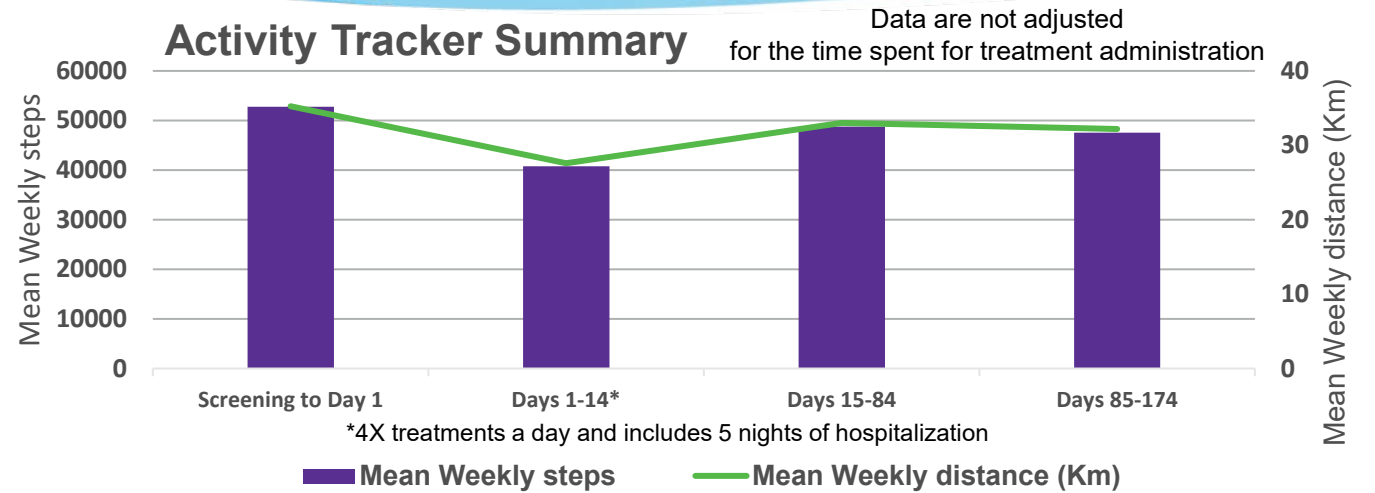


# Comparable Lung Function Throughout Treatment

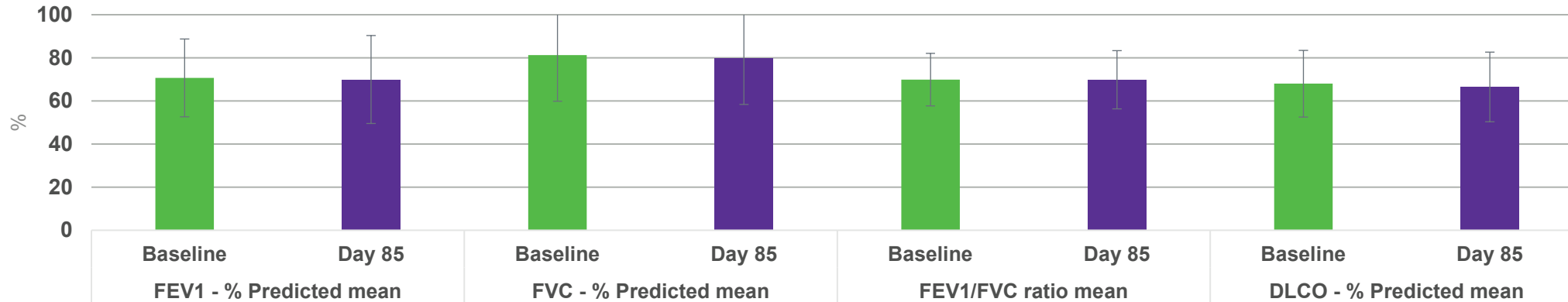
**Total distance walked in 6 minutes**



**Activity Tracker Summary**



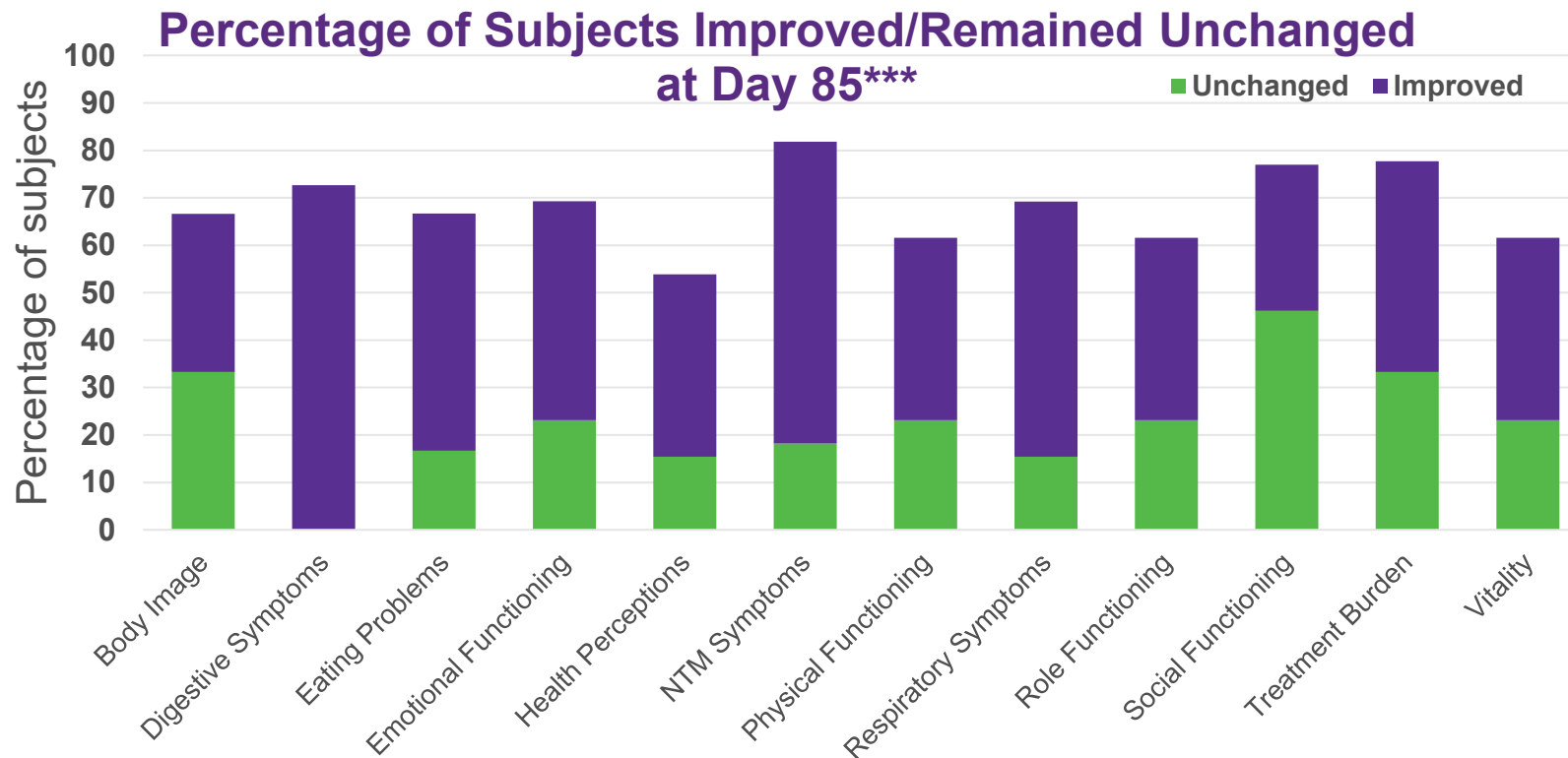
**Lung function**



Previous studies have shown that patients on antibiotic therapy alone experience declines in respiratory and physical function

# Improvement in Key Secondary Endpoint

## Quality of Life (QoL-B)



\*\*\*Calculated only for subjects completing treatment period

## Pivotal Study Endpoint

- Overall QoL improvement shown in majority of categories
- Latest FDA draft guidance for NTM-pulmonary disease caused by MAC is
  - "To support approval, FDA expects that drugs will provide benefit on a clinically meaningful endpoint"
  - "Primary efficacy endpoints should be based on clinical outcome assessments, such as a PRO instrument assessing symptoms"

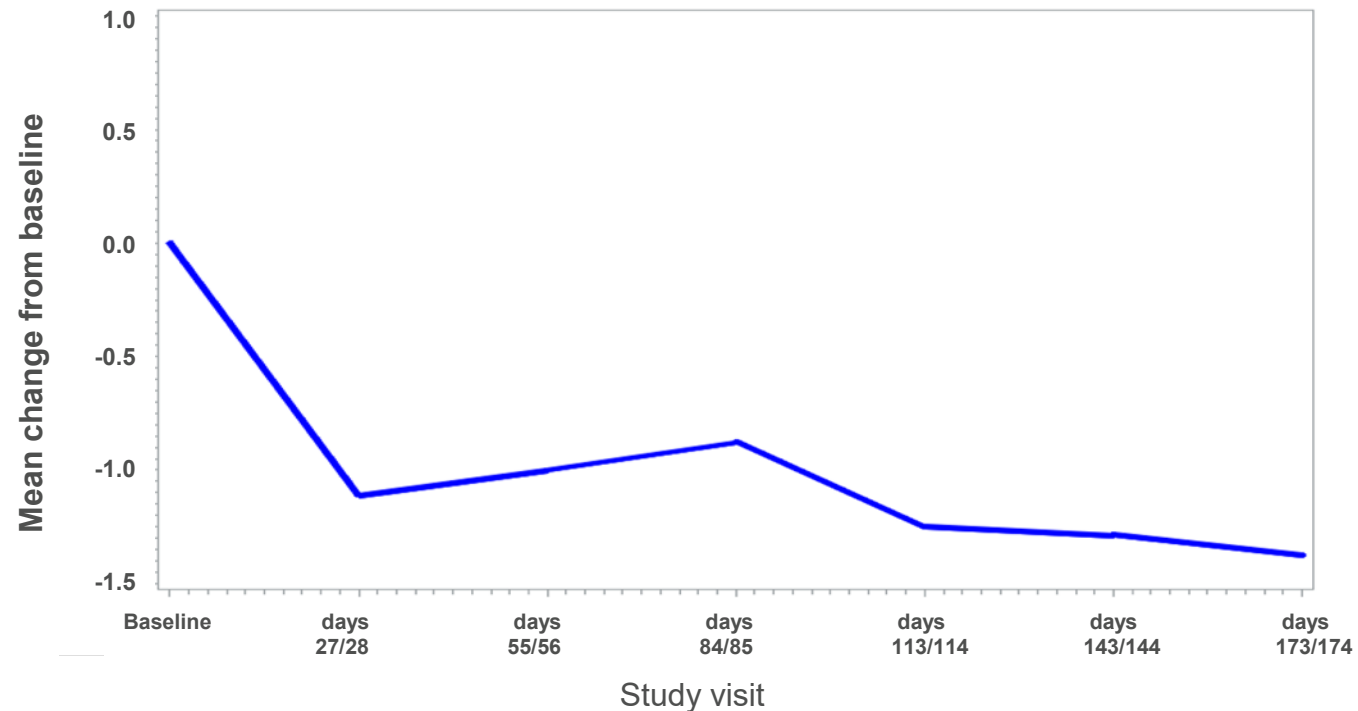
# Reduction in Microbial Load

- The changes reach **statistical significance at study day 113/114**, and a trend in favor of a decrease in mycobacterial load was observed at other time points.
- One subject achieved **culture conversion** with 3 consecutive negative cultures
- One subject was positive at baseline and tested only negative after NO treatments began, but was unable to produce 3 sputum samples throughout the 24 weeks of the study

Semiquantitative scale for mycobacterial culture growth at baseline

Score		N	%
0	no growth in broth/solid medium	3	23.08
1	broth medium growth only	4	30.77
2	< 50 countable colonies on solid medium	0	0
3	1+ growth on solid medium	2	15.38
4	2+ growth on solid medium	1	7.69
5	3+ growth on solid medium	0	0
6	4+ growth on solid medium	3	23.08
All		13	100.00

Mean change from baseline on the semiquantitative scale for mycobacterial culture growth





# Introducing the Role of Nitric Oxide in Autism Spectrum Disorder





# Beyond Air Partners with Hebrew University

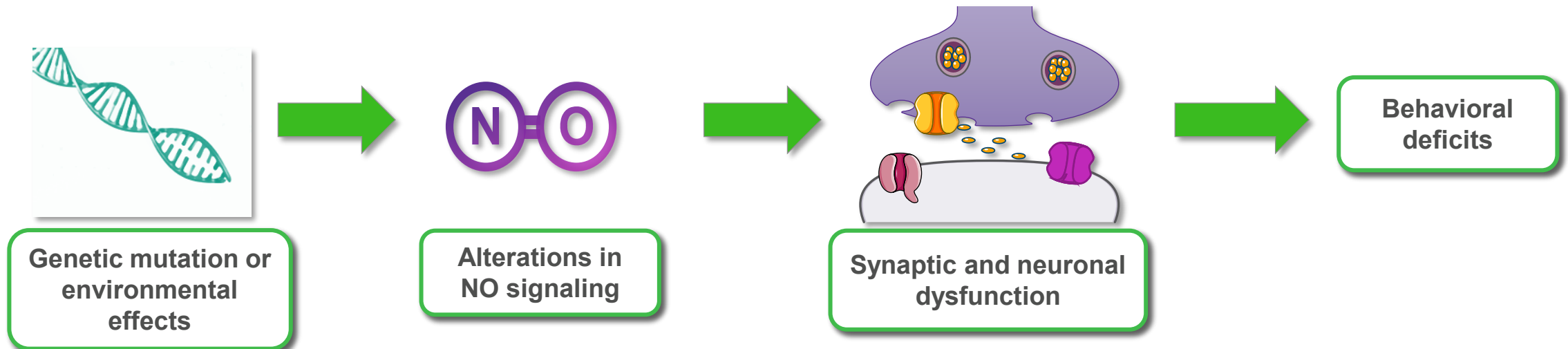
**Beyond Air has acquired exclusive global commercial rights to several compounds that partially inhibit the activity of neuronal nitric oxide synthase (nNOS)**

- Nitric Oxide (NO) has been linked to autism spectrum disorder (ASD) in humans
- More specifically, nNOS over-activity has been linked to ASD
- Hebrew University will perform all pre-clinical work (excluding toxicity)
- Beyond Air will perform all clinical, regulatory and commercial functions
- There are no FDA approved therapies to treat ASD
- ASD is an unmet medical need with CDC estimating a population in excess of 9 million in the US
  - Beyond Air estimates ~33% would be the addressable population

**Beyond Air is a world leader in NO research and this collaboration further reinforces this position**

# Nitric Oxide and Autism

- NO plays a major role in neuronal function and synaptic transmission<sup>1</sup>
- NO was found to be involved in a human mutation-based mouse models for ASD
- Nitrosative stress, marked by high levels of NO, is associated with a number of neurological disorders
- Recently, the Amal lab at Hebrew University showed that nNOS overactivity is linked to ASD and that increased levels of nitrosative stress biomarkers are present in low-functioning ASD patients



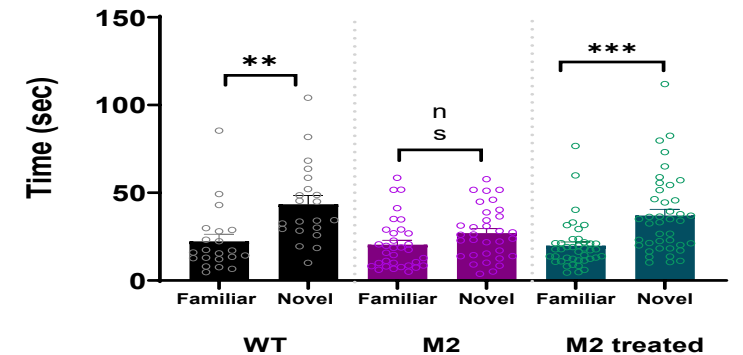
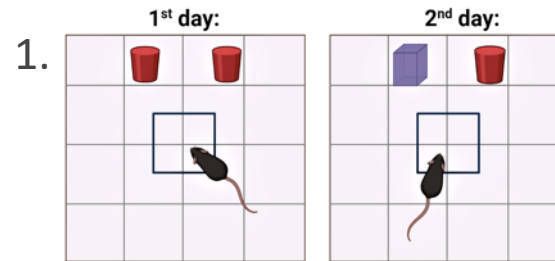
1. The role of nitric oxide in brain disorders: Autism spectrum disorder and other psychiatric, neurological, and neurodegenerative disorders, Manish Kumar Tripathi, Maryam Kartawy, Haitham Amal, Redox Biology, Volume 34, 2020.

# nNOS inhibition Reversed ASD Behaviors

In the ASD mouse model, the nNOS inhibitor leads to:

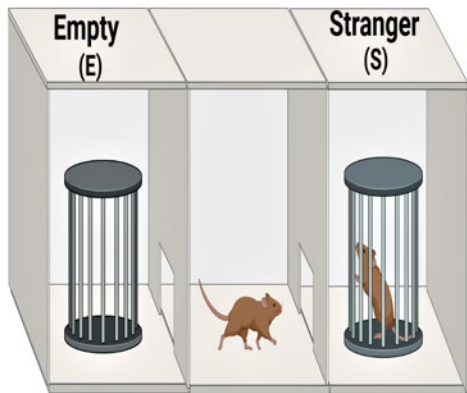
1. increased novelty seeking and improved memory
2. improved social behavior
3. decreased anxiety-like behavior

## Novel Object Recognition Test

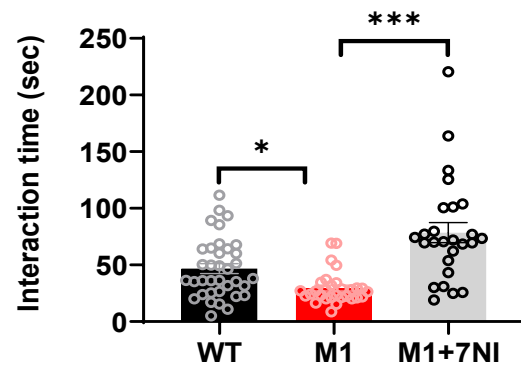


Number of mice: WT= 21, M2= 33, M2+7NI=41  
 One Way Anova was conducted. \*\* $P < 0.01$ , \*\*\* $P < 0.001$

2.

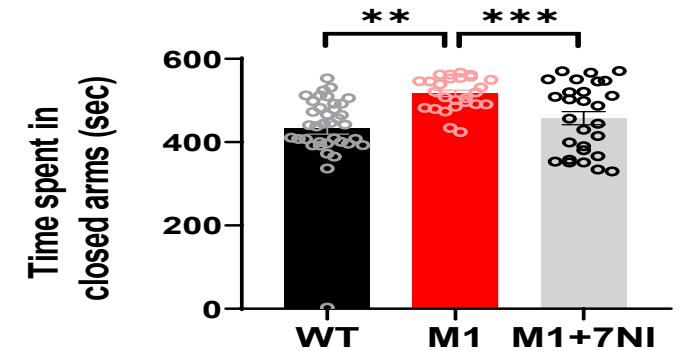
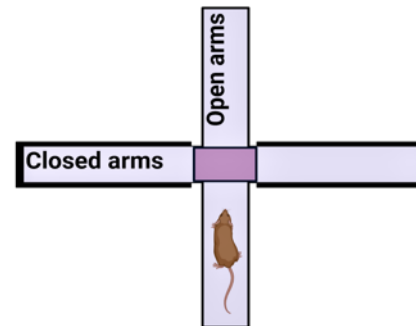


## Interaction with the stranger mouse



Number of mice: WT= 38, M1= 30, M1+7NI=28  
 One Way Anova was conducted. \* $P < 0.05$ , \*\*\* $P < 0.001$

3.



Number of mice: WT= 37, M1= 26, M1+7NI=28  
 One Way Anova was conducted. \*\* $P < 0.01$ , \*\*\* $P < 0.001$

# Achievements and Upcoming Milestones<sup>1</sup>

	2022	1H 2023	2H 2023	1H 2024	2H 2024	2025
<b>LungFit<sup>®</sup>PH</b> Persistent Pulmonary Hypertension of the Newborn (PPHN), and cardiac surgery	<ul style="list-style-type: none"> <li>US PMA approval</li> <li>US commercial launch</li> </ul>		<ul style="list-style-type: none"> <li>US cardiac surgery PMA submission</li> <li>Asia-Pacific partnership (Getz)</li> </ul>	CE Mark	US cardiac surgery PMA approval	Generation 2 LungFit PH FDA approval
<b>LungFit<sup>®</sup>PRO</b> Viral Community-Acquired Pneumonia (VCAP), including COVID-19  Bronchiolitis		<ul style="list-style-type: none"> <li>VCAP data presentation at the 32<sup>nd</sup> ECCMID 2022 and ID Week</li> </ul>	<ul style="list-style-type: none"> <li>Initiate US VCAP Pilot Study</li> </ul>		Announce initial data from VCAP pilot study	Initiate pivotal US study pending discussion with FDA
<b>LungFit<sup>®</sup>GO</b> NTM Lung Infection (home self-administration)  Severe Exacerbations in COPD		<ul style="list-style-type: none"> <li>Complete pilot NTM study - data presented at ATS and CHEST</li> </ul>			Discuss next steps with FDA in NTM	Initiate pivotal US study for NTM pending discussion with FDA
<b>BEYOND CANCER<sup>®</sup></b> Multiple Solid Tumors	<ul style="list-style-type: none"> <li>Initiate human study</li> <li>Preclinical data presentation at AACR</li> </ul>	<ul style="list-style-type: none"> <li>Preclinical combo data presentation &amp; manuscript publication</li> </ul>	<ul style="list-style-type: none"> <li>Announce initial human data</li> </ul>		Initiate phase 1b study	
<b>nNOS Inhibitor</b> Autism Spectrum Disorder (ASD)		<ul style="list-style-type: none"> <li>Partnership with Hebrew University</li> </ul>		Continue pre-clinical work		First-in-human study



## For more information contact:

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