

August 14, 2019



Beyond Air™ Reports Financial Results for Fiscal First Quarter 2020

*Began trading under new ticker symbol, **XAIR**, on the NASDAQ stock exchange on July 15, 2019*

Anticipate submitting a PMA for LungFit for the treatment of persistent pulmonary hypertension of the newborn (PPHN) in the third quarter of calendar 2019*

Anticipate receiving CE Mark for LungFit in the first half of calendar 2020 for PPHN and pulmonary hypertension associated with cardiac surgery*

Conference Call scheduled for today, Wednesday, August 14th at 4:30 pm Eastern Time

GARDEN CITY, N.Y. and REHOVOT, Israel, Aug. 14, 2019 (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 financial results for its fiscal first quarter ended June 30, 2019.

Key Highlights

- Remains on track to file a Premarket Approval (PMA) submission with the FDA for the treatment of persistent pulmonary hypertension of the newborn (PPHN) with our LungFit* PH system in the third quarter of calendar 2019.
- Anticipates obtaining CE Mark for LungFit* PH for the treatment of PPHN and for the treatment of pulmonary hypertension associated with heart surgery in the first half of calendar 2020.
- Preparing to initiate a 12-week, self-administered, at-home study in nontuberculous mycobacteria (NTM) patients in the second quarter of calendar 2020.
- Preparing to initiate a pilot bronchiolitis study in Israel in the fourth quarter of calendar 2019.
- Completed dosing in a 30-day rat study (in both male and female rats) with our LungFit* system in which 3 doses were studied, 150 ppm, 250 ppm and 400 ppm, compared to placebo, each for 80 minutes twice daily. Initial results showed no deaths, normal weight gain in all groups, and normal clinical exams including normal gross pathology at necropsy. The company awaits confirmation of the results via clinical pathology and histopathology. These data will support both the bronchiolitis and NTM programs.
- Began trading under new ticker symbol, **XAIR**, on the NASDAQ stock exchange on

July 15, 2019.

- Ended the quarter with \$11.7 million in cash and cash equivalents after completing a private investment in public equity (PIPE) financing with gross proceeds of \$7.96 million in June 2019.

“We continue to make steady progress towards achieving our goal of submitting our Premarket Approval (PMA) for the LungFit PH system in this current quarter,” said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air. “With the completion of a PIPE transaction last June, we have the financial resources to execute and achieve our goals over the next 14 months. This includes gaining FDA approval and CE Mark for our LungFit PH system; completing a pilot study in bronchiolitis; and initiating an at-home study in patients suffering from NTM lung infection. I am confident in our ability to execute on all three of our programs as the Beyond Air team has done an exceptional job over the past 2 years.”

Financial results for three months ended June 30, 2019

Revenue for the three months ended June 30, 2019 was \$0.6 million, all of which is licensing revenue. No revenue was generated in the same three-month period of 2018.

Research and development expenses for the three months ended June 30, 2019 were \$2.3 million, compared to \$1.1 million in the same three-month period of 2018.

General and administrative expenses for the three months ended June 30, 2019 were \$2.3 million, compared to \$0.7 million for the same three-month period of 2018.

For the three months ended June 30, 2019, the Company had a net loss of \$6.2 million, or \$0.67 per share, compared to a net loss of \$1.7 million, or \$0.20 per share in the same three-month period of 2018.

Cash on hand is sufficient to fund operations through September 2020 exclusive of any milestones from the Circassia partnership, warrant exercises, proceeds from the potential sale of equity under the line of credit in place, or any compensation from potential future partnerships.

Conference Call & Webcast

Wednesday, August 14 @ 4:30 pm Eastern Time

Domestic: 877-407-0784

International: 201-689-8560

Passcode: 13692522

Webcast: <http://public.viavid.com/index.php?id=135344>

About Beyond Air, Inc.

Beyond Air, Inc. is a clinical-stage medical device and biopharmaceutical company developing a revolutionary NO Generator and Delivery System that uses NO generated from ambient air and delivers precise amounts of NO to the lungs for the potential treatment of respiratory and other diseases. The Beyond Air NO Delivery System 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 NO Generator and Delivery System in clinical trials for the treatment of bronchiolitis and severe lung infections such as nontuberculous mycobacteria (NTM). For more information, visit www.beyondair.net.

*LungFit is expected to be the final commercial name of our NO Generator and Delivery System.

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 PPHN

Persistent pulmonary hypertension of the newborn (PPHN) is a lethal condition and a 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 (EMO) 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 LungFit**

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 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 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 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. The LungFit is for investigational purposes only.

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, 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

	June 30, 2019	March 31, 2019
	<u>(Unaudited)</u>	<u></u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 636,193	\$ 1,340,203
Restricted cash	16,827	16,934
Marketable securities	11,007,238	6,542,667
Right-of-use asset	69,271	-
Other current assets and prepaid expenses	545,151	788,409
Total current assets	<u>12,274,680</u>	<u>8,688,213</u>
Licensed right to use technology	441,320	495,000
Right-of-use lease assets	174,199	-
Property and equipment, net	230,082	244,872
TOTAL ASSETS	<u>\$ 13,120,281</u>	<u>\$ 9,428,085</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,553,002	\$ 1,164,672
Accrued expenses	1,514,549	1,567,638
Deferred revenue	1,635,825	2,263,294
Stock to be issued to a vendor	166,500	144,000
Operating lease liability	63,642	-
Loan payable	147,238	263,604
Total current liabilities	<u>5,080,756</u>	<u>5,403,208</u>
Long-term liabilities		
Operating lease liability	<u>179,270</u>	<u>-</u>

Total liabilities	<u>5,260,026</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, 10,580,680 and 8,714,815 shares issued and outstanding as of June 30, 2019 and March 31, 2019, respectively	1,058	871
Treasury stock	(25,000)	(25,000)
Additional paid-in capital	51,709,590	41,693,578
Accumulated deficit	(43,825,393)	(37,644,572)
Total shareholders' equity	<u>7,860,255</u>	<u>4,024,877</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 13,120,281</u>	<u>\$ 9,428,085</u>

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

	For the Three Months	
	Ended June 30,	
	<u>2019</u>	<u>2018</u>
License revenues	<u>\$ 627,469</u>	<u>\$ -</u>
Operating expenses		
Research and development	2,323,513	1,063,145
General and administrative	<u>2,182,558</u>	<u>693,005</u>
Operating loss	<u>(3,878,602)</u>	<u>(1,756,150)</u>
Other income (loss)		
Realized and unrealized loss on marketable equity securities	(2,307,319)	-
Dividend income	3,376	32,901
Foreign exchange gain	1,724	3,201
Other expenses	-	(3,702)
Total other (loss) income	<u>(2,302,219)</u>	<u>32,400</u>
Net loss	<u>\$(6,180,821)</u>	<u>\$(1,723,750)</u>
Unrealized gain on marketable securities	<u>-</u>	<u>5,403</u>
Total other comprehensive loss	<u>\$(6,180,821)</u>	<u>\$(1,718,347)</u>

Net loss per share – basic and diluted	\$	(0.67)	\$	(0.20)
Weighted average number of common shares outstanding – basic and diluted		9,201,855		8,400,327



Source: Beyond Air™