Corporate Presentation June 2021



Beyond Air® The Magic of Breathing

Forward Looking Statement

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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.

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.



Our Vision

Harnessing the power of Nitric Oxide to transform the lives of patients



Company Overview

- Nasdaq listed: XAIR
- Headquarters: Garden City, NY
- Locations: Ireland, Israel, USA Experienced leadership team



Multiple Major Catalysts in the Next 12 Months

PMA Pending for Pulmonary Hypertension of the Newborn (PPHN)





Ability to transition between hospital use and untapped athome market





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



LungFit[®] PH is an innovative alternative to currently used cylinder systems in the hospital for ventilated patients





LungFit[®] PRO allows for the use of high concentration NO to treat a range of lung infections in the hospital setting



LungFit[®] GO safely moves high concentration NO into untapped home market to allow self-administration

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Generating NO from Ambient Air – High Barrier to Entry



During electric discharge in a lightning storm, the nitrogen and oxygen in air react to produce nitric oxide

LungFit[®] safely reproduces the reaction in a chamber using proprietary technology



Late Stage, Active Pipeline



1) All dates are based on projections and appropriate financing, anticipated first launch on a global basis pending appropriate regulatory approvals

2) Label expected to include cardiac surgery and PPHN

Our Programs Represent Large Market Opportunities

PPHN Opportunity:	Annual Viral Pneumonia Hospitalizations:	Annual Bronchiolitis Hospitalizations:	Total Refractory NTM Patient Populations:	Annual Acute COPD exacerbation-related Hospitalizations:	
7.5k cases in US ¹	350k US ²	120K US⁴	15K US ⁶		
ex-US includes PPHN &	16M ex-US ³	3.2M ex-US ^{4,5}	4k EU5 ⁷ 15k Japan ⁸	1M US ⁹	
Cardiac Patients			iok jupun		Solid Tumor Opportunity:
LungFit [®] PH	LungFi	t® PRO	LungF	it® GO	Solid Tumor Program
>\$300M	>\$1.5B	>\$500M	>\$1B	>\$2.5B	> \$23 Billion Global Checkpoint Inhibitor
>\$600M	>\$3B	>\$1.2B	>\$2.5B	>\$6B	Growing ¹⁰
US Sales Potential	Sources 1) Lakshminrusimha et al. Neore	views. 2015;16(12):e680–92.			
WW Sales Potential	 NCHS, National Hospital Ambu Rudan et al. WHO Child Health Hall et al N Engl J Med. 2009; UNICEF Winthrop et al. Ann Am Thora Ringshausen et al Emerg Infe Izumi et al. Ann Am Thorac So. 	ulatory Medical Care Survey, 2017. CE n Epidemiology Reference Group. Bu 360(6):588–598. nc Soc, 17 (2020), pp. 178-185 ect Dis. 2016;22(6):1102-1105. doi:10. c. 2019 Mar:16(3):341-347. doi: 10.15	DC. Il World Health Organ. 2004 Dec;82(1) 3201/eid2206.151642 13/AnnalsATS.201806-366OC. PMID: 3	2):895-903. 30339468.	

9) Jinjuvadia, Chetna et al. . COPD. 2017;14(1):72-79.

A Beyond

10) Company Presentations and Regulatory Filings from Bristol-Myers Squibb , Merck , Roche, AstraZeneca, Pfizer, Regeneron ; Sanofi 2011-2019.



The Role of Nitric Oxide in the Human Body

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



Nitric Oxide Has 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 diversification¹

Antimicrobial

- Antiviral
 - Inhibition of viral enzymes²
 - Blocking of RNA synthesis³
 - Blocking of viral replication cycle by modifying target molecules essential for replication³
- 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 peroxidation⁴



Nitric Oxide 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-γ, TNF TGF-β, G-CSF, M-CSF, VEGF, MIP- 1α, 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





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 workload¹





Beyond Air The Magic of Breathing 1) Inhaled Medical Gases: More to Breathe Than Oxygen, Michael A Gentile, Respiratory Care September 2011, 56 (9) 1341-1359; DOI: LINK

2) Persistent Pulmonary Hypertension of the Newborn, Satyan Lakshminrusimha and Martin Keszler, NeoReviews December 2015, 16 (12) e680-e692; DOI: LINK

3) Left ventricular heart failure and pulmonary hypertension, October 2015, European Heart Journal 37(12) LINK

Current Nitric Oxide US Market Dynamics

Established standard of care for 20+ years for pulmonary hypertension in the hospital setting (only PPHN on label)



Monopoly Broken 2019



Bevond Ai

Incidence ~1.9 per 1,000 live births (range 0.4-6.8 per 1,000 births)⁴

~7.5K Newborns in the US affected by

PPHN every year

(1) Mallinckrodt Company Reports

(2) American Academy of Pediatrics NICU Search

(3) According to the CDC(4) Lakshminrusimha et al. 2015.



Evolution of Innovation in Nitric Oxide Therapy for PPHN



a) GENOSYL DS image vero-biotech.com
 b) INOmax [package inset]. Clinton, NJ: INO Therapeutics, INC; 1999. Revised April 2004.

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Minimum Differentiation Among Major Market Players



INOmax Front

Beyond Air®







Introducing LungFit[®] PH – Nitric Oxide Generated from Ambient Air

LungFit[®] PH: Revolutionary, Smart Design

On-demand NO generation from ambient air First truly integrated unit (no need for tanks, cassettes or cartridges)

Easy to Use

Proprietary smart filter removes NO₂

Reduced training burden

No purging

Ample accessory storage

Alarms monitor performance

Usable with any electrical outlet 110/220V



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"



Introducing LungFit[®] PH – Nitric Oxide Generated from Ambient Air

LungFit[®] PH: Portable Unit

LungFit⁻PH Increased optionality with lightweight detachable unit - 38 lbs STATUS ALARMS FILTERTIME: 10h 32m Modern, compact design for limited NICU space MAINSPOWER BATTERY D 60% Easy to transport and store for medical staff NO Set (ppm) LungFit^{PH} NO2(ppm) | NO(ppm) 02% 80 60 40 20 Simple, intuitive, and familiar user interface MUTE 22 MENL 0.5 20 NO2(ppm) NO(ppm) ZERO 22 0.5 20 HIGH 18 100 3.0 15 25 CAL 18 100 15 25 NO SET **Backup Switch User Interface** Bagging Connector NO₂ filter NO₂ Filter Release Beyond Air Bevon †Caution - LungFit® is an Investigational Device, Limited by Federal (or United States) Law to Investigational Use. 17 **Detachable Unit** Dimensions are estimates.

The LungFit[®] PH Advantage

Hospitals currently use large, bulky, and heavy cylinders

LungFit[®] PH generates NO from ambient air



†Caution - LungFit® is an Investigational Device, Limited by Federal (or United States) Law to Investigational Use. Dimensions are estimates.

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Beyond Air Smart Filter vs. Cylinder

Smart filter is the "razor" in our "razor-blade" business model

Proprietary smart filter removes toxic nitrogen dioxide (NO₂) 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-Razor blade model
- Safety prevents NO₂ toxicity
- Encryption prevents counterfeits

Filter programs the system

– Sets concentration and flow rate (not true for LungFit® PH)

Smart filter ensure hospitals and insurers are only charged for what they use

Favorable economics for institutions



*not displayed to scale



LungFit[®] PH has Significant Advantages for Hospitals



LungFit[®] PH 2H21 US Launch Anticipated

Beyond Air is prepared to launch in the United States pending FDA approval

Key launch elements in place

- ✓ Commercial scale manufacturing in place for both LungFit[®] PH and Smart Filter
- ✓ Accessory kits complete
- Calibration gas supply secured
- ✓ Commercial leadership, quality systems, global supply chain, service center, etc. in place
- ✓ Multiple respiratory therapists (RTs) on staff for training

LungFit[®] PH is well positioned vs other players in market current environment

- Market leader recently lost monopoly and is moving to defend share by extending contracts
- Increased competition has led to a rational price decline
- Opportunity to help hospitals with a historically very expensive and complex product
- LungFit[®] PH advantages will be showcased in a phased launch

Ex-US plans

- CE Mark anticipated in 2H21 with a launch via partnership expected in 2022
- ROW launches to begin in 2022 via partnership





LungFit[®] Devices

Nitric oxide generation from ambient air







LungFit[®] For Treating Lung Infections

Simple, safe and convenient

- 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
- Usable 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

One filter per treatment

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 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

2,500+	140+	9	0
Treatments	Patients	Different	Serious Adverse Events
administered		clinical settings	(SAEs) related to NO

Date	Study	Indication	Primary	Results
2011	Phase 1 Safety (n=10)	All comers	Safety	No SAEs
2013 –2014	POC double blind randomized (n=43)	Bronchiolitis (due to any virus)	Safety & Efficacy	No SAEs; 24hr reduction in hospital length of stay
2013 - 2014	Pilot open label (n=9)	Cystic Fibrosis (CF)	Safety & Efficacy	No SAEs; Lowered bacterial load
2016	Compassionate use ISR (n=2)	NTM abscessus (CF)	Safety & Efficacy	No SAEs; clinical & surrogate endpoints improved
2017	Compassionate use National Institute of Health, US (n=1)	NTM abscessus (CF)	Safety & Efficacy	No SAEs; Improvements in clinical endpoints
2017	Pilot open label (N=9)	NTM abscessus	Safety & Efficacy	No SAEs; clinical & surrogate endpoints improved
2018	Pilot: double blind randomized (n=67)	Bronchiolitis (due to any virus)	Safety & Efficacy	No SAEs; 27hr reduction in hospital length of stay
2018	Compassionate use ISR (n=1)	NTM abscessus (CF)	Safety	No SAEs at 250 ppm NO dose
2019 – 2020	Pilot: double blind randomized (n=89)	Bronchiolitis (due to any virus)	Safety & Efficacy	 No SAEs; 150 ppm treatment showed statistically significant improvements in primary and key secondary

significant improvements in primary and key secondar endpoints compared to both 85 ppm and control



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



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



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



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





Viral Pneumonia in Hospitalized Patients

Nitric oxide has demonstrated antiviral activity



Viral Lung Disease Overview



Adult Acute Viral Pneumonia

Influenza virus is the most common cause of viral pneumonia in adults¹

- Other viruses that cause viral pneumonia include¹: 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 causes²

Benefits of Nitric Oxide

Nitric Oxide has broad-spectrum activity

- Preclinical studies show high dose NO has antibacterial and antiviral properties³⁻⁴
- Presented *in vitro* preclinical data at CHEST 2020 which support highconcentration NO has anticoronavirus properties within hours
- Pulmonary vasodilatory properties
 - FDA/EMA approved for ~20 years

Bronchiolitis

- RSV is the most common cause of bronchiolitis and viral pneumonia in children⁵
- Usually affects children <2 years, with a peak in infants aged 3-6 months⁶
- Leading cause of infant hospitalizations, accounting for >120,000 hospitalizations with a direct cost of at least \$550 million each year⁶



Leading cause of childhood

mortality

- Cesario T., Viruses Associated With Pneumonia in Adults, Clinical Infectious Diseases, V. 55, I. 1, 1 July 2012, Pgs 107–113
 American Thoracic Society- Top 20 Pneumonia Facts 2019 (<u>here</u>)
 Saura, M., et al., An antiviral mechanism of nitric oxide: inhibition of a viral protease. Immunity, 1999. 10(1): p. 21-8
 Wink DA et al., Chemical biology of nitric oxide." Free Rad Biol Med 1998; (4-5): 434-55.
 - 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. 27

Vaccines are not available for all causes of pneumonia



Nitric Oxide Market Dynamics for Viral Pneumonia



(7)

In 2019 according to the CDC

²⁸

NO Tested in Three Bronchiolitis Pilot Trials

	Trial 1	Trial 2	Trial 3	
Treatment groups	160 ppm NO + SST 160 ppm NO + SST SST alone (control) SST alone (control)		150 ppm NO + SST 85 ppm NO + SST SST alone (control)	
Total Intent to Treat (ITT) Subjects Enrolled & Evaluated as the Safety Population	43	68	87	
Study Treatment Protocol	Inhaled NO was given for 30 minutes, 5 times per day for up to 5 days	Inhaled NO was given for 30 minutes, 5 times per day for up to 5 days	Inhaled NO was given for 40 minutes, 4 times per day for up to 5 days	
Primary objective	Safety	Efficacy (Length of Stay)	Efficacy (Time to Fit for Discharge)	
Published or Presented	PEDIATRIC PULMONOLOGY OKIGINAL ARTICLE RESPIRATORY INFECTIONS Nitric oxide inhalations in bronchiolitis: A pilot, randomized, double-blinded, controlled trial Aher Tai@, David Greenberg, Yossef Av-Gay, Inbal Golan-Tripto, Yael Feinstein, Shalom Ben-Shimol, Ron Dagm, Avb O, Goldbart First published:27 November 2017 https://doi.org/10.1002/ppul.23965 Clastons: 1	SCIENTIFIC REPORTS naturesearch Inhaled nitric oxide therapy in acute bronchiolitis: A multicenter randomized clinical trial Avidedwet ⁽¹⁾ , Wald (was High Calif Line Leaver, Ori Effet ⁽¹⁾ , Boospiew ⁽²⁾ , Wald (was High Calif Line Leaver, Ori Effet ⁽²⁾ , Boospiew ⁽²⁾ , Wald (was High Calif Line Leaver, Ori Effet ⁽²⁾ , Boospiew ⁽²⁾ , Wald (was High Calif Line Leaver, Ori Effet ⁽²⁾ , Boospiew ⁽²⁾ , Wald (was High Calif Line Leaver, Ori Effet ⁽²⁾ , Boospiew ⁽²⁾ , Wald (was High Calif Line Leaver, Ori Effet ⁽²⁾ , Boospiew ⁽²⁾ , Wald (was High Calif Line Leaver, Ori Effet ⁽²⁾ , Boospiew ⁽²⁾ , Wald (was High Calif Line Leaver, Ori Effet ⁽²⁾), Boospiew ⁽²⁾ , Wald (was High Calif Line Leaver, Ori Effet ⁽²⁾), Boospiew ⁽²⁾ , Wald (was High Calif Line Leaver, Ori Effet ⁽²⁾), Boospiew ⁽²⁾ , Wald (was High Calif Line Leaver, Ori Effet ⁽²⁾), Boospiew ⁽²⁾ , Wald (was High Calif Line Leaver, Ori Effet ⁽²⁾), Boospiew ⁽²⁾ , Wald (was High Calif Line Leaver, Ori High Calif Line Leaver, Ori Effet ⁽²⁾), Boospiew ⁽²⁾ , Wald (was High Calif Line Leaver, Ori Effet ⁽²⁾), Boospiew ⁽²⁾ , Wald (was High Calif Line Leaver, Ori Effet ⁽²⁾), Boospiew ⁽²⁾ , Wald (was High Calif Line Leaver, Ori High Calif Line	Annual Meeting	

Next Steps: Pivotal Study

Pivotal study on hold due to COVID-19 – Beyond Air is prepared to initiate in the fourth quarter of 2022 pandemic permitting



NO Safe & Well Tolerated in Bronchiolitis Studies

Pooled Safety Results Presented at American Thoracic Society International Conference 2021

	SST (N	J=82)	85 ppm (N=	NO + SST =32)	150 ppm (N=	NO + SST 29)	160 ppm (N=	NO + SST =55)	All (N	=198)
	Ν	%	Ν	%	Ν	%	N	%	Ν	%
Any AE	45	54.9%	20	62.5%	18	62.1%	25	45.5%	108	54.5%
Any SAE	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



150 PPM NO is Minimum Therapeutic Dose

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
Primary endpoint: Time to Fit-to-Discharge (FTD)			
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
Secondary Endpoint: Hospital Length of Stay (LOS)			
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



150 PPM NO Evaluated in Adult AVP Pilot Study

Interim Results Presented at American Thoracic Society International Conference 2021

Intent to Treat Population: 19 subjects (9 iNO + SST vs 10 SST)

		LungFit- 150 ppm NO +SST	SST
	Ν	9	10
Duration of bosnital stay	Mean	2.7	3.1
(days)	Median	2.2	2.1
(uays)	Min	1.2	0.1
	Мах	4.9	7.9

Influence of extreme values* on duration of hospital stay

		LungFit- 150 ppm NO +SST	SST*
	Ν	9	8
Duration of bognital stay	Mean	2.7	3.8
(days)	Median	2.2	2.2
(uays)	Min	1.2	1.0
	Мах	4.9	7.9

*2 subjects discharged from hospital within 6 hours of study admission were excluded from analysis



Adult AVP Interim Results Follow Similar Safety & Efficacy Trends

Interim Results Presented at American Thoracic Society International Conference 2021

Intent to Treat Population: 19 subjects (9 iNO + SST vs 10 SST)

		LungFit- 150 ppm NO +SST	SST
	Ν	9	10
Duration of Oxygen	Mean	3.2	5.2
Support	Median	1.9	4.9
(days)	Min	0.0	0.0
	Max	12.0	16.7

In the ITT population (n=19), 22.2% of subjects in the NO + SST group required oxygen support beyond their hospital stay, compared with 40% of control subjects.

- 150 ppm NO treatment administered via LungFit® PRO was safe and well tolerated with no reported treatment-related, or possibly related, adverse events or severe adverse events
- NO₂ levels were below 4 ppm at all timepoints (safety threshold is 5 ppm)
- MetHb levels were below 4% at all times (safety threshold is 10%)
- A total of 15 adverse events were reported in 8 subjects (5 NO + SST vs. 3 SST) and two serious adverse events were reported in the NO + SST group both were related to the underlying condition of the subject and were assessed to be unrelated to study treatment.



Ongoing Acute Viral Pneumonia Pilot Study Design

Pilot Clinical Trial in Israel

- ✓ Commenced enrollment in November 2020
- Interim data presented at ATS 2021
- Multicenter open label study of adult patients hospitalized with acute viral pneumonia, including SARS-CoV-2
- Objective: establish 150 ppm NO is safe and tolerable in target patient population







Nontuberculous Mycobacteria

Expanding NO into the home market for lung infections



Home Market: Nontuberculous Mycobacteria (NTM)

How is NTM acquired?

- Acquired by inhalation from the environment
- Water thought to be the main source
 - US study across 25 states showed that NTM bacteria were found in nearly 8 out of 10 water samples¹
- Warmer climates have higher infection rates
 - Gulf States account for 70% of annual NTM cases in the United States²
- Patient to patient transmission possible

Who is at risk?

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



1) Donohue et al. Environ Sci Technol. 2015;49(10):6127-6133.

2) Hall-Stoodley et al. Biofilm formation by the rapidly growing mycobacterial species Mycobacterium fortuitum. FEMS Microbiol Lett. 1998;168(1):77-84.

3) 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)

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

5) 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). 201



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Nitric Oxide Market Dynamics for NTM

Refractory NTM patients in US¹

Targeting Refractory Mycobacterium avium complex (MAC) & M. abscesses NTM Patients ~15K ~4K ~15K

NTM is an FDA disease area of focus with limited treatment options resulting in high unmet medical need

Refractory NTM patients in the EU5²





3) Izumi et al. Epidemiology of Adults and Children Treated for Nontuberculous Mycobacterial Pulmonary Disease in Japan. Ann Am Thorac Soc. 2019 Mar;16(3):341-347.

A) Diel R et al. High mortality in patients with MAC lung disease: a systematic review. BMC Infect Dis. 2018;18(1):206. Published 2018 May 3
 5) According to the Cystic Fibrosis Foundation

Refractory NTM patients in Japan³

Pilot Study in CF Patients with NTM Lung Infections Demonstrates Safety and Efficacy

Single arm study with 160 ppm NO showed a reduction in bacterial load and improvements in quality of life Data Published in the Journal of Cystic Fibrosis (Bentur et al., 2019)



- 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

Pilot Clinical Trial in Australia

- ✓ Began Screening in December 2020
- ✓ First Patient Dosed in January 2021
- Received grant for up to \$2.17 million from the Cystic Fibrosis Foundation to help fund pilot study
- 12-week, single-arm, multicenter study enrolling ~20 adult Cystic Fibrosis (CF) or non-CF bronchiectasis patients with refractory *Mycobacterium avium* complex (MAC) or *Mycobacterium abscessus* complex (MABSC) lung infections
- Objective: establish safety at up to 250 ppm NO when patients self-administer treatment in the home setting
- Interim results expected Fall-2021 and final results first half 2022



How Big is the Home Market for Severe Lung Infections?



- ...is the largest atrisk population for recurrent and opportunistic lung infections
- There are an estimated 30m people in the US suffering from COPD¹ with 10% considered severe²

 1,075,575 estimated acute COPD exacerbation-related hospitalizations in 2010

Data from

2010 Show³

- Average COPD exacerbation hospital LOS was 6 days in 2010
- \$38,455 cost per hospitalization in 2010 translates to >\$41b in cost

 After hospitalization varies between 16% and 19% in the 3 months following hospitalization, between 23% and 43% at 1 yr and is 55–60% at 5 yrs⁴.

Mortality

rate

 In the ECLIPSE⁵ study (Hurst et al. NEJM 2010), a 3 year observation of 1,679 moderate to severe COPD patients (GOLD 2,3 & 4)

ECLIPSE

- 77% of patients had at least one exacerbation during the observation period
- 47% of patients had ≥2 exacerbations in at least one of the three study years
- 30% of patients had \geq 1 exacerbation in each of the three study years
- 12% of patients had ≥2 exacerbations in each of the three study years

1) COPD Foundation

Mannino and Braman: Epidemiology and Economics of COPD. American Thoracic Society. Volume 4. 2007
 Jinjuvadia et al. Journal of Chronic Obstructive Pulmonary Disease 2017;
 Raherison C and Girodet PO. Epidemiology of COPD. Eur Respir Rev. 2009;18(114):213-221;

5) Evaluation of COPD Longitudinally to Identify Predictive Surrogate Endpoints

Beyond Air[®]

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Nitric Oxide for Solid Tumors

Ultra high concentration nitric oxide has cytotoxic effects and data suggest immunostimulatory activity



Nitric Oxide is an Anti-Cancer Agent

- NO has shown anticancer properties at high concentrations by activating innate and adaptive responses of the immune system
- Our data suggest that our innovative gaseous NO-based treatment may treat solid tumors locally and their distant metastases systemically via stimulation of an anti-tumor immune response

Hypothesis: Exogenous high-concentration gaseous NO (>10,000 ppm) administered directly to a solid tumor may result in local cell death resulting in systemic exposure to tumor antigens. Tumor antigens may trigger a systemic immune response, thereby creating a memory immune response that will recognize and attack subsequent primary tumor regrowth as well as distal metastases.





Findings from *In Vivo* Murine Lung Cancer Model Are Consistent with Previous Data

In vivo results showed that lung tumor-bearing mice treated with 50,000 ppm gNO for 10 minutes were resistant to a second LLC1 cancer cell inoculation



Challenge assay: The tumors of lung cancer tumor-bearing mice were treated with NO. Up to 14 days post NO treatment, mice were re-inoculated with lung cancer cells (LLC1 cells) and the percentage of tumor take was monitored.



* P-value (chi-square) < 0.05

Treatment: 50,000 ppm NO for 10 minutes

Data presented at the IASLC 2020 North America Conference on Lung Cancer (NACLC) October 16, 2020



High-Concentration gNO Inhibits Colon and Breast Cancer Cell Line Viability *In Vitro* and Challenge Tumor Take *In Vivo*

Data presented at the AACR Conference on Tumor Immunology and Immunotherapy, October 16, 2020

- Colon and breast tumor-bearing mice (CT26 and 4T1) received a single treatment with high-concentration gNO intratumorally
- CT26 study mice received either 20,000 or 50,000 ppm gNO for 5 minutes & 4T1 study mice received 50,000 ppm gNO for 10 minutes
- Naïve mice inoculated with the same cancer cells served as an internal control, with the 4T1 study having an additional control arm of N₂treated mice
- Up to 21 days after gNO administration to the primary tumor, all mice were inoculated with a challenge tumor and growth of that tumor was tracked



- At day 45, challenge tumor uptake was observed in 100% of naïve mice, 27% of 20,000 ppm gNO mice, and 0% of 50,000 ppm gNO mice, suggesting dose-dependence
- At day 45, 25% of naïve mice, 73% of 20,000 ppm gNO mice and 100% of 50,000 ppm gNO mice were alive



 Delay in challenge tumor take was observed with NO as compared with naïve and N₂ controls

Financial and Patent Information



IMPORTANT MESSAGE: DEVELOPMENT COMPLETED



Achievements & Upcoming Milestones

Estimated timelines for pipeline progress and commercialization¹

	2H20	1H21	2H21	1H22
LungFit [®] PH ventilator compatible				
In-hospital use for Persistent Pulmonary Hypertension of the Newborn (PPHN) & Heart Surgery ²	Submit PMA to US FDA		US FDA approval anticipated: Commercial launch in the US Obtain CE Mark	Continue to launch globally
.ungFit [®] PRO				
Acute viral pneumonia (including COVID- 19)	Initiate study at 150 ppm NO	Report interim data	Report full dataset	
Bronchiolitis		Piv	votal study initiation delayed	due to COVID-19 pandemi
ungFit® GO				
Nontuberculous mycobacteria (NTM) lung infection	Begin self-administration at home study		Report interim data	Report full dataset from home study
Severe exacerbations due to lung infections in COPD patients			Report in	i vitro data
olid Tumor Program				
Multiple Solid Tumors	Present pre-clinical data at a major medical conference (NACLC)		Potentially initiate first in human studies by end of 2021	
eyond Air [®]	= ACHIEVED	= ON	HOLD	(1) Company estimates

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