

November 11, 2021



## **Beyond Air® Reports Financial Results for the Second Quarter of Fiscal Year 2022**

*U.S. FDA actively reviewing premarket approval (PMA) submission for LungFit® PH to treat persistent pulmonary hypertension of the newborn (PPHN); Remain on track for commercial launch in the fourth quarter of calendar year 2021*

*Raised \$23.9 million to form a new private, independently managed entity, called Beyond Cancer, Ltd, to advance the development of ultra-high concentration nitric oxide (UNO) for the treatment of solid tumors*

*Positive interim results reported from the LungFit® GO Nontuberculous Mycobacteria (NTM) lung infection at-home pilot study (self-administration), with full efficacy and safety data expected in CY2022*

*Conference call scheduled for today, November 11<sup>th</sup>, at 4:30 p.m. ET*

GARDEN CITY, N.Y., Nov. 11, 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, through its affiliate Beyond Cancer, ultra-high concentration nitric oxide (UNO) for the treatment of solid tumors, today announced financial results for its first fiscal quarter ended September 30, 2021.

Steve Lisi, Chairman and Chief Executive Officer of Beyond Air commented, "This has been an exciting quarter for Beyond Air, as the team continues to deliver both operationally and strategically. On the strategic front, the launch of Beyond Cancer under the new leadership of CEO Selena Chaisson, M.D. is a special achievement. The separation of the UNO franchise to an independently managed affiliate was made possible through the support of investors in a \$23.9 million ongoing private financing. We believe that the spin-off will accelerate UNO's path to the clinic and create long-term value for shareholders. Beyond Cancer will leverage our NO expertise, IP portfolio, preclinical oncology team, regulatory progress, and initially use existing Company infrastructure. The separation enables Beyond Air to focus on its core business of advancing its LungFit® platform for the treatment of respiratory diseases."

Mr. Lisi continued, "Consistent with our global regulatory update from September, our PMA for LungFit® PH continues to be under review at FDA. We successfully completed our Stage 1 Assessment Audit for a CE Mark in Europe and anticipate approval during the first half of calendar year 2022, after which we plan to partner the program internationally. In the United States, we continue to guide a commercial launch in the fourth quarter of this calendar year. Our commercial team has grown considerably and is ready to bring the first-ever integrated generator and delivery system that produces NO to hospitals across the country. The Beyond Air team also continues to execute on the R&D front with the release of interim data

from our NTM pilot study using LungFit® GO to deliver up to 250 ppm NO in a home setting. Despite the COVID-19 related lockdowns in Australia, as of September 6<sup>th</sup> we had 8 patients successfully enrolled and titrated up to 250 ppm NO, with no study discontinuations and no treatment-related serious adverse events. The pilot study continues enrolling patients, and we expect to report complete safety and efficacy results in 2022.”

## Recent Highlights and Upcoming Milestones

- **LungFit® PH**

- Commercial launch in the United States on track for the fourth quarter of calendar year 2021, pending FDA PMA approval
- Successfully completed Stage 1 Assessment Audit in the CE Mark process; expect to receive CE Mark in 1H CY2022 followed by international commercial partnership

- **LungFit® PRO**

- Acute Viral Pneumonia Data*

- Ongoing pilot study for acute viral pneumonia in adults, including COVID-19 patients, in Israel using LungFit® PRO at 150 ppm NO
- Upcoming Study (pending discussion with FDA)*
- Plan on initiating a pivotal trial for patients hospitalized with viral lung infections in the fourth quarter of calendar year 2022

- **LungFit® GO**

- Reported positive interim data for 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
- Interim results showed that 250 ppm NO was well-tolerated with no study discontinuations or treatment-related serious adverse events observed in 8 patients, with methemoglobin and NO<sub>2</sub> concentrations remaining within acceptable safety ranges in all subjects
- Expect to report full efficacy and safety data for the at-home NTM lung infection pilot study at a medical or scientific conference in calendar year 2022
- Published a compassionate use case study called “*Non-tuberculous mycobacteria infection treated with intermittently inhaled high-dose nitric oxide*” using high concentration NO treatment to treat the *Mycobacterium abscessus* strain of NTM in The BMJ<sup>1</sup>

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

- Secured commitments of \$23.9 million in a concurrent private placement of common shares, not to exceed \$30 million, to form Beyond Cancer that will leverage Beyond Air’s NO experience and accelerate and enhance the solid tumor pipeline
- After this financing, Beyond Air will retain at least 80% equity ownership in Beyond Cancer
- Anticipate beginning enrollment of patients in the first half of calendar year 2022

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<sup>1</sup> Goldbart A, Gatt D, Golan Tripto I. BMJ Case Rep 2021;14:e243979. doi:10.1136/bcr-2021-243979

### **Financial results for the fiscal quarter ended September 30, 2021**

Revenue for the fiscal quarter ended September 30, 2021 was \$0 as compared to \$350,000 for the fiscal quarter ended September 30, 2020, all of which was licensing revenue.

Research and development expenses for the fiscal quarter ended September 30, 2021 were \$2.8 million, compared to \$3.1 million for the fiscal quarter ended September 30, 2020.

General and administrative expenses for the fiscal quarter ended September 30, 2021 were \$3.4 million, compared to \$2.2 million for the fiscal quarter ended September 30, 2020.

Other income and expense for the fiscal quarter ended September 30, 2021 was a loss of \$2.5 million, compared to a loss of \$0.2 million for the fiscal quarter ended September 30, 2020.

For the fiscal quarter ended September 30, 2021, the Company had a net loss of \$8.7 million, or (\$0.36) per share, compared to a net loss of \$5.1 million, or (\$0.30) per share for the fiscal quarter ended September 30, 2020.

As of September 30, 2021, the Company had cash, cash equivalents and restricted cash of \$48.7 million.

### **Conference Call & Webcast**

***Thursday, November 11th @ 4:30 PM ET***

Domestic: 877-407-0784

International: 201-689-8560

Passcode: 13722892

Webcast: <http://public.viavid.com/index.php?id=146470> 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<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 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) 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, Ltd.**

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<sup>®</sup>† product, including statements with regard to potential regulatory developments, the potential impact on patients and anticipated benefits associated with its use and concerning the expected closing date of the Beyond Cancer private placement; the extent to which the proposed transaction will allow Beyond Air to focus on the development of its LungFit<sup>™</sup> product and invest in the treatment of other respiratory diseases; the extent to which Beyond Cancer will be able to utilize Beyond Air's prior knowledge and experience;*

*the long-term value created for Beyond Cancer shareholders; the eventual equity ownership stakes in Beyond Cancer, including those owned by Beyond Air; the anticipated use of proceeds from the private placement; the potential safety and efficacy of the ultra-high concentration nitric oxide product candidate, as well as its therapeutic potential in a number of indications; and the potential impact on patients and anticipated benefits associated with the ultra-high concentration nitric oxide product candidate. 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: Beyond Cancer’s ability to successfully close the private placement; Beyond Cancer’s ability to raise additional capital; the timing and results of future pre-clinical studies and clinical trials concerning the ultra-high concentration nitric oxide product candidate; the FDA potentially requiring additional clinical trials or data; the potential that regulatory authorities, including the FDA and comparable non-U.S. regulatory authorities, may not grant or may delay approval for the ultra-high concentration nitric oxide product candidate; the impact of the COVID-19 pandemic on potential pre-clinical studies, clinical trials and 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 and Beyond Cancer’s ability to fund and the results of further pre-clinical studies and clinical trials of our product candidates and the ultra-high concentration nitric oxide product candidate; 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; 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.*

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

	<u>September 30, 2021</u>	<u>March 31, 2021</u>
	(Unaudited)	
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 47,699	\$ 34,631
Restricted cash	1,047	637
Grant receivable	-	425
Other current assets and prepaid expenses	1,550	1,530
Total current assets	<u>50,295</u>	<u>37,223</u>
Licensed right to use technology	356	375
Right-of-use lease assets	1,769	1,861
Property and equipment, net	1,424	929
Other assets	211	138
<b>TOTAL ASSETS</b>	<u>\$ 54,056</u>	<u>\$ 40,525</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 2,241	\$ 1,325
Accrued expenses	4,352	1,805
Operating lease liability	178	113
Loan payable	140	557
Total current liabilities	<u>6,912</u>	<u>3,800</u>
Long-term liabilities		
Operating lease liability	1,684	1,789
Long-term debt, net	4,539	4,472
Total liabilities	<u>13,134</u>	<u>10,061</u>
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, 25,209,749 and 21,828,244 shares issued and outstanding as of September 30, 2021 and March 31, 2021, respectively	3	2
Treasury stock	(25)	(25)
Additional paid-in capital	136,840	110,948
Accumulated deficit	(95,897)	(80,462)
Total stockholders' equity	<u>40,921</u>	<u>30,464</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 54,056	40,525

**BEYOND AIR, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(amounts in thousands, except share and per share data)  
**(UNAUDITED)**

	<b>For the Three Months Ended</b>	
	<b>September 30,</b>	
	<u>2021</u>	<u>2020</u>
License revenues	\$ -	\$ 350
Operating expenses:		
Research and development	2,807	3,147
General and administrative	3,395	2,169
Operating expenses	<u>6,201</u>	<u>5,316</u>
Operating loss	<u>(6,201)</u>	<u>(4,967)</u>
Other income (loss)		
Dividend and interest income	1	1
Interest expense	(161)	(159)
Foreign exchange loss	(0)	(7)
Estimated Liability for Contingent Loss	(2,330)	-
Total other income (loss)	<u>(2,490)</u>	<u>(165)</u>
Net loss	\$ (8,692)	\$ (5,132)
Net basic and diluted loss per share	\$ (0.36)	\$ (0.30)

Weighted average number of shares of common stock used in computing basic and diluted net loss per share	24,165,965	17,120,801
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Source: Beyond Air™