

March 5, 2020



# Beyond Air Hosting Analyst Day Today, March 5, 2020 at 2:00 p.m. ET

*Announces new program targeting solid tumors with nitric oxide*

*Secured a \$25 million line of credit*

*Timelines remain on track for PPHN, BRO and NTM programs*

GARDEN CITY, N.Y. and REHOVOT, Israel, March 05, 2020 (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 gaseous NO for the treatment of solid tumors, will host an analyst day in New York City today, March 5, 2020.

Topics to be discussed this afternoon:

- COVID-19
  - LungFit™ potential impact
- Persistent Pulmonary Hypertension of the Newborn (PPHN)
  - Premarket Approval (PMA) submission to FDA on track for the second quarter of calendar 2020
  - Assessing option of marketing alone or out-licensing in the United States
- Bronchiolitis (BRO)
  - Enrollment for third pilot study in Israel complete with data anticipated early in the second quarter of calendar 2020
  - US pivotal study on track for winter 2020/21
- Nontuberculous mycobacteria (NTM)
  - June 2020 home study initiation on track
  - First indication for the severe home lung infection market – COPD to follow
- NO for treating solid tumors
  - Pre-clinical data to be presented at the American Association for Cancer Research (AACR) April 24-29, 2020
- \$25 million line of credit available for two years
  - Drawable in tranches of \$5m
  - First two tranches can be drawn at the Company's discretion
    - 10% annual interest rate and 25% warrant coverage with pricing based on a pre-determined formula
  - Tranches three through five can only be drawn after FDA approval of LungFit™ PH
    - 10% interest rate and 10% warrant coverage with pricing based on a pre-determined formula
  - Warrant term is five years

- All debt is five years regardless of when tranche is drawn
  - First three years is interest only payments
  - Years four and five are interest plus principle payments
- Debt is unsecured

“The Beyond Air team continues to execute. There will be several team members at our analyst day this afternoon along with three KOLs to showcase our expertise and answer questions about LungFit™ and nitric oxide therapy,” said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. “The addition of a \$25 million line of credit provides another source of cash which gives us the ability to move ahead with confidence on our new solid tumor indication and potentially launch LungFit™ PH ourselves.”

The event this afternoon is intended for institutional investors, sell-side analysts, and business development professionals. Please [RSVP](#) in advance if you plan to attend, as space is limited. For those who are unable to attend in person, a live webcast and replay will be accessible via the link [here](#).

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

Beyond Air, Inc. is a clinical-stage medical device and biopharmaceutical company using developing a revolutionary NO Generator and Delivery System, LungFit™ 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™ 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 lower respiratory tract infections that are not effectively addressed with current standards of care. Beyond Air is currently advancing its revolutionary LungFit™ in clinical trials for the treatment of bronchiolitis and severe lung infections such as 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 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 and is used in adult respiratory distress syndrome and persistent pulmonary hypertension of the newborn. 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 organisms, including mycobacteria, fungi, yeast and parasites, and has the potential to eliminate multi-drug resistant strains.

### **About the LungFit™ NO Generator and Delivery System\***

Beyond Air's NO Generator and Delivery System is a cylinder-free, phasic flow Nitric Oxide delivery system and has been designated as a medical device by the US 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™ 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™ can also deliver NO at concentrations above 80 ppm for which intended treatments are: bronchiolitis in the hospital setting, and chronic, refractory lung infections in the home setting. For the first time, Beyond Air intends to offer NO treatment in the home setting with the elimination of cylinders.

\* Beyond Air's LungFit™ is not approved for commercial use and Beyond Air is not suggesting use over 80 ppm or use at home. Beyond Air's LungFit™ is for investigational purposes only.

### **About PPHN**

Persistent pulmonary hypertension of the newborn (PPHN) is a lethal condition and secondary to failure of normal circulatory transition at birth. It is a syndrome characterized by elevated pulmonary vascular resistance (PVR) that causes labile hypoxemia due to decreased pulmonary blood flow and right-to-left shunting of blood. Its incidence has been reported as 1.9 per 1000 live births (0.4–6.8/1000 live births) with mortality rate ranging between 4–33%. This syndrome complicates the course of about 10% of infants with respiratory failure and remains a source of considerable morbidity and mortality. NO gas is a vasodilator, is approved in dozens of countries to improve oxygenation and reduces the need for extracorporeal membrane oxygenation (ECMO) 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 ventilator support and other appropriate agents.

### **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 over 80 ppm NO, for which preliminary studies indicate may eliminate bacteria, viruses, fungi and other microbes from the lungs.

### **About NTM**

Nontuberculous mycobacteria (NTM) is a rare and serious bacterial infection in the lungs causing debilitating pulmonary disease associated with increased morbidity and mortality. NTM infection is acquired by breathing in aerosolized bacteria from the environment, and if ignored can lead to NTM lung disease, a progressive and chronic condition. NTM is an emerging public health concern worldwide because of its multi-drug antibiotic resistance. Current treatment guidelines suggest a combination of multiple antibiotics delivered continually for as long as two years. These complex, expensive and invasive regimens have a poor record in the treatment of *Mycobacterium abscessus complex* (MABSC) and refractory *Mycobacterium avium complex* (MAC) and have the potential for causing severe adverse events. Beyond Air's system is designed to effectively deliver 150 - 400 ppm NO to the lung, and early data indicate that this range of NO concentration may have a positive effect on patients infected with NTM.

### **About Solid Tumors**

Cancer is caused when defected cells divide uncontrollably and spread into surrounding and distant tissues. Most cancers form solid tumors, which are masses of tissues. There are more than 100 types of cancer, including breast, skin, lung, colon, prostate, pancreatic, and liver cancer. Treatment protocols vary according to the type and stage of the cancer. However, most treatments may include chemotherapy, radiation, and/or surgery. Cancer is the second leading cause of death globally, having tumor metastases responsible for approximately 90% of all cancer-related deaths. High levels of NO promote DNA damage, oxidative/nitrosative stress, cytotoxicity and apoptosis. Nitric oxide at high concentration has been reported to show anticancer properties and to serve as a chemosensitizer and radiotherapy enhancer. Beyond Air is developing treatment protocols using ultra-high NO concentrations to destruct tumor outgrowths based on its current findings.

### **Forward-Looking Statement**

This press release contains “forward-looking statements.” 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: our approach to discover and develop novel drugs, which is unproven and may never lead to 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; and our short operating history. 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.

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