

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): February 9, 2021

Beyond Air, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-38892
(Commission
File Number)

47-3812456
(I.R.S. Employer
Identification No.)

825 East Gate Blvd., Suite 320
Garden City, NY 11530
(Address of Principal Executive Offices and Zip Code)

(516) 665-8200
Registrant's Telephone Number, Including Area Code

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	XAIR	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Conditions.

On February 9, 2021, Beyond Air, Inc. issued a press release announcing its financial results for its third fiscal quarter ended December 31, 2020. A copy of the press release is furnished hereto as Exhibit 99.1 hereto.

This information, including the exhibit attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

**Exhibit
No.**

Description

99.1

[Press Release of Beyond Air, Inc., dated February 9, 2021.](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BEYOND AIR, INC.

Date: February 11, 2021

By: /s/ Steven A. Lisi

Name: Steven A. Lisi

Title Chief Executive Officer

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

U.S. FDA reviewing premarket approval (PMA) submission for LungFit™ PH to treat persistent pulmonary hypertension of the newborn (PPHN), as Company prepares for commercialization

Interim results from the acute viral pneumonia (including SARS-CoV-2) pilot study using 150 ppm nitric oxide (NO) with LungFit™ PRO expected in Spring 2021

Interim results expected mid-calendar year 2021 for Nontuberculous Mycobacteria (NTM) lung infection at-home pilot study where NO is self-administered at concentrations up to 250 ppm nitric oxide with LungFit™ GO

Conference call scheduled for today, February 9th, at 4:30 p.m. ET

Garden City, NY, February 9, 2021 – Beyond Air, Inc. (NASDAQ: XAIR), a clinical-stage medical device and biopharmaceutical company focused on developing inhaled nitric 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 third fiscal quarter ended December 31, 2020.

“Over the past several months, Beyond Air has made significant clinical and regulatory progress across several indications, led by the filing of our PMA for LungFit™ PH to treat PPHN. This PMA is currently undergoing the 180-day review process at FDA, and if approved, LungFit™ PH will be the first and only commercially available product able to generate NO from ambient air. Commercial preparations are underway for a launch this summer,” said Steve Lisi, Chairman and Chief Executive Officer of Beyond Air.

“The Beyond Air team has continued to deliver on the R&D front throughout 2020 and into 2021, with interim data expected from two additional pilot trials over the next six months: the acute viral pneumonia (including COVID-19) study using LungFit™ PRO, and the at-home NTM study with LungFit™ GO. Success in these indications will further validate the safety and efficacy of the broader LungFit™ platform technology and allow us to move to high concentration NO in hospitals as well as the large, untapped home market where we can help patients with other severe lung infections with various underlying conditions such as COPD. We also continue to make progress in our solid tumor program using ultra-high concentration gNO, with the goal of starting human studies by the end of 2021. Finally, the bronchiolitis program remains on hold with the start date of the pivotal study relying heavily on the state of the COVID-19 pandemic.”

Fiscal Third Quarter and Recent Highlights

- **LungFit™ PH**
 - FDA review of the PMA to treat PPHN is ongoing; It was submitted in November 2020 and is subject to the 180-day review process
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- **LungFit™ PRO**
 - Initiated an acute viral pneumonia (including COVID-19) pilot study in Israel using LungFit™ PRO at 150 ppm NO
 - *In vitro* data with NO-treated OC43 human coronavirus infected cells presented at the CHEST Annual Meeting 2020; data suggested that the LungFit™ PRO system may be effective for both prevention and treatment of human coronavirus infection with 150-250 ppm NO intermittent dosing regimen
 - Announced positive efficacy and safety data from the third bronchiolitis pilot study at the CHEST Annual Meeting 2020 supporting the development of inhaled NO as a treatment for this unmet medical need; the program is currently on hold due to the COVID-19 pandemic
 - **LungFit™ GO**
 - Initiated an at-home pilot study in Australia using LungFit™ GO for self-administration of up to 250 ppm NO for the treatment of refractory Nontuberculous Mycobacteria (NTM) lung disease in adult patients
 - **Solid Tumor Program**
 - Presented preclinical data for exogenous high concentration gNO at the AACR Conference on Tumor Immunology and Immunotherapy. These data suggest that direct administration of gNO to solid tumors triggers a systemic anti-tumor immune response, which could serve as the basis for an effective immunotherapy
 - *In vitro* and *in vivo* preclinical data presented at the International Association for the Study of Lung Cancer’s (IASLC) North America Conference on Lung Cancer 2020 (NACLC 2020) suggest that high concentration gNO may treat lung cancer locally and its metastases systemically

Upcoming Milestones

- **LungFit™ PH**
 - Anticipate receiving FDA approval to treat PPHN in the second quarter of calendar year 2021
 - Commercial launch in the United States planned for approximately 4-6 weeks after FDA approval
- **LungFit™ PRO**
 - Planning to report interim data for the acute viral pneumonia study in Spring 2021
- **LungFit™ GO**
 - Expect to report interim data for the at-home NTM lung infection pilot study in the middle of calendar year 2021
- **Solid Tumor Program**
 - Anticipate initiation of human studies by the end of calendar year 2021

Financial results for three months ended December 31, 2020

Revenue for the three months ended December 31, 2020 was \$149,000 as compared to \$314,000 for the three months ended December 31, 2019, all of which was licensing revenue.

Research and development expenses for the three months ended December 31, 2020 were \$3.3 million, compared to \$2.6 million for the three months ended December 31, 2019.

General and administrative expenses for the three months ended December 31, 2020 were \$2.5 million, compared to \$2.5 million for the three months ended December 31, 2019.

For the three months ended December 31, 2020, the Company had a net loss of \$5.8 million, or (\$0.33) per share, compared to a net loss of \$4.9 million, or (\$0.43) per share for the three months ended December 31, 2019.

As of December 31, 2020, the Company had cash, cash equivalents and restricted cash of \$22.7 million.

Conference Call & Webcast

Tuesday, February 9th @ 4:30 pm ET

Domestic: 877-407-0784

International: 201-689-8560

Passcode: 13715084

Webcast: <http://public.viavid.com/index.php?id=143050>

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.

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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 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.

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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 February 1, 2021, more than 103 million confirmed cases of COVID-19 and more than 2.23 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 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 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 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 150 - 400 ppm NO, for which preliminary studies indicate may eliminate bacteria, viruses, fungi and other microbes from the lungs.

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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

	December 31, 2020 (Unaudited)	March 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	\$ 22,016,310	\$ 19,829,275
Restricted cash	637,699	5,635,836
Other current assets and prepaid expenses	425,362	1,149,806
Total current assets	23,079,371	26,614,917
Licensed right to use technology	384,206	412,763
Right-of-use lease assets	357,871	195,727
Property and equipment, net	956,759	211,337
Other assets	38,880	-
TOTAL ASSETS	\$ 24,817,087	\$ 27,434,744
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,223,839	\$ 2,256,229

Accrued expenses	1,434,087	1,097,534
Deferred revenue	145,628	873,190
Stock to be issued to a vendor	-	240,000
Operating lease liability	84,388	69,342
Loan payable	-	335,358
Total current liabilities	<u>2,887,942</u>	<u>4,871,653</u>
Long-term liabilities		
Operating lease liability	279,594	131,581
Facility agreement loan, net	4,439,373	4,339,065
Total liabilities	<u>7,606,909</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, 18,381,227 and 16,056,360 shares issued and outstanding as of December 31, 2020 and March 31, 2020, respectively	1,838	1,606
Treasury stock	(25,000)	(25,000)
Additional paid-in capital	92,463,661	75,702,915
Accumulated deficit	(75,230,321)	(57,587,076)
Total shareholders' equity	<u>17,210,178</u>	<u>18,092,445</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 24,817,087</u>	<u>\$ 27,434,744</u>

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

	<u>For the Three Months Ended</u> <u>December 31,</u>		<u>For the Nine Months Ended</u> <u>December 31,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
License revenues	\$ 148,794	\$ 314,379	\$ 727,562	\$ 1,587,450
Operating expenses:				
Research and development	3,294,102	2,580,622	10,773,192	7,754,125
General and administrative	2,471,065	2,471,714	7,134,090	6,719,144
Operating expenses	<u>5,765,167</u>	<u>5,052,336</u>	<u>17,907,282</u>	<u>14,473,269</u>
Operating loss	<u>(5,616,373)</u>	<u>(4,737,957)</u>	<u>(17,179,720)</u>	<u>(12,885,819)</u>
Other income (loss)				
Realized and unrealized gain (loss) from marketable securities	-	314,889	-	(1,849,624)
Dividend and interest income	378	25,692	16,241	59,759
Interest expense	(157,960)	-	(480,234)	-
Foreign exchange gain (loss)	6,147	1,765	468	1,512
Other loss	(1,843)	-	-	-
Total other income (loss)	<u>(153,278)</u>	<u>342,346</u>	<u>(463,525)</u>	<u>(1,788,353)</u>
Net loss	<u>\$ (5,769,651)</u>	<u>\$ (4,395,611)</u>	<u>\$ (17,643,245)</u>	<u>\$ (14,674,172)</u>
Deemed dividend from warrant modification	-	(522,478)	-	(522,478)
Net loss attributed to common shareholders	<u>\$ (5,769,651)</u>	<u>\$ (4,918,089)</u>	<u>\$ (17,643,245)</u>	<u>\$ (15,196,650)</u>
Net basic and diluted loss per share	<u>\$ (0.33)</u>	<u>\$ (0.43)</u>	<u>\$ (1.03)</u>	<u>\$ (1.46)</u>
Weighted average number of shares of common stock used in computing basic and diluted net loss per share	<u>17,609,328</u>	<u>11,398,413</u>	<u>17,086,871</u>	<u>10,437,690</u>

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