

August 6, 2020



# Beyond Air® Reports Financial Results for First Quarter of Fiscal Year 2021 and Provides Business Update

*U.S. COVID-19 study showing positive safety profile for patients enrolled to date*

*PMA for LungFit™ PH to treat persistent pulmonary hypertension of the newborn (PPHN) expected to be submitted to the FDA at the end of September 2020*

*LungFit™ HOME nontuberculous mycobacteria (NTM) lung infection pilot study expected to start by the end of calendar 2020*

*Commercial supply agreement executed for LungFit™ and LungFit™ PH*

*Conference call scheduled for today, Thursday, August 6<sup>th</sup> at 8:30 am ET*

GARDEN CITY, N.Y., Aug. 06, 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, today announced financial results for its fiscal first quarter ended June 30, 2020.

“Throughout the quarter ended June 30<sup>th</sup>, the entire Beyond Air team continued to show their exceptional capabilities as we initiated our U.S. COVID-19 study, released positive data in bronchiolitis showing vastly improved benefit with the 150 ppm nitric oxide compared to the 85 ppm nitric oxide and control arms and revealed our potentially ground-breaking data in solid tumors. This positive momentum is set to continue over the next few quarters with a planned submission of the PMA for the LungFit™ PH to treat persistent pulmonary hypertension of the newborn (PPHN), continued enrollment in the U.S. study of the LungFit in COVID-19 patients, initiation of our AT-Home NTM study using the LungFit™ HOME system and progress in our solid tumor program,” said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air.

“We believe that nitric oxide can be an effective treatment for mild-to-moderate COVID-19 patients, and the LungFit™ is by far the optimal system to deliver the 150 parts per million concentration needed in order for nitric oxide to be effective against SARS-CoV-2. Given the progress we are making, we anticipate the opportunity this fall to evaluate the efficacy of nitric oxide delivered by LungFit™ to COVID-19 patients,” concluded Mr. Lisi.

## **Fiscal First Quarter and Recent Highlights**

- Initiated U.S. clinical study using the LungFit™ system to treat COVID-19 patients with

NO therapy.

- Completed a commercial supply agreement with Spartronics, formerly Sparton, for the manufacture of LungFit™ and LungFit™ PH.
- Announced positive top-line results from the third pilot study in bronchiolitis patients that showed high concentration NO (150 ppm) plus standard supportive therapy (SST) was statistically significant compared to both low concentration nitric oxide (85 ppm) plus SST and to SST alone on both the primary endpoint of fit-to-discharge and the key secondary endpoint of hospital length of stay with no serious adverse events related to NO reported. The company's bronchiolitis program is currently on hold, but is expected to resume once the pandemic subsides.
- 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 hospitalized infants with bronchiolitis.
- Presented preclinical data in solid tumors showing NO, 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.
- Ended the quarter with \$24.4 million in cash and cash equivalents.

### **Upcoming Milestones**

- Expect to submit a PMA for the LungFit™ PH to treat persistent pulmonary hypertension of the newborn (PPHN) to the FDA at the end of September 2020. This filing has been delayed due to the ongoing COVID-19 pandemic.
- Expect to initiate the At-Home nontuberculous mycobacteria (NTM) lung infection pilot study using the LungFit™ HOME by the end of 2020. This study start has been delayed due to the ongoing COVID-19 pandemic.
- Updates expected over the coming months for the U.S. clinical program using the LungFit™ system to treat COVID-19 patients with NO.
- Announce additional preclinical data this fall for high concentration NO as a potential treatment for ablating solid tumors and inducing an anti-tumor immune response.

### **Financial results for three months ended June 30, 2020**

Revenue for the three months ended June 30, 2020 was \$229,161 as compared to \$627,469 for the three month ended June 30, 2019, all of which was licensing revenue.

Research and development expenses for the three months ended June 30, 2020 were \$4.3 million, compared to \$2.3 million for the three month ended June 30, 2019.

General and administrative expenses for the three months ended June 30, 2020 were \$2.5 million, compared to \$2.2 million for the three month period ended June 30, 2019.

For the three months ended June 30, 2020, the Company had a net loss of \$6.7 million, or (\$0.40) per share, compared to a net loss of \$6.2 million, or (\$0.67) per share for the three months ended June 30, 2019.

As of June 30, 2020, the Company had cash, cash equivalents and restricted cash of \$24.4 million.

### **Conference Call & Webcast**

**Thursday, August 6<sup>th</sup> @ 8:30 am ET**

Domestic: 888-220-8474

International: 323-794-2590

Passcode: 7088663

Webcast: <http://public.viavid.com/index.php?id=140846>

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

Beyond Air, Inc. is a clinical-stage medical device and biopharmaceutical company developing a revolutionary NO Generator and Delivery System, the LungFit™, that uses NO generated from ambient air to deliver precise amounts of NO to the lungs of ventilated and non-ventilated patients 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™ in clinical trials for the treatment of severe lung infections such as SARS-CoV-2, bronchiolitis and nontuberculous mycobacteria (NTM). Additionally, Beyond Air is using ultra-high concentrations of NO with a proprietary delivery system, separate from the LungFit™, 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™ NO Generator and Delivery System\***

Beyond Air's LungFit™ 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™ 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™ 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 nor 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 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 COVID-19**

COVID-19 (coronavirus disease 2019) is an infectious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). COVID-19 first emerged in Wuhan, China in December of 2019. Those affected develop fever, cough, shortness of breath and/or difficulty breathing. While the majority of cases result in mild symptoms, some can progress to pneumonia and multi-organ failure. Older adults and people who have serious chronic medical conditions are at an increased risk of developing severe complications from COVID-19. There is no specific treatment approved for COVID-19 and patients are managed with supportive care. NO may prove to be a treatment as the impact on the lung should

result in bronchodilation, reduction in inflammation and inhibition of the viral replication process<sup>1,2,3</sup>. As of August 5, 2020, more than 18 million confirmed cases of COVID-19 and more than 690,000 deaths have been reported globally.

[1] Tripathi et al, FEMS Immunology and Medical Microbiology, December 2017

[2] Saura, M., et al., An antiviral mechanism of nitric oxide: inhibition of a viral protease. Immunity, 1999. 10(1): p. 21-8.

[3] Akerström S et al. Nitric oxide inhibits the replication cycle of severe acute respiratory syndrome coronavirus. J Virol. 2005; 79(3):1966-9.

### **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 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 devices and 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 various 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.

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**BEYOND AIR, INC. AND SUBSIDIARIES  
 CONDENSED CONSOLIDATED BALANCE SHEETS**

	<b>June 30, 2020</b>	<b>March 31, 2020</b>
	(Unaudited)	
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 23,808,900	\$ 19,829,275
Restricted cash	636,317	5,635,836
Other current assets and prepaid expenses	1,207,238	1,149,806
<b>Total current assets</b>	<b>25,652,455</b>	<b>26,614,917</b>
Licensed right to use technology	403,244	412,763
Right-of-use lease assets	398,102	195,727
Property and equipment, net	421,214	211,337
<b>TOTAL ASSETS</b>	<b>\$ 26,875,015</b>	<b>\$ 27,434,744</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 1,920,337	\$ 2,256,229
Accrued expenses	1,084,604	1,097,534
Deferred revenue	644,029	873,190
Stock to be issued to a vendor	-	240,000
Operating lease liability	79,668	69,342
Loan payable	209,579	335,358
<b>Total current liabilities</b>	<b>3,938,217</b>	<b>4,871,653</b>
Long-term liabilities		
Operating lease liability	323,270	131,581
Facility agreement loan, net	4,372,257	4,339,065
<b>Total liabilities</b>	<b>8,633,744</b>	<b>9,342,299</b>
Commitments and contingencies		
Shareholders' 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, 16,841,555 and 16,056,360 shares issued and outstanding as of June  
 30, 2020 and March 31, 2020, respectively

Treasury stock	1,684	1,606
Additional paid-in capital	(25,000 )	(25,000 )
Accumulated deficit	82,593,467	75,702,915
Total shareholders' equity	(64,328,880 )	(57,587,076 )
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>18,241,271</u>	<u>18,092,445</u>
	<u>\$ 26,875,015</u>	<u>27,434,744</u>

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

	<b>For the Three Months Ended</b>	
	<b>June 30,</b>	
	<u>2020</u>	<u>2019</u>
License revenues	\$ 229,161	\$ 627,469
Operating expenses		
Research and development	4,331,814	2,323,513
General and administrative	2,494,014	2,182,558
Operating loss	<u>(6,596,667 )</u>	<u>(3,878,602 )</u>
Other income (loss)		
Realized and unrealized loss on marketable equity securities	-	(2,307,319 )
Dividend income	14,985	6,410
Foreign exchange gain	1,275	1,724
Interest expense	(163,240 )	(3,034 )
Other	1,843	-
Total other loss	<u>(145,137 )</u>	<u>(2,302,219 )</u>
Net loss	<u>\$ (6,741,804 )</u>	<u>\$ (6,180,821 )</u>
Net loss per share – basic and diluted	<u>\$ (0.40 )</u>	<u>\$ (0.67 )</u>
Weighted average number of common shares outstanding – basic and diluted	<u>16,529,392</u>	<u>9,201,855</u>



Source: Beyond Air™