

June 10, 2021



Beyond Air® Reports Financial Results for Fourth Fiscal Quarter and Year-End 2021

Submitted first premarket approval (PMA) application in the Company's history to FDA for LungFit® PH to treat persistent pulmonary hypertension of the newborn (PPHN); Company preparing for commercial launch in the fourth quarter of calendar year 2021

Expanded the commercial and business development teams by appointing executives with extensive nitric oxide (NO) experience

Presented positive data for 150 – 160 ppm NO from LungFit® PRO programs in hospitalized patients (adults and infants) with viral lung infections at CHEST 2020 and at ATS 2021

Received grant from the Cystic Fibrosis Foundation (CFF) for ongoing nontuberculous mycobacteria (NTM) at-home pilot study delivering up to 250 ppm NO via LungFit® GO

Presented positive preclinical data for the solid tumor program at three scientific conferences; data suggest exogenous ultra-high concentration gaseous NO (gNO) can trigger anti-tumor immunity

Conference call scheduled for today, Thursday, June 10th, at 4:30 p.m. ET

GARDEN CITY, N.Y., June 10, 2021 (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 (gNO) for the treatment of solid tumors, today announced financial results for its fourth quarter and fiscal year ended March 31, 2021.

“The submission of the first PMA application to the FDA in our Company’s history has placed us on a clear path for the transformative year ahead. I am confident that when approved to treat PPHN, LungFit® PH will revolutionize the market as the first and only commercially available system that is capable of generating NO from ambient air. In preparation for commercial launch, our organization has grown considerably over the past twelve months, recruiting unparalleled talent with extensive experience in the NO market. I believe our team is more than prepared to bring our first NO generator and delivery system to NICUs across the United States later this year,” said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air.

“Looking beyond PPHN, we have made progress in our other potential indications for the LungFit® platform, which have much larger underserved patient populations. We recently presented positive data at ATS 2021 for high concentration NO in patients hospitalized with acute viral pneumonia, including COVID-19. We believe the entirety of data that we have presented at 150 – 160 ppm NO in both adult and infant patient populations supports further

development of LungFit[®] PRO. Given the seasonality of viral pneumonia, we anticipate completing a pivotal study at the end of the 2022-23 pneumonia season in the United States. Additionally, our at-home NTM pilot study using LungFit[®] GO is progressing nicely, and we are pleased with the performance of our device. We expect to present interim results from this study at a medical or scientific conference in the Fall of 2021. Success in NTM will further validate the safety and efficacy of LungFit[®] GO and allow us to move high concentration NO into the large, untapped home market for lung infections. Finally, we expect to receive regulatory clearance to start human studies in our solid tumor program using ultra-high concentration gNO around the end of calendar year 2021.”

Fiscal Year 2021 and Recent Highlights

- **LungFit[®] PH**

- Submitted a PMA application to the U.S. FDA in November 2020 for the treatment of PPHN
- Appointed NO industry veterans to the roles of Head of Sales, Head of Marketing, and Director of Business Development to support the commercial launch, as well as lead partnership efforts outside of the U.S.
- Completed the rigorous task of implementing our global supply chain through the Company’s subsidiary in Ireland

- **LungFit[®] PRO**

Acute Viral Pneumonia Data

- Presented interim analysis from the ongoing pilot study for acute viral pneumonia, including COVID-19 patients, at the American Thoracic Society (ATS) International Conference in May 2021; results showed that 150 ppm NO was well-tolerated with no treatment-related adverse events, and showed encouraging efficacy signals for hospital length of stay and duration of oxygen supplementation
- Initiated a pilot study for acute viral pneumonia, including COVID-19 patients, in Israel using LungFit[®] PRO at 150 ppm NO; patient enrollment began in November 2020
- Presented *in vitro* data on NO-treated OC43 human coronavirus at the CHEST Annual Meeting in October 2020; data suggested that 150 – 250 ppm NO delivered intermittently via LungFit[®] PRO may be effective for both prevention and treatment of human coronavirus infection

Bronchiolitis Data

- Presented further analysis of three previously reported pilot studies in bronchiolitis at the American Thoracic Society (ATS) International Conference in May 2021; results show that 150 – 160 ppm NO demonstrated a favorable safety profile and consistent efficacy across multiple endpoints, as well as statistical significance on multiple efficacy endpoints of 150 ppm compared to 85 ppm in a head-to-head study
- Announced detailed positive efficacy and safety data from the third bronchiolitis pilot study at the CHEST Annual Meeting in October 2020, supporting the development of 150 ppm inhaled NO as a treatment for this unmet medical need
- Published a peer-reviewed paper in the journal *Scientific Reports* that showed encouraging results from our second bronchiolitis study, indicating that NO is safe and efficacious in infants hospitalized with bronchiolitis

- **LungFit® GO**
 - Received a grant for up to \$2.17 million from the CFF to advance the clinical development of inhaled NO to treat NTM lung disease by helping fund the ongoing pilot study
 - Initiated an at-home pilot study in Australia using LungFit® GO for self-administration of up to 250 ppm NO for the treatment of refractory NTM lung disease in adult patients; patient screening began December 2020
 - Published the results from a compassionate use patient case study using NO to treat pulmonary *Mycobacterium abscessus* infection at the National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health, in a scientific article in the August 2020 edition of Access Microbiology
- **Solid Tumor Program**
 - Presented *in vivo* preclinical data for exogenous ultra-high concentration gNO at the American Association for Cancer Research (AACR) Conference on Tumor Immunology and Immunotherapy in October 2020. These data suggest that direct administration of gNO to solid tumors triggers a systemic anti-tumor immune response, which could serve as the basis for an effective immunotherapy
 - Presented *in vitro* and *in vivo* preclinical data at the International Association for the Study of Lung Cancer's (IASLC) North America Conference on Lung Cancer 2020 (NACLC 2020) in October 2020, that suggest ultra-high concentration gNO may treat lung cancer locally and its metastases systemically
 - Presented *in vivo* and *in vitro* preclinical data in solid tumors at the AACR Virtual Annual Meeting II in June 2020. The data showed that gNO, at concentrations of 25,000 to 200,000 ppm, eliminates colon and breast cancer cells *in vitro* and conveys anti-tumor immunity *in vivo* in a colon cancer model

Upcoming Milestones

- **LungFit® PH**
 - Anticipate receiving FDA approval to treat PPHN late in the third quarter of calendar year 2021
 - Commercial launch in the United States planned for the fourth quarter of calendar year 2021
 - Expect to secure ex-U.S. commercial partnership in 2022 after obtaining CE Mark in the European Union around the end of calendar year 2021
- **LungFit® PRO**
 - Plan on initiating a pivotal trial for patients hospitalized with viral lung infections, either for acute viral pneumonia or bronchiolitis, in the fourth quarter of calendar year 2022
- **LungFit® GO**
 - Expect to report interim data for the at-home NTM lung infection pilot study at a medical or scientific conference in Fall 2021 with the trial completing in the first half of calendar year 2022
- **Solid Tumor Program**
 - Anticipate receiving regulatory clearance to initiate human studies around the end of calendar year 2021

Financial results for the fiscal year ended March 31, 2021

Revenue for the fiscal year ended March 31, 2021 was \$873 thousand as compared to \$1.4 million for the fiscal year ended March 31, 2020, all of which was licensing revenue.

Research and development expenses for the fiscal year ended March 31, 2021 were \$12.6 million, compared to \$10.6 million for the fiscal year ended March 31, 2020.

General and administrative expenses for the fiscal year ended March 31, 2021 were \$10.5 million, compared to \$8.9 million for the fiscal year ended March 31, 2020.

For the fiscal year ended March 31, 2021, the Company had a net loss of \$22.9 million, or (\$1.27) per share, compared to a net loss of \$20.5 million, or (\$1.78) per share for the fiscal year ended March 31, 2020.

In May 2021, the Company reached a settlement agreement with former LungFit[®] PH commercial licensee, Circassia Group plc ("Circassia"). Under the terms of the agreement, Beyond Air retains global commercialization rights to LungFit[®] PH for payment of \$10.5 million, along with future royalty payments capped at \$6.0 million. Beyond Air will begin making payments only after receiving U.S. FDA approval for LungFit[®] PH in accordance with the following schedule: \$2.5 million upon FDA approval, \$3.5 million one year after FDA approval, and \$4.5 million two years after FDA approval. Beginning in year three post-approval, Circassia will receive a quarterly royalty payment equal to 5% of LungFit[®] PH net sales in the U.S. This royalty will terminate once the aggregate payment reaches \$6.0 million.

As of March 31, 2021, the Company had cash, cash equivalents and restricted cash of \$35.3 million. Additionally, as previously reported, the Company had cash, cash equivalents, and restricted cash of \$34.9 million as of April 30, 2021.

Conference Call & Webcast

Thursday, June 10th @ 4:30 pm ET

Domestic: 877-407-0784

International: 201-689-8560

Passcode: 13720144

Webcast: <http://public.viavid.com/index.php?id=145098> or the Events page of the Company's website

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[®], 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 respiratory tract infections that are not effectively addressed with current standards of care. Beyond Air is currently advancing its revolutionary LungFit[®] 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.

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^{®*}

Beyond Air's LungFit[®] 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[®] 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 NO₂ purging steps, and other benefits. The LungFit[®] 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[®] is not approved for commercial use. Beyond Air's LungFit[®] is for investigational use only. Beyond Air is not suggesting NO use over 80 ppm or use at home.*

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 Acute Viral Pneumonia

In adults, viruses have been identified as the causative agents in approximately 100 million

cases of community-acquired pneumonia per year. While viral pneumonia in adults is most commonly caused by rhinovirus, respiratory syncytial virus (RSV) and influenza virus, newly emerging viruses (including SARS-CoV-1, SARS-CoV-2, avian influenza A, and H1N1 viruses) have been identified as pathogens contributing to the overall burden of adult viral pneumonia. Patients aged 65 years or older are at particular risk for death from the disease, as are patients with other underlying health conditions or weakened immune systems. There is no consensus regarding the use of antiviral drugs to treat viral pneumonia, and specific preventative measures are currently limited to the influenza vaccine. Given that current treatment recommendations are largely limited to supportive care, there is an unmet medical need for effective treatment options.

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; early data indicate that this range of NO concentration may have a positive effect on patients infected with NTM.

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.

About Solid Tumors

Cancer is the second leading cause of death globally, with tumor metastases responsible for approximately 90% of all cancer-related deaths. Current cancer treatment modalities generally include chemotherapy, immunotherapy, radiation, and/or surgery. Nitric oxide at ultra-high concentrations has been reported to show anticancer properties and to serve as a chemosensitizer and radiotherapy enhancer. Based on its current findings, Beyond Air is developing treatment protocols using ultra-high nitric oxide concentrations to ablate primary tumors and treat metastatic disease.

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, 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: 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

Corey Davis, Ph.D.

LifeSci Advisors, LLC

Cdavis@lifesciadvisors.com

(212) 915-2577

BEYOND AIR, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS

**March 31,
2021**

**March 31,
2020**

ASSETS		
Current assets		
Cash and cash equivalents	\$ 34,630,682	\$ 19,829,275
Restricted cash	637,025	5,635,836
Grant receivable	425,000	-
Other current assets and prepaid expenses	1,530,096	1,149,806
Total current assets	37,222,803	26,681,917
Licensed right to use technology	374,686	412,763
Right-of-use lease assets	1,860,885	195,727
Property and equipment, net	928,842	211,337
Other assets	137,880	-
TOTAL ASSETS	\$ 40,525,096	\$ 27,434,744

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities		
Accounts payable	\$ 1,324,988	\$ 2,256,229
Accrued expenses	1,804,938	1,097,534
Deferred revenue	-	873,190
Stock to be issued to a vendor	-	240,000
Operating lease liability	113,141	69,342
Loan payable	556,514	335,358
Total current liabilities	3,799,581	4,871,653
Operating lease liability	1,789,461	131,581
Long-term loan, net	4,472,201	4,339,065
Total liabilities	10,061,243	9,342,299

Commitments and contingencies

Stockholders' equity

Preferred Stock, \$0.0001 par value per share:
10,000,000 shares authorized, 0 shares issued and
outstanding

- -

Common Stock, \$0.0001 par value per share:
100,000,000 shares authorized, 21,828,244 and
16,056,360 shares issued and outstanding as of March
31, 2021 and 2020, respectively

2,183 1,606

Treasury stock

(25,000) (25,000)

Additional paid-in capital

110,948,477 75,702,915

Accumulated deficit

(80,461,807) (57,587,076)

Total stockholders' equity

30,463,853 18,092,445

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY

\$ 40,525,096 \$ 27,434,744

BEYOND AIR, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	<u>Year Ended March 31, 2021</u>	<u>Year Ended March 31, 2020</u>
License revenue	\$ 873,190	\$ 1,390,104
Operating expenses		
Research and development	(12,618,349)	(10,648,920)
General and administrative	(10,468,341)	(8,883,119)
Loss from Operations	<u>(22,213,500)</u>	<u>(18,141,935)</u>
Other income (expense)		
Realized and unrealized loss from marketable securities	-	(2,075,602)
Dividend and interest income	16,901	115,716
Interest and finance expense	(641,626)	(30,543)
Foreign exchange loss (gain)	(36,506)	35,560
Total other loss	<u>(661,231)</u>	<u>(1,954,869)</u>
Net loss before income taxes	(22,874,731)	(20,096,804)
Benefit for income taxes	<u>-</u>	<u>154,300</u>
Net loss	\$(22,874,731)	\$(19,942,504)
Deemed dividend from warrant modification	<u>-</u>	<u>(522,478)</u>
Net loss attributed to common stockholder	\$(22,874,731)	\$(20,464,982)
Net loss per share – basic and diluted	\$ (1.27)	\$ (1.78)
Weighted average number of shares of common stock outstanding – basic and diluted	18,005,226	11,506,212



Source: Beyond Air™