

February 10, 2022



Beyond Air® Reports Financial Results for the Third Quarter of Fiscal Year 2022

LungFit® PH premarket approval (PMA) submission under active review by U.S. FDA; approval and commercial launch anticipated in the first half of calendar year 2022 along with European CE Mark

Raised \$30 million for oncology affiliate Beyond Cancer™, Beyond Air maintained an 80% equity ownership; first in human trial initiation on track for first half of calendar year 2022

Expansion of leadership team with appointment of Dr. Andrew Colin to Chief Medical Officer tasked with leading the strategic efforts for LungFit® PRO and LungFit® GO clinical programs

Four abstracts accepted for presentation at leading scientific conferences for ongoing clinical programs in the first half of calendar year 2022

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

GARDEN CITY, N.Y., Feb. 10, 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 financial results for its third fiscal quarter ended December 31, 2021.

Steve Lisi, Chairman and Chief Executive Officer of Beyond Air, commented, “The Beyond Air team continues to maintain a collaborative relationship with FDA to work towards the approval of LungFit® PH for the treatment of persistent pulmonary hypertension of the newborn, or PPHN, in the United States. Our goal remains to bring this groundbreaking therapy to the market as soon as possible, which we now anticipate being in the first half of this year. With our strong cash balance of \$54.5 million, exclusive of Beyond Cancer cash, we are in a favorable position for commercial launch of LungFit® PH, pending approval. In Europe, we are on track to receive CE Mark in the first half of calendar year 2022 as well and will look to partner the program internationally later in the year.”

“I am happy to report progress in our other programs under the leadership of our new Chief Medical Officer, Dr. Andrew Colin,” continued Mr. Lisi. “Notably, we will be presenting additional safety and efficacy data from our community-acquired viral pneumonia (CAVP), including COVID-19, pilot study at ECCMID in April of this year. Recall, we presented an interim analysis of 19 COVID-19 patients at ATS 2021 in May, where 150 PPM NO was well tolerated and showed encouraging efficacy signals in adult hospitalized patients. Despite COVID-related lockdowns in Australia, we expect to present efficacy and safety data from our NTM pilot study using LungFit® GO to deliver up to 250 ppm NO in the home setting at

the American Thoracic Society conference in May of this year. Finally, our private oncology affiliate is on track to begin enrolling patients for a first in human study for UNO therapy in solid tumors in the first half of this year.”

Recent Highlights and Upcoming Milestones

- **LungFit® PH**

- Commercial launch for PPHN in the United States expected in the first half of calendar year 2022, pending U.S. FDA PMA approval
- CE Mark approval anticipated in the first half of calendar year 2022 with an international commercial partnership expected to follow later in the year

- **LungFit® PRO**

Community-Acquired Viral Pneumonia (CAVP) Data (including COVID-19)

- Abstract for ongoing pilot study for 150 PPM NO delivered to adult hospitalized CAVP patients accepted for presentation at the 32nd European Congress of Clinical Microbiology and Infectious Disease being held April 23 – 26, 2022 in Lisbon, Portugal

Upcoming Study

- Plan on initiating a US trial for patients hospitalized with viral lung infections in the fourth quarter of calendar year 2022 (*pending discussion with FDA and pandemic permitting*)

- **LungFit® GO**

- Abstract for ongoing pilot study for 250 PPM NO self-administered by refractory NTM lung infection patients in the home-setting accepted for presentation at the American Thoracic Society (ATS) 2022 International Conference being held from May 13 – 18, 2022 in San Francisco, CA
- Anticipate beginning a pilot study in severe exacerbations due to lung infections in COPD patients in 2022 or 2023

- **Beyond Cancer’s Solid Tumor Program**

- Raised \$30 million to form private oncology affiliate Beyond Cancer that will leverage Beyond Air’s NO experience and accelerate and enhance the solid tumor pipeline. Beyond Air retained an 80% equity ownership
- On track to begin the enrollment of patients in first in human studies in the first half of calendar year 2022
- Two abstracts accepted for poster presentation at the American Association for Cancer Research (AACR) Annual Meeting 2022 in New Orleans, Louisiana being held from April 8 – 13, 2022
- Completed six-member Board of Directors with the agreement to serve of David C. Dvorak, former President and CEO of Zimmer Biomet Holdings and current Chairman and CEO of Deep Think Health, and Dr. Greg Berk, currently serving as the Interim CEO, President of Research & Development and CMO of GT Biopharma

Financial results for the fiscal quarter ended December 31, 2021

Revenue for the fiscal quarter ended December 31, 2021 was \$0 as compared to \$0.1 million for the fiscal quarter ended December 31, 2020, all of which was licensing revenue.

Research and development expenses for the fiscal quarter ended December 31, 2021 were \$2.5 million, compared to \$3.3 million for the fiscal quarter ended December 31, 2020.

General and administrative expenses for the fiscal quarter ended December 31, 2021 were \$4.9 million, compared to \$2.5 million for the fiscal quarter ended December 31, 2020.

Other income and expense for the fiscal quarter ended December 31, 2021 was a loss of \$0.5 million.

For the fiscal quarter ended December 31, 2021, the Company had a net loss of \$8.0 million of which \$7.7m or (\$0.29) per share was attributable to the shareholders of Beyond Air, compared to a net loss of \$5.8 million, or (\$0.33) per share for the fiscal quarter ended December 31, 2020.

As of December 31, 2021, the Company had cash and cash equivalents of \$83.5 million.

Conference Call & Webcast

Thursday, February 10th @ 4:30 PM ET

Domestic: 877-407-0784

International: 201-689-8560

Passcode: 13726696

Webcast: https://viaid.webcasts.com/starthere.jsp?ei=1526516&tp_key=78e079398f 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 Community Acquired 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) infection is a rare and serious bacterial infection in the lungs causing debilitating pulmonary disease associated with high morbidity and mortality. NTM infection is acquired by inhaling aerosolized bacteria from the environment, and can lead to NTM lung disease, a progressive and chronic condition. According to the Cystic Fibrosis Foundation, 13% of U.S. cystic fibrosis patients had a positive culture for a NTM species in 2017. NTM is an emerging public health concern worldwide because of its multi-drug antibiotic resistance. Current treatment guidelines suggest a combination of multiple antibiotics dosed chronically 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 to cause severe adverse events. Beyond Air's system is designed to deliver 150 - 400 ppm NO to the lung, and early data indicate that this range of NO concentrations could 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 Beyond Cancer: UNO Therapy for 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 Cancer 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 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

Corey Davis, Ph.D.

LifeSci Advisors, LLC

Cdavis@lifesciadvisors.com

(212) 915-2577

BEYOND AIR, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS (amounts in thousands, except share and per share data)

	December 31, 2021	March 31, 2021
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 83,468	\$ 34,631

Restricted cash	9,239	637
Grant receivable	661	425
Other current assets and prepaid expenses	1,317	1,530
Total current assets	94,684	37,223
Licensed right to use technology	346	375
Right-of-use lease assets	2,299	1,861
Property and equipment, net	1,772	929
Other assets	209	138
TOTAL ASSETS	\$ 99,311	\$ 40,525

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities

Accounts payable	\$ 1,611	\$ 1,325
Accrued expenses	4,328	1,805
Operating lease liability	239	113
Loan payable	-	557
Total current liabilities	6,178	3,800

Long-term liabilities

Operating lease liability	2,162	1,789
Long-term debt, net	200	4,472
Total liabilities	8,540	10,061

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, 28,161,446 and
21,828,244 shares issued and outstanding as of
December 31, 2021 and March 31, 2021, respectively

3 2

Treasury stock	(25)	(25)
Additional paid-in capital	188,652	110,948
Accumulated deficit	(103,636)	(80,462)
Total stockholders' equity attributable to Beyond Air, Inc	84,994	30,464
Non-controlling interests	5,777	-
Total Equity	90,771	30,464
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 99,311	40,525

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

(amounts in thousands, except share and per share data)
(UNAUDITED)

	For the Three Months Ended December 31,		For the Nine Months Ended December 31,	
	2021	2020	2021	2020
License revenues	\$ -	\$ 149	\$ -	\$ 728
Operating expenses:				
Research and development	2,543	3,294	8,091	10,773
General and administrative	4,943	2,471	12,188	7,134
Operating expenses	<u>7,486</u>	<u>5,765</u>	<u>20,279</u>	<u>17,907</u>
Operating loss	<u>(7,486)</u>	<u>(5,616)</u>	<u>(20,279)</u>	<u>(17,180)</u>
Other income (loss)				
Interest expense	(57)	(158)	(377)	(464)
Foreign exchange gain / (loss)	(8)	7	2	0
Other income / (expense)	(412)	(2)		0
Estimated Liability for Contingent Loss	<u>-</u>	<u>-</u>	<u>(2,742)</u>	<u>-</u>
Total other income (loss)	<u>(476)</u>	<u>(153)</u>	<u>(3,118)</u>	<u>(464)</u>
Provision for income taxes	-	-	-	-
Net Loss	<u>\$ (7,962)</u>	<u>\$ (5,770)</u>	<u>\$ (23,397)</u>	<u>\$ (17,643)</u>
Less : net loss attributable to non-controlling interests	(223)	-	(223)	-
Net loss attributable to Beyond Air, Inc.	\$ (7,739)	(5,770)	(23,174)	(17,643)
Net basic and diluted loss per share attributable to Beyond Air, Inc.	\$ (0.29)	\$ (0.33)	\$ (0.95)	\$ (1.03)
Weighted average number of shares, outstanding basic and diluted	26,822,302	17,609,328	24,319,771	17,086,871



Source: Beyond Air™