

November 11, 2020



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

Submitted a premarket approval (PMA) to the FDA for LungFit™ PH to treat persistent pulmonary hypertension of the newborn (PPHN)

Expect patient enrollment to begin next week for the acute viral pneumonia (including SARS-CoV-2) study; Patients will be treated with 150 ppm nitric oxide with LungFit™ PRO

LungFit™ GO nontuberculous mycobacteria (NTM) lung infection at-home pilot study expected to start in December 2020

Conference call scheduled for today, November 11th at 4:30 pm ET

GARDEN CITY, N.Y., Nov. 11, 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 (gNO) for the treatment of solid tumors, today announced financial results for its second fiscal quarter ended September 30, 2020.

“Over the past few months we have achieved several significant milestones, both regulatory and clinical, across our development pipeline. Most notably, we filed a PMA for the LungFit™ PH system for the treatment of PPHN, which will be subject to the standard 180-day FDA review. If approved, LungFit™ PH will be our first commercially available product from the LungFit™ platform technology that generates nitric oxide from ambient air. I am very proud and humbled by the resilience and execution of the Beyond Air team, as we have faced many pandemic related setbacks. We are now on a clear path towards recognizing the potential of our LungFit™ platform for the treatment of respiratory conditions with the goal of improving the lives of patients,” said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air.

“As the coronavirus pandemic continues to adversely affect everyday life in the United States and around the world, the Beyond Air team has adapted. Site initiation visits are ongoing for the acute viral pneumonia study, which includes patients infected with SARS-CoV-2, and we have overcome significant logistical challenges with our at-home NTM lung infection study, which is expected to begin next month. The team also identified a new opportunity in the development pipeline for ultra-high concentration gNO to treat solid tumors. This program has generated exciting preclinical data demonstrating the conveyance of tumor immunity to the host, which we have presented at three different major medical and scientific conferences this year. We believe this new approach has the potential to elicit a paradigm shift in the standard of care for solid tumors and their metastases, which are

responsible for approximately 90% of all cancer-related deaths,” concluded Mr. Lisi.

Fiscal Second Quarter and Recent Highlights

• LungFit™ PH

- Submitted a PMA for LungFit™ PH to the FDA for the treatment of PPHN, which will be subject to the standard 180-day review process

• LungFit™ PRO

- Received all necessary approvals to perform our acute viral pneumonia study in Israel using the LungFit™ PRO at 150 ppm nitric oxide
- Presented promising in vitro data using OC43 human coronavirus infected cells at CHEST, which suggest that the LungFit™ PRO system may be effective for both prevention and treatment of human coronavirus infection with 150-250 ppm nitric oxide intermittent dosing regimens
- Announced positive new efficacy and safety data from the third bronchiolitis pilot study at CHEST that support the development of inhaled NO as a treatment for this unmet medical need
- Published results from a compassionate use patient case study using NO to treat pulmonary Mycobacterium abscessus disease at the National Heart, Lung, and Blood Institute, part of the National Institutes of Health (NIH), in the August edition of Access Microbiology

• Solid Tumor Program

- Announced preclinical data for exogenous high concentration gNO at the AACR Conference on Tumor Immunology and Immunotherapy that suggest direct administration to solid tumors triggers a systemic anti-tumor immune response, which could serve as the basis for an effective immunotherapy
- Presented new in vitro and in vivo preclinical data for the gNO program at the International Association for the Study of Lung Cancer’s (IASLC) North America Conference on Lung Cancer 2020 (NACLC 2020) that suggest high concentration gNO may treat lung cancer locally and its metastases systemically

• Ended the quarter with \$22.4 million in cash, cash equivalents and restricted cash

Upcoming Milestones

• LungFit™ PH

- Anticipate receiving FDA approval of the PMA for LungFit™ PH to treat PPHN in the second quarter of calendar year 2021
- LungFit™ PH commercial launch in the United States approximately 4-6 weeks post FDA approval

• LungFit™ PRO

- Expect to announce topline data for the acute viral pneumonia study in the middle of calendar year 2021

• LungFit™ GO

- Expect to initiate the at-home NTM lung infection pilot study in December 2020. This study start has been delayed due to the ongoing COVID-19 pandemic.

Financial results for three months ended September 30, 2020

Revenue for the three months ended September 30, 2020 was \$350,000 as compared to \$646,000 for the three months ended September 30, 2019, all of which was licensing revenue.

Research and development expenses for the three months ended September 30, 2020 were \$3.1 million, compared to \$2.8 million for the three months ended September 30, 2019.

General and administrative expenses for the three months ended September 30, 2020 were \$2.2 million, compared to \$2.1 million for the three months ended September 30, 2019.

For the three months ended September 30, 2020, the Company had a net loss of \$5.1 million, or (\$0.30) per share, compared to a net loss of \$4.1 million, or (\$0.38) per share for the three months ended September 30, 2019.

As of September 30, 2020, the Company had cash, cash equivalents and restricted cash of \$22.4 million.

Conference Call & Webcast

Wednesday, November 11th @ 4:30 pm ET

Domestic: 877-407-0784

International: 201-689-8560

Passcode: 13711694

Webcast: <http://public.viavid.com/index.php?id=141855>

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 SARS-CoV-2 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 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 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 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^{1,2,3}. As of November 9, 2020, more than 50.6 million confirmed cases of COVID-19 and more than 1.26 million 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.

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.

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.

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BEYOND AIR, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2020	March 31, 2020
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 21,716,778	\$ 19,829,275
Restricted cash	636,444	5,635,836
Other current assets and prepaid expenses	438,910	1,149,806
Total current assets	<u>22,792,132</u>	<u>26,614,917</u>
Licensed right to use technology	393,725	412,763
Right-of-use lease assets	378,188	195,727
Property and equipment, net	868,868	211,337
Other assets	38,880	-
TOTAL ASSETS	\$ 24,471,793	\$ 27,434,744
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,825,767	\$ 2,256,229
Accrued expenses	1,347,505	1,097,534
Deferred revenue	294,422	873,190
Stock to be issued to a vendor	-	240,000
Operating lease liability	82,003	69,342
Loan payable	84,280	335,358
Total current liabilities	<u>3,633,977</u>	<u>4,871,653</u>
Long-term liabilities		
Operating lease liability	301,664	131,581
Facility agreement loan, net	4,405,815	4,339,065
Total liabilities	<u>8,341,456</u>	<u>9,342,299</u>
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, 17,152,414 and 16,056,360 shares issued and outstanding as of September 30, 2020 and March 31, 2020, respectively	1,715	1,606
Treasury stock	(25,000)	(25,000)
Additional paid-in capital	85,614,292	75,702,915
Accumulated deficit	(69,460,670)	(57,587,076)
Total shareholders' equity	<u>16,130,337</u>	<u>18,092,445</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 24,471,793	27,434,744

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

	For the Three Months		For the Six Month Ended	
	Ended		September 30,	
	September 30,	September 30,	September 30,	September 30,
	2020	2019	2020	2019
License revenues	<u>\$ 349,607</u>	<u>\$ 645,602</u>	<u>\$ 578,768</u>	<u>\$ 1,273,071</u>
Operating expenses:				
Research and development	3,147,276	2,849,990	7,479,090	5,173,503
General and administrative	2,169,011	2,064,872	4,663,025	4,247,430
Operating expenses	<u>5,316,287</u>	<u>4,914,862</u>	<u>12,142,115</u>	<u>9,420,933</u>
Operating loss	<u>(4,966,680)</u>	<u>(4,269,260)</u>	<u>(11,563,347)</u>	<u>(8,147,862)</u>
Other income (loss)				
Realized and unrealized gain (loss) from marketable securities	-	142,806	-	(2,164,513)
Dividend and interest income	878	30,691	15,863	34,067
Interest expense	(159,034)	-	(322,274)	-
Foreign exchange loss	(6,954)	(1,977)	(5,679)	(253)
Other income	-	-	1,843	-
Total other income (loss)	<u>(165,110)</u>	<u>171,520</u>	<u>(310,247)</u>	<u>(2,130,699)</u>
Net loss	<u>\$ (5,131,790)</u>	<u>\$ (4,097,740)</u>	<u>\$ (11,873,594)</u>	<u>\$ (10,278,561)</u>
Net basic and diluted loss per share	\$ (0.30)	\$ (0.38)	\$ (0.71)	\$ (1.03)

Weighted average number of shares of common stock used in computing basic and diluted net loss per share

17,120,801	10,699,370	16,826,712	9,935,444
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Source: Beyond Air™