

February 7, 2020



Beyond Air Reports Financial Results for Fiscal Third Quarter 2020

LungFit™ PH U.S. market launch for the treatment of persistent pulmonary hypertension of the newborn (PPHN) expected calendar 4Q 2020

Third pilot study for LungFit™ BRO program nearing completion of enrollment; Results expected calendar 2Q 2020

Pivotal LungFit BRO™ study on track for calendar 4Q 2020 start and calendar 2Q 2021 completion

LungFit™ NTM At-Home nontuberculous mycobacteria (NTM) lung infection pilot study start targeted for mid-2020; Patients to self-administer Nitric Oxide (NO) over a 12-week period

Animal toxicity data from multiple studies support strong safety profile of high concentration NO

Save the date for Analyst Day: *March 5, 2020 at 2:00 pm Eastern Time in New York City*

Conference Call scheduled for today, Friday, February 7th at 11:00 am ET

GARDEN CITY, N.Y. and REHOVOT, Israel, Feb. 07, 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, today announced its financial results for its fiscal third quarter ended December 31, 2019.

Recent Highlights and Upcoming Milestones

- Raised \$11.5 million in gross proceeds via an offering of 3,152,985 shares of common stock in December 2019.
- Announced an exclusive five-year global supply agreement for NO and NO₂ (Nitrogen Dioxide) calibration gas with MESA Specialty Gases & Equipment. The five-year term is to begin on the earlier of FDA approval for the LungFit™ PH system or December 31, 2020.
- Terminated for material breach its agreement with Circassia Pharmaceuticals PLC for the commercial rights to LungFit™ PH in the United States and China for use in the hospital setting at NO concentrations <80 ppm. Beyond Air is evaluating options for the commercialization of LungFit™ PH, which is still on track for the fourth quarter of calendar 2020 in the United States.

- Received the final histopathology reports for 3 separate animal toxicity studies where no differences were seen when compared to control animals. One study was for 30 days with a peak concentration of 400 ppm NO. The other 2 studies were for 12 weeks and mimicked the protocol that will be used for the company's planned 12 week at-home NTM study.
- Ended the quarter with \$15.5 million in cash and cash equivalents

"After a very productive quarter, we enter calendar 2020 with three programs on the cusp of significant milestones. We are nearing completion of our **LungFit™ BRO** pilot study, and anticipate topline data in the second quarter. We plan to initiate a pivotal trial in bronchiolitis in the U.S. in the fourth quarter of 2020. Commercial launch for our **LungFit™ PH** system is on track for the fourth quarter of 2020, and we are prepared to launch on our own or with a partner," said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. "We are also planning to initiate our **LungFit™ NTM At-Home** study in mid-2020 and believe that the success of this study may allow for us to treat all patients with chronic, refractory, persistent lung infections of various types in the comfort and convenience of the home setting. Given the robust safety profile to date in both humans and animals, our confidence for clinical success is quite high and we believe our **LungFit™** system can offer significant benefits for patients."

Beyond Air's goals over the next 18 months include:

- **LungFit™ PH**

- Submit a PMA in the second quarter of calendar 2020
- Expect approval and commercial launch of **LungFit™ PH** in the U.S. in the fourth quarter of calendar 2020

- **LungFit™ BRO**

- Announce results from a pilot study in the second quarter of 2020.
- Initiate a pivotal study in the U.S. in the fourth quarter of calendar 2020, with anticipated completion in the second quarter of calendar 2021

- **LungFit™ NTM**

- Initiate a multi-center, 12-week, self-administered, at-home pilot study, including both *Mycobacterium abscessus* complex (MABSC) and *Mycobacterium avium* complex (MAC) patients, at concentrations up to 250 ppm in mid 2020, with data anticipated in 1H 2021

Financial results for three months ended December 31, 2019

Revenue for the three months ended December 31, 2019 was \$300,000, all of which was licensing revenue. No revenue was generated in the same three-month period of 2018.

Research and development expenses for the three months ended December 31, 2019 were \$2.6 million, compared to \$0.6 million in the three months ended December 31, 2018.

General and administrative expenses for the three months ended December 31, 2019 were \$2.5 million, compared to \$1.8 million for the same three-month period of 2018.

For the three months ended December 31, 2019, the Company had a net loss of \$4.9 million, or \$(0.43) per share, compared to a net loss of \$2.4 million, or \$(0.28) per share in the same three-month period of 2018.

As of December 31, 2019, the Company had cash and cash equivalents, restricted cash and marketable securities of \$15.5 million.

Conference Call & Webcast

Friday, February 7th @ 11:00 am ET

Domestic: 877-407-0784

International: 201-689-8560

Passcode: 13698390

Webcast: <http://public.viavid.com/index.php?id=137802>

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 lower 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 bronchiolitis and severe lung infections such as nontuberculous mycobacteria (NTM). For more information, visit www.beyondair.net.

About Nitric Oxide (NO)

Nitric Oxide (NO) is a powerful molecule 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 and is used in adult respiratory distress syndrome and persistent pulmonary hypertension of the neonate. 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 organisms, including mycobacteria, 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 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 NO Generator and Delivery 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 system can also deliver NO at concentrations above 80 ppm for which intended treatments are: bronchiolitis in the hospital setting, and chronic, refractory lung infections in the home setting. For the first time, Beyond Air intends to offer NO treatment in the home setting with the elimination of cylinders.

* Beyond Air's LungFit™ is not approved for commercial use and Beyond Air is not suggesting use over 80 ppm or use at home. Beyond Air's LungFit™ is for investigational purposes only.

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 160 - 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.

Forward-Looking Statement

This press release contains "forward-looking statements." 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," "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 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; and our short operating history. 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

	December 31, 2019 (Unaudited)	March 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	\$ 2,140,162	\$ 1,340,203
Restricted cash	636,364	16,934
Marketable securities	12,699,964	6,542,667
Right-of-use lease assets	66,115	-
Other current assets and prepaid expenses	429,780	788,409
Total current assets	15,972,385	8,688,213
Licensed right to use technology	422,282	495,000
Right-of-use lease assets	145,848	-
Property and equipment, net	216,111	244,872

TOTAL ASSETS	<u>\$ 16,756,626</u>	<u>\$ 9,428,085</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 2,013,931	\$ 1,164,672
Accrued expenses	1,675,069	1,567,638
Deferred revenue	675,844	2,263,294
Stock to be issued to a vendor	156,900	144,000
Operating lease liability	67,403	-
Loan payable	-	263,604
Total current liabilities	<u>4,589,147</u>	<u>5,403,208</u>
Long-term liabilities		
Operating lease liability	<u>151,384</u>	<u>-</u>
Total liabilities	<u>4,740,531</u>	<u>5,403,208</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, 13,901,745 and 8,714,815 shares issued and outstanding as of December 31, 2019 and March 31, 2019, respectively	1,390	871
Treasury stock	(25,000)	(25,000)
Additional paid-in capital	64,358,449	41,693,578
Accumulated deficit	(52,318,744)	(37,644,572)
Total shareholders' equity	<u>12,016,095</u>	<u>4,024,877</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 16,756,626</u>	<u>\$ 9,428,085</u>

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

	<u>For the Three Months Ended</u>		<u>For the Nine Months Ended</u>	
	<u>December 31,</u>		<u>December 31,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
License revenues	<u>\$ 314,379</u>	<u>\$ -</u>	<u>\$ 1,587,450</u>	<u>\$ -</u>
Operating expenses:				
Research and development	(2,580,622)	(588,256)	(7,754,125)	(2,299,267)
General and administrative	(2,471,714)	(1,814,305)	(6,719,144)	(4,272,799)
Operating expenses	<u>(5,052,336)</u>	<u>(2,402,561)</u>	<u>(14,473,269)</u>	<u>(6,572,066)</u>
Operating loss	<u>(4,737,957)</u>	<u>(2,402,561)</u>	<u>(12,885,819)</u>	<u>(6,572,066)</u>
Other income (loss)				

Realized and unrealized gain (loss) from marketable securities	314,889	18,234	(1,849,624)	13,142
Dividend income	25,692	10,737	59,759	74,723
Foreign exchange gain (loss)	1,765	678	1,512	(288)
Other income (expenses)	-	6,392	-	(2,897)
Total other income (loss)	<u>342,346</u>	<u>36,041</u>	<u>(1,788,353)</u>	<u>84,680</u>
Net loss	<u>\$ (4,395,611)</u>	<u>\$ (2,366,520)</u>	<u>\$ (14,674,172)</u>	<u>\$ (6,487,386)</u>
Deemed dividend from warrant modification	<u>(522,478)</u>	<u>-</u>	<u>(522,478)</u>	<u>-</u>
Net loss attributed to common shareholders	<u>\$ (4,918,089)</u>	<u>\$ (2,366,520)</u>	<u>\$ (15,196,650)</u>	<u>\$ (6,487,386)</u>
Net basic and diluted loss per share	<u>\$ (0.43)</u>	<u>\$ (0.28)</u>	<u>\$ (1.46)</u>	<u>\$ (0.77)</u>
Weighted average number of shares of common stock used in computing basic and diluted net loss per share	<u>11,398,413</u>	<u>8,530,580</u>	<u>10,437,690</u>	<u>8,466,243</u>



Source: Beyond Air™