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): September 21, 2021

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

Delaware	001-38892	47-3812456
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

900 Stewart Avenue, Suite 301
Garden City, NY 11530
(Address of Principal Executive Offices and Zip Code)

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

825 East Gate Blvd., Suite 320
Garden City, NY 11530
(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 $.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 8.01. Other Events.

On September 21, 2021, Beyond Air, Inc. (the "Company") issued a press release (the "Press Release") providing an update on the global regulatory approval process for the LungFit® PH system. A copy of the Press Release is attached hereto and incorporated herein by reference in its entirety as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description

99.1	Press Release of Beyond Air, Inc. dated September 21, 2021.
104	Cover Page Interactive Data File (embedded within the inline XBRL document).

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: September 27, 2021

By: */s/ Steven A. Lisi*
Name: Steven A. Lisi
Title Chief Executive Officer

Exhibit 99.1

Beyond Air® Provides Global Regulatory Update for LungFit® PH

FDA inspection of facilities is ongoing; US commercial launch remains on track for 4Q CY2021, pending FDA approval

Stage 1 Assessment Audit in the CE Mark process is complete; expect to receive CE Mark in 1H CY2022

GARDEN CITY, N.Y., Sept. 21, 2021 (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 provided an update on the global regulatory approval process for the LungFit® PH system.

- Beyond Air has successfully completed the Stage 1 Assessment Audit of its quality system conducted by the Notified Body for the LungFit® PH system, a necessary step for achieving CE Mark (European Union approval). This is the first part of a two-stage inspection and quality review audit. LungFit® PH is expected to receive CE Mark in Europe in the first half of calendar year 2022.
- The US Food and Drug Administration (FDA) facility inspections that are required for the approval of the LungFit® PH premarket application (PMA) are ongoing. Beyond Air management reiterates its guidance for the US commercial launch of LungFit® PH for persistent pulmonary hypertension of the newborn (PPHN) in the fourth calendar quarter of 2021.

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 acute viral pneumonia (including COVID-19) 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 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 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 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.

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, product launches for the LungFit® PH system, and the timing thereof; the potential safety and efficacy of our product candidate, as well as its therapeutic potential in a number of indications; and the potential impact on patients and anticipated benefits associated with the use of the LungFit® system. 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: the potential that regulatory authorities, including the FDA and EMA, may not grant or may delay approval for our product candidate; the impact of the COVID-19 pandemic on the FDA's review process; 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; 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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