

June 22, 2020



Beyond Air Reports Financial Results for Fiscal Fourth Quarter and Year-End 2020

*Reported **positive clinical data for third bronchiolitis study** using high concentration nitric oxide, achieving primary and key secondary endpoints*

*Enrolled first patient in the **U.S. COVID-19 study** using the LungFit™ system*

*Announced **positive pre-clinical data** validating high concentration nitric oxide as a potential treatment for ablating solid tumors and inducing an anti-tumor immune response*

***PMA for the LungFit™ PH** to treat persistent pulmonary hypertension of the newborn (PPHN) expected to be submitted to the FDA in the second half of 2020*

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

Conference call scheduled for today, Monday, June 22nd at 4:30 pm ET

GARDEN CITY, N.Y., June 22, 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 fourth quarter and fiscal year ended March 31, 2020.

Recent Highlights and Upcoming Milestones

- 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) is statistically significant compared to both low concentration nitric oxide (85 ppm) plus SST and 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
- Published a peer-reviewed paper in the Scientific Reports journal that showed encouraging results from our second bronchiolitis study which indicate NO is safe and efficacious in hospitalized infants with bronchiolitis
- Enrolled the first patient in the U.S. clinical study using the LungFit™ system to treat COVID-19 with NO therapy
- Received approval from Health Canada to use the LungFit™ system for a study in hospitalized patients diagnosed with COVID-19
- The PMA for the LungFit™ PH to treat persistent pulmonary hypertension of the newborn (PPHN) is currently expected to be submitted to the FDA in the second half of 2020. This filing was delayed due to the ongoing COVID-19 pandemic
- The initiation of the At-Home nontuberculous mycobacteria (NTM) lung infection pilot

study using the LungFit™ HOME is currently expected to start by the end of 2020. This study start was delayed due to the ongoing COVID-19 pandemic

- Ended the quarter with \$25.5 million in cash and cash equivalents

“This is an exciting time for Beyond Air as we continue to make progress in our development pipeline. We have several opportunities to drive long-term shareholder value, with a number of significant milestones expected to occur in the second half of this year and into 2021, most notably our LungFit™ PH PMA submission and, subsequent anticipated FDA approval,” said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. “During the past three months, we rapidly responded to the ongoing pandemic environment and launched a U.S. COVID-19 study using our LungFit™ system, also receiving approval to begin a similar study in Canada. Considering the data compiled to date with high concentration NO, most notably the three completed pilot clinical studies in bronchiolitis where infants were hospitalized due to viral infections, we believe that this system could be a significant tool in the battle against this coronavirus. As such, we look forward to announcing the data from the U.S. and Canadian COVID-19 studies. The rapid response to the pandemic of developing this program is quite an impressive accomplishment by a very special team here at Beyond Air.”

Financial results for three months ended March 31, 2020

Revenue for the three months ended March 31, 2020 was (\$200,000) as compared to \$7.7 million for the three month ended March 31, 2019, all of which was licensing revenue.

Research and development expenses for the three months ended March 31, 2020 were \$2.9 million, compared to \$1.6 million for the three month ended March 31, 2019.

General and administrative expenses for the three months ended March 31, 2020 were \$2.2 million, compared to \$2.6 million for the three month period ended March 31, 2019.

For the three months ended March 31, 2020, the Company had a net loss of \$5.3 million, or (\$0.36) per share, compared to a net loss of \$100,000, or (\$0.01) per share for the three months ended March 31, 2019.

Financial results for fiscal year ended March 31, 2020

Revenue for the fiscal year ended March 31, 2020 was \$1.4 million as compared to \$7.7 million for fiscal the year ended March 31, 2019, all of which was licensing revenue.

Research and development expenses for the fiscal year ended March 31, 2020 were \$10.6 million, compared to \$3.9 million for the fiscal year ended March 31, 2019.

General and administrative expenses for the fiscal year ended March 31, 2020 were \$8.9 million, compared to \$6.9 million for the fiscal year March 31, 2019.

For the fiscal year ended March 31, 2020, the Company had a net loss attributed to common shareholders of \$20.5 million, or (\$1.78) per share, compared to a net loss of \$6.6 million, or (\$0.77) per share for the fiscal year ended March 31, 2019.

As of March 31, 2020, the Company had cash, cash equivalents and restricted cash of \$25.5 million.

Conference Call & Webcast

Monday, June 22nd @ 4:30 pm ET

Domestic: 877-407-0784

International: 201-689-8560

Passcode: 13704923

Webcast: <http://public.viavid.com/index.php?id=140183>

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.

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 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 June 22, 2020, more than 9 million confirmed cases of COVID-19 and more than 470,000 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 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:

Steven Lisi, Chief Executive Officer
 Beyond Air, Inc.
Slisi@beyondair.net

Corey Davis, Ph.D.
 LifeSci Advisors, LLC
cdavis@lifesciadvisors.com
 (212) 915-2577

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

	<u>March 31, 2020</u>	<u>March 31, 2019</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 19,829,275	\$ 1,340,203
Restricted cash	5,635,836	16,934
Marketable securities	-	6,542,667
Other current assets and prepaid expenses	1,149,806	788,409
Right-of-use lease assets	66,970	-
Total current assets	<u>26,681,887</u>	<u>8,688,213</u>
Licensing right to use technology	412,763	495,000
Right-of-use lease assets	128,757	-
Property and equipment, net	211,337	244,872
TOTAL ASSETS	<u><u>\$ 27,434,744</u></u>	<u><u>\$ 9,428,085</u></u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 2,256,229	\$ 1,164,672
Accrued expenses	1,097,534	1,567,638
Deferred revenue	873,190	2,263,294
Stock to be issued to a vendor	240,000	144,000
Operating lease liability	69,342	-
Loan payable	335,358	263,604
Total current liabilities	<u>4,871,653</u>	<u>5,403,208</u>
Operating lease liability	131,581	-
Facility Agreement loan, net	4,339,065	-
Total liabilities	<u><u>9,342,299</u></u>	<u><u>5,403,208</u></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, 16,056,360 and 8,714,815 shares issued and outstanding as of March 31, 2020 and March 31, 2019, respectively	1,606	871
Treasury stock	(25,000)	(25,000)
Additional paid-in capital	75,702,915	41,693,578
Accumulated deficit	(57,587,076)	(37,644,572)
Total shareholders' equity	18,092,445	4,024,877
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 27,434,744</u>	<u>\$ 9,428,085</u>

**BEYOND AIR, INC. AND ITS SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS**

	(Unaudited) Three Months Ended March 31, 2020	(Unaudited) Three Months Ended March 31, 2019	Year Ended March 31, 2020	Year Ended March 31, 2019
License revenue	\$ (197,346)	\$ 7,724,001	\$ 1,390,104	\$ 7,724,001
Operating expenses				
Research and development	(2,894,795)	(1,630,291)	(10,648,920)	(3,929,558)
General and administrative	(2,163,975)	(2,580,189)	(8,883,119)	(6,852,988)
Operating loss	(5,256,116)	(3,513,521)	(18,141,935)	(3,058,545)
Other income (loss)				
Realized and unrealized loss on available for sale marketable securities	(225,978)	(3,594,335)	(2,075,602)	(3,581,193)
Dividend income	55,957	12,025	115,716	86,748
Interest expense	(30,543)	(1,506)	(30,543)	(1,506)
Foreign exchange gain (loss)	35,560	(632)	35,560	(920)
Other expenses	(1,512)	(137)	-	(3,034)
Total other loss	(166,516)	(3,584,585)	(1,954,869)	(3,499,905)
Net loss before income taxes	(5,422,632)	(71,064)	(20,096,804)	\$ (6,588,450)
Benefit for income taxes	154,300	-	154,300	-
Net loss	<u>\$ (5,268,332)</u>	<u>\$ (71,064)</u>	<u>\$ (19,942,504)</u>	<u>\$ (6,558,450)</u>

Deemed dividend from warrant modification	-	-	(522,478)	-
Net loss attributed to common shareholders	\$ (5,268,332)	\$ (71,064)	\$ 20,464,982	\$ (6,558,450)
Net loss per share – basic and diluted	\$ (0.36)	\$ (0.01)	\$ (1.78)	\$ (0.77)
Weighted average number of common shares outstanding – basic and diluted	14,713,505	8,599,479	11,506,212	8,498,525

**BEYOND AIR, INC. AND ITS SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS**

	For The Year Ended March 31, 2020	For The Year Ended March 31, 2019
Cash flows from operating activities		
Net loss	\$ (19,942,504)	\$ (6,558,450)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities		
Depreciation and amortization	159,403	64,787
Stock-based compensation	3,577,649	2,399,321
Operating lease expense	62,875	
Unrealized and realized loss on marketable securities to available for sale marketable securities	2,075,602	3,498,883
Change of management's assessment of prior year research and development to licensing right to use technology	-	(200,000)
Adoption of ASU 2016-01	-	2,986
Amortization of debt issuance cost and deferred financing fees	4,652	-
Changes in:		
Other current assets and prepaid expenses	(361,395)	(729,159)
Accounts payable	1,091,557	322,633
Accrued expenses	(470,105)	276,757
Deferred revenue	(1,390,104)	2,263,294
Net cash (used in) provided by operating activities	<u>(15,192,370)</u>	<u>1,341,052</u>
Cash flows from investing activities		
Investment in available for sale marketable securities	(37,320,235)	(12,222,774)
Proceeds from redemption of marketable securities	41,787,299	10,485,610
Purchase of property and equipment	(43,631)	(56,475)
Net cash provided by (used in) investing activities	<u>4,423,433</u>	<u>(1,793,639)</u>
Cash flows provided by from financing activities		
Issuance of common stock in an underwritten offering and private placement, net of offering costs	10,169,343	
Issuance of common stock in private placement, net of offering costs	7,839,495	-

Issuance of common stock related to at the market offerings, net of offering costs	7,745,012	-
Issuance of common stock, net of offering cost	-	799,185
Proceeds from credit facility loan	5,000,000	
Proceeds from loan	375,570	292,250
Payment of loan	(303,806)	(28,646)
Payment of operating lease liability	(57,679)	
Proceeds from the exercise of warrants	3,968,944	-
Payment of debt issuance costs	(70,618)	-
Proceeds from the exercise of stock options	210,650	8,701
Net cash provided by financing activities	<u>34,876,911</u>	<u>1,071,490</u>
Increase in cash, cash equivalents and restricted cash	24,107,974	618,903
Cash, cash equivalents and restricted cash at beginning of period	1,357,137	738,234
Cash, cash equivalents and restricted cash at end of period	<u>\$ 25,465,111</u>	<u>\$ 1,357,137</u>
Supplemental disclosure of non-cash financing and investing activities:		
Right of use assets	\$ 258,605	\$ -
Operating lease liability	\$ 264,570	\$ -
Deemed dividend as a result of a warrant modification	\$ 522,478	\$ -
Fair market value of warrants allocated to debt discount and stockholders' equity	\$ 594,979	\$ -
Fair market value of options issued to NitricGen for the licensing right to use technology	\$ -	\$ 295,000
Supplemental disclosure of cash flow items:		
Interest paid	\$ 23,112	\$ -
Income taxes paid	\$ -	\$ -



Source: Beyond Air™