

April 18, 2022



# Beyond Air® to Participate in Three Upcoming Medical Conferences

GARDEN CITY, N.Y., April 18, 2022 (GLOBE NEWSWIRE) -- Beyond Air, Inc. (NASDAQ: XAIR), a clinical-stage medical device and biopharmaceutical company focused on developing inhaled nitric oxide (NO) for the treatment of patients with respiratory conditions, including serious lung infections and pulmonary hypertension and, through its affiliate Beyond Cancer, ultra-high concentration nitric oxide (UNO) for the treatment of solid tumors, today announced that the Company is scheduled to present new data at three upcoming medical conferences.

## **The Pediatric Academic Societies 2022 Meeting (PAS 2022)**

The Company is scheduled to present new long-term safety data for high concentration inhaled nitric oxide for the treatment of bronchiolitis at the PAS 2022 Meeting, which is scheduled to be held April 21-25 in Denver, Colorado. Details of the presentation are as follows:

**Abstract Title:** 1179165 – Long-term effects of inhaled nitric oxide in infants with bronchiolitis – a multi-center study

**Session:** Pulmonology – Oral Abstract

**Date:** Monday April 25, 2022 at 1:00 PM - 3:30 PM MST

**Participant:** Aviv Goldbart, M.D. Professor, Head of Department Pediatrics, Soroka University Medical Center; Faculty of Health Sciences, Ben-Gurion University of the Negev, Beer-Sheva, Israel

## **32<sup>nd</sup> European Congress of Clinical Microbiology and Infectious Diseases (ECCMID 2022)**

The Company will present new data from the LungFit® PRO pilot study of high-concentration nitric oxide in Community-Acquired Viral Pneumonia (CAVP) including COVID-19 at the upcoming 32<sup>nd</sup> ECCMID 2022, which is scheduled to be held April 23-26, 2022 in Lisbon, Portugal. Details of the oral poster presentation are as follows:

**Abstract Title:** 00400 - Treatment of COVID-19 with inhaled nitric oxide using a novel nitric oxide generator

**Poster Session:** 12e. Drug development and treatment modalities (incl. clinical trials)

**Participant:** Talya Wolak, M.D. Faculty of Medicine, Hebrew University of Jerusalem, Israel; The Internal Medicine Department D at Shaare Zedek Medical Center, Israel

## **American Thoracic Society International Conference 2022 (ATS 2022),**

The Company will present new data from the LungFit® GO pilot study of high concentration inhaled nitric oxide in NTM at the upcoming ATS 2022, which is scheduled to be held May 13-18, 2022 in San Francisco. Details of the oral poster presentation are as follows:

**Title:** (Under Embargo)

**Session:** C28 - LET'S TALK NTM

**Date:** May 17, 2022 9:30 AM - 11:00 AM PT

**Participant:** Dr. Rachel Thomson MBBS, PhD, FRACP; Professor at University of Queensland, School of Medicine

### **About Beyond Air, Inc.**

Beyond Air, Inc. is a clinical-stage medical device and biopharmaceutical company developing a revolutionary NO Generator and Delivery System, LungFit<sup>®</sup>, that uses NO generated from ambient air to deliver precise amounts of NO to the lungs for the potential treatment of a variety of pulmonary diseases. The LungFit<sup>®</sup> can generate up to 400 ppm of NO, for delivery either continuously or for a fixed amount of time and has the ability to either titrate dose on demand or maintain a constant dose. The Company is currently applying its therapeutic expertise to develop treatments for pulmonary hypertension in various settings, in addition to treatments for respiratory tract infections that are not effectively addressed with current standards of care. Beyond Air is currently advancing its revolutionary LungFit<sup>®</sup> for clinical trials for the treatment of severe lung infections such as acute viral pneumonia (including COVID-19) and nontuberculous mycobacteria (NTM). Additionally, Beyond Air is using ultra-high concentrations of NO with a proprietary delivery system to target certain solid tumors in the pre-clinical setting. For more information, visit [www.beyondair.net](http://www.beyondair.net).

### **About Nitric Oxide (NO)**

Nitric Oxide (NO) is a powerful molecule, naturally synthesized in the human body, proven to play a critical role in a broad array of biological functions. In the airways, NO targets the vascular smooth muscle cells that surround the small resistance arteries in the lungs. Currently, exogenous inhaled NO is used in adult respiratory distress syndrome, post certain cardiac surgeries, and persistent pulmonary hypertension of the newborn to treat hypoxemia. Additionally, NO is believed to play a key role in the innate immune system and in vitro studies suggest that NO possesses anti-microbial activity not only against common bacteria, including both gram-positive and gram-negative, but also against other diverse pathogens, including mycobacteria, viruses, fungi, yeast, and parasites, and has the potential to eliminate multi-drug resistant strains.

### **About the LungFit<sup>®\*</sup>**

Beyond Air's LungFit<sup>®</sup> is a cylinder-free, phasic flow nitric oxide generator and delivery system and has been designated as a medical device by the U.S. Food and Drug Administration (FDA). The ventilator compatible version of the device can generate NO from ambient air on demand for delivery to the lungs at concentrations ranging from 1 part per million (ppm) to 80 ppm. The LungFit<sup>®</sup> system could potentially replace large, high-pressure NO cylinders providing significant advantages in the hospital setting, including greatly reducing inventory and storage requirements, improving overall safety with the elimination of NO<sub>2</sub> purging steps, and other benefits. The LungFit<sup>®</sup> can also deliver NO at concentrations at or above 80 ppm for potentially treating severe acute lung infections in the hospital setting (e.g. COVID-19, bronchiolitis) and chronic, refractory lung infections in the home setting (e.g. NTM). With the elimination of cylinders, Beyond Air intends to offer NO treatment in the home setting.

*\* Beyond Air's LungFit<sup>®</sup> is not approved for commercial use. Beyond Air's LungFit<sup>®</sup> is for*

*investigational use only. Beyond Air is not suggesting NO use over 80 ppm or use at home.*

### **About Bronchiolitis**

The majority of hospital admissions of infants with bronchiolitis are caused by respiratory syncytial virus (RSV). RSV is a common and highly transmissible virus that infects the respiratory tract of most children before their second birthday. While most infants with RSV present with minor respiratory symptoms, a small percentage develop serious lower airway infections, termed bronchiolitis, which can become life-threatening. The absence of treatment options for bronchiolitis limits the care of these sick infants to largely supportive measures. Beyond Air's system is designed to effectively deliver 150 - 400 ppm NO, for which preliminary studies indicate may eliminate bacteria, viruses, fungi, and other microbes from the lungs.

### **LungFit® PRO Pilot Trial Design**

The ongoing pilot study is a multi-center, open-label, randomized clinical trial in Israel with an emphasis on enrolling patients infected with SARS-CoV-2. Patients are randomized in a 1:1 ratio to receive inhalations of 150 ppm NO given intermittently for 40 minutes four times per day for up to seven days in addition to standard supportive treatment (NO + SST) or standard supportive treatment alone (SST, control group). Endpoints related to safety, oxygen saturation, fever and ICU admission, among others, will be assessed.

### **LungFit® GO NTM Trial Design**

The 12-week, multi-center, open-label clinical trial is taking place in Australia and will enroll up to 20 adult subjects with chronic refractory NTM lung disease. The trial is enrolling both cystic fibrosis (CF) and non-CF subjects chronically infected with Mycobacterium avium complex (MAC), Mycobacterium abscessus complex (MABSC) or other strains of NTM. The trial consists of a run-in period followed by two treatment phases. The run-in period provides a baseline for the efficacy endpoints, such as patient physical function and bacterial load. The first treatment phase takes place over a two-week period and begins in the hospital setting where subjects are titrated from 150 ppm NO up to 250 ppm NO over several days. During this first treatment phase subjects receive NO for 40 minutes, four times per day while methemoglobin and nitrogen dioxide (NO<sub>2</sub>) levels are monitored. Subjects are trained to use LungFit® GO and subsequently discharged to complete the remaining portion of this two-week treatment period at their home administering the highest tolerated NO concentration. For the second treatment phase, a 10-week maintenance phase, the inhalation treatments are administered twice daily. The study evaluates safety, quality of life, physical function, and bacterial load among other parameters, as compared to baseline measurements.

### **Forward Looking Statements**

*This press release contains "forward-looking statements" concerning inhaled nitric-oxide and the Company's LungFit® product, including statements with regard to potential regulatory developments and the expected timing thereof, expected product launch for the Company's LungFit® product and the timing thereof, and the potential impact on patients and anticipated benefits associated with its use. Forward-looking statements include statements about our expectations, beliefs, or intentions regarding our product offerings, business, financial condition, results of operations, strategies or prospects. You can identify such forward-looking statements by the words "anticipates," "expects," "intends," "impacts," "plans," "projects," "believes," "estimates," "likely," "goal," "assumes," "targets" and similar*

*expressions and/or the use of future tense or conditional constructions (such as “will,” “may,” “could,” “should” and the like) and by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including risks related to: the potential that regulatory authorities, including the FDA and EMA, may not grant or may delay approval for our product candidate; the impact of the COVID-19 pandemic on the FDA’s review process; our approach to discover and develop novel drugs, which is unproven and may never lead to efficacious or marketable products; our ability to fund and the results of further pre-clinical and clinical trials; obtaining, maintaining and protecting intellectual property utilized by our products; our ability to enforce our patents against infringers and to defend our patent portfolio against challenges from third parties; our ability to obtain additional funding to support our business activities; our dependence on third parties for development, manufacture, marketing, sales, and distribution of products; the successful development of our product candidates, all of which are in early stages of development; obtaining regulatory approval for products; competition from others using technology similar to ours and others developing products for similar uses; our dependence on collaborators; our short operating history and other risks identified and described in more detail in the “Risk Factors” section of the Company’s most recent Annual Report on Form 10-K and other filings with the SEC, all of which are available on our website. We undertake no obligation to update, and we do not have a policy of updating or revising, these forward-looking statements, except as required by applicable law.*

## **CONTACTS:**

Maria Yonkoski, Head of Investor Relations  
Beyond Air, Inc.

[Myonkoski@beyondair.net](mailto:Myonkoski@beyondair.net)

Corey Davis, Ph.D.  
LifeSci Advisors, LLC

[Cdavis@lifesciadvisors.com](mailto:Cdavis@lifesciadvisors.com)

(212) 915-2577



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