UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

[X] **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE FISCAL YEAR ENDED MARCH 31, 2021

OR

[ ] **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number: 001-38892

BEYOND AIR, INC.
(Exact name of registrant as specified in its charter)

Delaware	**47-3812456**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
825 East Gate Blvd., Avenue, Suite 325 Garden City, NY	**11530**
(Address of principal executive offices)	**(Zip Code)**

516-665-8200
(Registrant's telephone Number, including area code)

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

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

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

None

Indicate by a check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes [ ] No [X]

Indicate by a check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934.

Yes [ ] No [X]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

Yes [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes [X] No [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of the "large accelerated filer," "accelerated filer," "non-accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[X]	Smaller reporting company	[X]
Emerging growth company	[X]		

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. [ ]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes [ ] No [X]

As of September 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's voting stock held by non-affiliates was approximately $80,351,943 based on the last reported sale price of the registrant's common stock on the Nasdaq Capital Market.

There were 21,901,317 shares of common stock outstanding as of June 7, 2021.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Beyond Air, Inc.

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References in this Annual Report on Form 10-K (this "Annual Report") to the "Company," "Beyond Air," "we," "our," or "us" mean Beyond Air, Inc. and its subsidiaries except where the context otherwise requires.

FORWARD-LOOKING STATEMENTS AND MARKET DATA

This Annual Report contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933 (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). All statements other than statements of historical facts contained in this Annual Report, including statements regarding our future results of operations and financial position, business strategy, prospective product candidates and products, product certifications or approvals, timing of our clinical development activities, research and development costs, timing and likelihood of success, and the plans and objectives of management for future operations and future results of anticipated products are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "expect," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar conditional expressions. The forward-looking statements in this Annual Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the factors described under the sections in this Annual Report titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as the following:

- our status as a development-stage company and our expectation to incur losses in the future;

- our future capital needs and our need to raise additional funds;

- our ability to obtain U.S. Food and Drug Administration ("FDA") approval of the premarket approval ("PMA") application for the LungFit® system (as defined below);

- our ability to build a pipeline of product candidates and develop and commercialize products;

- our ability to enroll patients in clinical trials, timely and successfully complete those trials and receive necessary certification or regulatory approvals;

- our ability to maintain our existing or future collaborations or licenses;

- our ability to protect and enforce our intellectual property rights;

- federal, state, and foreign regulatory requirements, including the U.S. Food and Drug Administration or the FDA regulation of our product candidates;

- our ability to obtain and retain key executives and attract and retain qualified personnel;

- our ability to successfully manage our growth; and

- our ability to address business disruption and related risks resulting from the COVID-19 pandemic, which could have a material adverse effect on our business plan.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

You should read this Annual Report and the documents that we reference in this Annual Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Beyond Air, Inc. the Beyond Air logo, and other trademarks or service marks of Beyond Air, Inc. appearing in this Annual Report are the property of Beyond Air, Inc. This Annual Report also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this Annual Report appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these trademarks and tradenames.

MARKET, INDUSTRY AND OTHER DATA

This Annual Report contains estimates, projections, market research and other information concerning our industry, our business, markets for LungFit® PH and our other product candidates and the size of those markets, the prevalence of certain medical conditions, LungFit® PH market access, prescription data and other physician, patient and payor data. Unless otherwise expressly stated, we obtain this information from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources as well as from our own internal estimates and research and from publications, research, surveys and studies conducted by third parties on our behalf. Information that is based on estimates, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are reflected in this information. As a result, you are cautioned not to give undue weight to such information.

SUMMARY OF PRINCIPAL RISK FACTORS

This summary briefly lists the principal risks and uncertainties facing our business, which are only a select portion of those risks. A more complete discussion of those risks and uncertainties is set forth in Part I, Item 1A of this Annual Report, entitled Risk Factors. Additional risks not presently known to us or that we currently deem immaterial may also affect us. If any of these risks occur, our business, financial condition or results of operations could be materially and adversely affected.

Our business is subject to the following principal risks and uncertainties:

Risks Related to our Financial Position and Capital Requirements

- We have incurred significant losses since inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.
- Our limited operating history may make it difficult for our stockholders to evaluate the success of our business to date and to assess our future viability.
- We do not have an FDA-approved product in the market.
- We will need additional funding.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to technologies or product candidates.

Risks Related to the Discovery and Development of Our Product Candidates

- We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.
- We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of our product candidates.
- We have conducted, and may in the future conduct, clinical trials for certain of our product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations.
- If we experience any of a number of possible unforeseen events in connection with clinical trials of our product candidates, potential marketing approval or commercialization of our product candidates could be delayed or prevented.
- We may experience delays or difficulties in the enrollment of patients in clinical trials.
- Serious adverse events, or SAEs, or undesirable side effects of our product candidates may be identified.
- Even if we obtain regulatory approval for our product candidates, we will still face extensive, ongoing regulatory requirements and review, and our products may face future development and regulatory difficulties.

Risks Related to our Reliance on Third-Parties

- We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily.
- Any failure by a third-party supplier or manufacturer to produce or deliver supplies for us or to provide necessary servicing may delay or impair our ability to complete our clinical trials or commercialize our product candidates.
- We may seek to enter into collaborations with third parties for the development and commercialization of our product candidates. If we fail to enter into such collaborations, or such collaborations are not successful, we may not be able to capitalize on the market potential of our product candidates.
- The third-party manufacturing facilities on which we rely are subject to significant regulation and may not continue to meet regulatory requirements.
- Our reliance on third-parties necessitates the sharing of trade secrets, which increases the possibility of their improper disclosure or appropriation.

Risks Related to Commercialization of our Product Candidates

- If the market opportunities for our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.
- Even if we are able to commercialize any product candidate that we develop, the product may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or healthcare reform initiatives that could harm our business.
- Intense competition and rapid technological changes may adversely affect our ability to successfully commercialize our product candidates.
- If we are unable to establish sales and marketing capabilities or enter into agreements with third-parties to market and sell our product candidates, we may be unable to generate any revenue.
- Even if one of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success, and the market opportunity for the product candidate may be smaller than we estimate.
- Failure to comply with applicable privacy, data and security regulations could result in substantial penalties, liability and negative publicity which could adversely affect our business operations.

Risks Related to our Intellectual Property

- If we fail to obtain and maintain sufficiently broad patent protection of our technology, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.
- We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.
- We may be subject to claims by third-parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.
- Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.
- We may not be successful in obtaining or maintaining necessary intellectual or proprietary rights to our product candidates including, but not limited to acquisitions and in-licenses.

Risks Related to our Business Operations

- We will need to expand our operations and increase the size of our company, which may expose us to difficulties in managing growth as well as additional regulatory, operational and financial risks.
- The degree to which our business is subject to government regulation and oversight may result in additional delays and the incursion of additional expenses associated with any interruption in government-business, including, but not limited to a government shutdown.
- The use of any of our product candidates could result in product liability or similar claims that could be expensive, damage our reputation and harm our business.
- Our business has been and may continue to be adversely affected by the COVID-19 pandemic.
- We are dependent on information technology and our systems and infrastructure face certain risks, including from cybersecurity breaches and data leakage.

Risks Related to the Ownership of our Common Stock

- Stockholder disputes may be limited by the terms of our amended and restated certificate of incorporation.
- Recent trading in our common stock has been volatile and may continue to be volatile in the future.
- Antidilution provisions in certain of our outstanding warrants may affect the interests of our common stockholders.
- Equity issuances or raising additional capital may cause dilution to our stockholders or restrict our operations.

Risks Related to Employee Matters

- Our employees may engage in misconduct.
- Employee litigation and unfavorable publicity could negatively affect our future business.
- We may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.

General Risk Factors

- The increasing use and relevance of social media platforms may present new risks.
- Our business may be affected by unfavorable global or U.S. economic conditions.

PART I

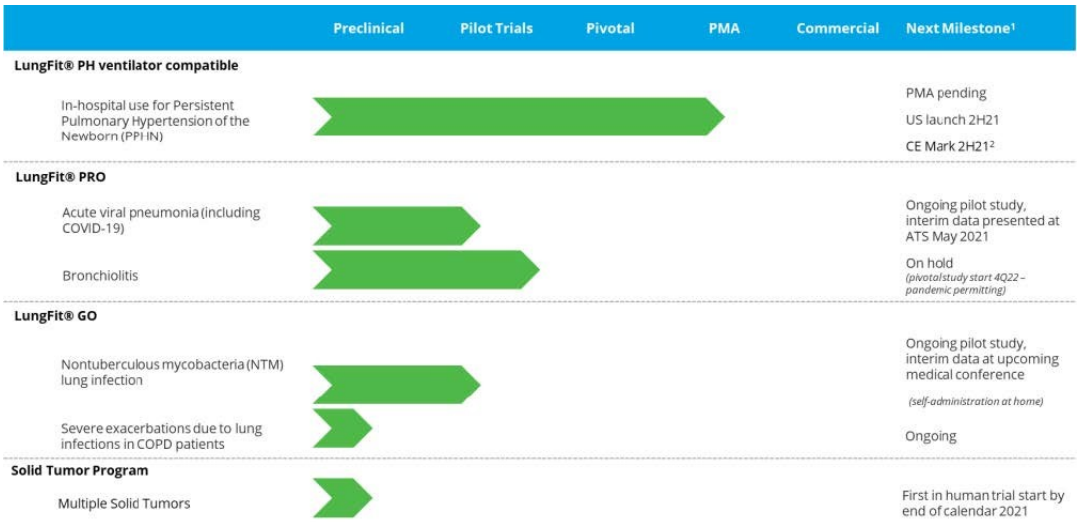
ITEM 1. BUSINESS

Business Overview

We are a clinical-stage medical device and biopharmaceutical company developing a nitric oxide ("NO") generator and delivery system (the "LungFit® system") that is capable of generating NO from ambient air. The LungFit® platform can generate NO up to 400 parts per million ("ppm") for delivery to a patient's lungs directly or via a ventilator. LungFit® can deliver NO either continuously or for a fixed amount of time at various flow rates and has the ability to either titrate dose on demand or maintain a constant dose. We believe that LungFit® can be used to treat patients on ventilators that require NO, as well as patients with chronic or acute severe lung infections via delivery through a breathing mask or similar apparatus. Furthermore, we believe that there is a high unmet medical need for patients suffering from certain severe lung infections that the LungFit® platform can potentially address. Our current areas of focus with LungFit® are persistent pulmonary hypertension of the newborn ("PPHN"), acute viral pneumonia ("AVP") including COVID-19, bronchiolitis ("BRO") and nontuberculous mycobacteria ("NTM") lung infection. Our current product candidates will be subject to premarket reviews and certifications or approvals by the U.S. Food and Drug Administration, (the "FDA"), as well as similar regulatory agencies in other countries or regions. If approved, our system will be marketed as a medical device in the United States.

An additional focus of ours is solid tumors. For this indication the LungFit® platform is not utilized due to need for ultra-high concentrations of gaseous nitric oxide ("gNO"). We have developed a delivery system that can safely deliver gNO in excess of 10,000 ppm directly to a solid tumor. This program is in pre-clinical development and will require approval from the FDA or similar agencies in other countries to enter human studies. We expect to receive regulatory approval to enter a first in human trial by the end of calendar year 2021.

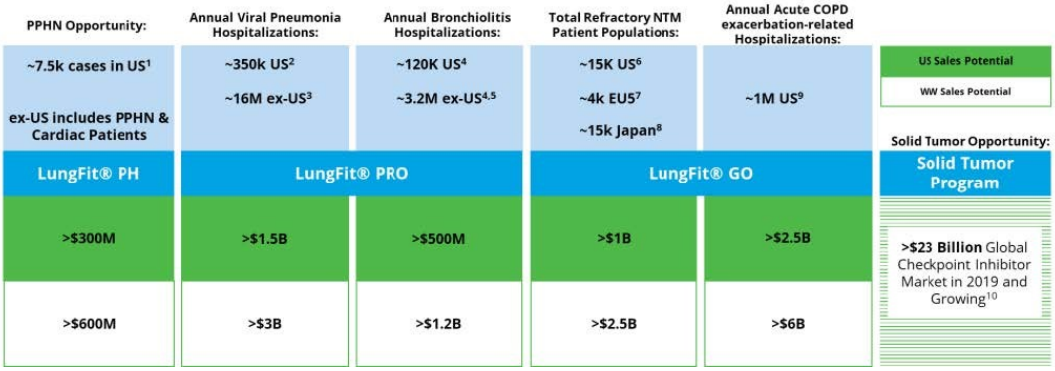
Our active pipeline of product candidates is shown in the table below:



†Caution - LungFit® is an Investigational Device, Limited by Federal (or United States) Law to Investigational Use.

(1) All dates are based on projections and appropriate financing, anticipated first launch on a global basis pending appropriate regulatory approvals
(2) Label expected to include cardiac surgery and PPHN

Our programs represent large market opportunities:



†Caution - LungFit® is an Investigational Device, Limited by Federal (or United States) Law to Investigational Use. All figures are Company estimates for peak year sales: Global sales potential includes US sales potential

The LungFit® system generates NO from ambient air by simulating the electric discharge caused from a lightning strike. Our proprietary technology allows for this reaction to occur in a plasma chamber. We believe the on-demand delivery, either to a ventilator circuit or directly to a patient's lungs, is safe due to our system design and our proprietary nitrogen dioxide ("NO_2") filter. The NO_2 filter removes toxic NO_2 for 12 hours when used for PPHN and shorter periods for treating other conditions that require NO concentrations of 150 ppm or more.

With respect to PPHN, our novel LungFit® PH is designed to deliver a dosage of NO to the lungs that is consistent with current guidelines for delivery of 20 ppm NO with a range of 0.5 ppm – 80 ppm (low-concentration NO) for ventilated patients. We believe the ability of LungFit® PH to generate NO from ambient air provides Beyond Air many competitive advantages over the current standard of NO delivery systems in the U.S., European Union, Japan and other markets. For example, LungFit® PH does not require the use of a high-pressure cylinder, does not require cumbersome purging procedures and places less burden on hospital staff in carrying out safety procedures.

Our novel LungFit® platform can also deliver a high concentration (≥150 ppm) of NO directly to the lungs, which we believe has the potential to eliminate microbial infections including bacteria, fungi, and viruses, among others. We believe current FDA-approved NO vasodilation treatments would have limited success in treating microbial infections given the low concentrations of NO being delivered (<100 ppm). Given that NO is produced naturally by the body as an innate immunity mechanism at a concentration of 200 ppm, supplemental high dose NO should aid in the body's fight against infection. Based on our pre-clinical and clinical studies, we believe that 150 ppm is the minimum therapeutic dose to achieve the desired pulmonary antimicrobial effect of NO. To date, neither the FDA nor equivalent regulatory agencies in other countries or regions have approved any NO formulation and/or delivery system for >80 ppm NO.

LungFit® PH for the treatment of Persistent Pulmonary Hypertension of the Newborn

On November 10, 2020 we submitted a premarket approval ("PMA") application to the FDA for the use of LungFit® PH in PPHN. There is a standard 180-day review process that starts upon FDA acknowledgement of submission, though due in part to the ongoing COVID-19 pandemic, we anticipate an FDA response towards the end of calendar 3Q 2021. We also expect to receive CE Mark under the MDR in the European Union around the end of calendar year 2021. According to the most recent year-end report from Mallinckrodt Pharmaceuticals, sales of NO were $574.1 million in 2020 (up from $571.4 million in 2019) for the United States, Canada, Japan, Mexico and Australia, with >90% in the United States. Outside of the U.S. there are multiple market participants which translates to considerably lower sales than in the U.S. We believe the U.S. sales potential of LungFit® PH in PPHN to be greater than $300 million and worldwide sales potential to be greater than $600 million. If regulatory approval is obtained, we anticipate a product launch in the U.S. in calendar 4Q 2021 and will continue to launch in the EU and globally in 2022 and beyond.

LungFit® PRO for the treatment of viral lung infections in hospitalized patients

Acute Viral Pneumonia (including COVID-19)

Viral pneumonia in adults is most commonly caused by rhinovirus, respiratory syncytial virus ("RSV") and influenza virus. However, 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. COVID-19 is an infectious disease caused by SARS-CoV-2, that has resulted in a global pandemic. Excluding the pandemic, there are approximately 350,000 annual viral pneumonia hospitalizations in the US, and 16 million annual viral pneumonia hospitalizations globally. For the broader AVP, we believe U.S. sales potential to be greater than $1.5 billion and worldwide market potential to be greater than $3 billion.

We initiated a pilot study in late 2020 using our novel LungFit® PRO system at 150 ppm to treat patients with acute viral pneumonia, including COVID-19. The ongoing trial is a multi-center, open-label, randomized clinical trial in Israel, including patients infected with SARS-CoV-2. Patients are randomized in a 1:1 ratio to receive either inhalations of 150 ppm NO given intermittently for 40 minutes four times per day for up to seven days in addition to standard supportive treatment ("NO+SST") or standard supportive treatment alone ("SST"). Endpoints related to safety (primary endpoint), oxygen saturation, and ICU admission, among others, will be assessed.

We reported interim data from this ongoing trial at the American Thoracic Society or ATS International Conference 2021, which was held virtually from May 14 – May 19. At the time of the data cut off, the intent-to-treat ("ITT") analysis population included 19 COVID-19 patients (9 NO + SST vs 10 SST). The data readout showed that 150 ppm NO treatment administered via LungFit® PRO was safe and well tolerated and demonstrated encouraging efficacy signals. From a safety perspective, there were no treatment-related, or possibly related, adverse events or severe adverse events. NO_2 levels were below 4 ppm at all timepoints (trial safety threshold is 5 ppm) and methemoglobin ("MetHb") levels were below 4% at all times (trial safety threshold is 10%). With respect to the requirement of oxygen support beyond hospital stay, 22.2% of subjects in the NO + SST group compared with 40% of control subjects had this requirement. There was an observable trend of shortening the duration of hospital stay and duration on oxygen support for treated patients. Additional detailed study results may be submitted for presentation at an upcoming scientific meeting.

Bronchiolitis

Bronchiolitis is the leading cause of hospital admission in children less than 1 year of age. The incidence is estimated to be 150 million new cases a year worldwide, with 2-3% (over 3 million) of them severe enough to require hospitalization. Worldwide, 95%[3] of all cases occur in developing countries. In the U.S., there are more than 120,000 annual bronchiolitis hospitalizations and approximately 3.2 million annual child hospitalizations globally. Currently, there is no approved treatment for bronchiolitis. The treatment for acute viral lung infections that cause bronchiolitis in infants is largely supportive care and is based primarily on prolonged hospitalization during which the infant receives a constant flow of oxygen to treat hypoxemia, a reduced concentration of oxygen in the blood. In addition, systemic steroids and inhalation with bronchodilators are sometimes utilized until recovery, but we believe these treatments do not successfully reduce hospital length of stay. We believe the U.S. market potential for bronchiolitis to be greater than $500 million and worldwide market potential to be greater than $1.2 billion.

Our BRO program is currently on hold due to the COVID-19 pandemic. The pivotal study for bronchiolitis was originally set to be performed in the winter of 2020/21 but was delayed due to the pandemic. We have completed three successful pilot studies for bronchiolitis. A further analysis of the three previously reported pilot studies was presented at the ATS International Conference 2021, which was held virtually from May 14 – May 19. Analysis across the studies (n=198 infants, mean age 3.9 months) showed that 150 – 160 ppm NO administered intermittently was generally safe and well tolerated with adverse event rates similar among treatment groups with no reported treatment-related serious adverse events. The short course of treatments with intermittent high concentration inhaled NO was effective in shortening hospital length of stay and accelerating time to fit for discharge – a composite endpoint of clinical signs and symptoms to indicate readiness to be evaluated for hospital discharge. This treatment was also effective in accelerating time to stable oxygen saturation – measured as SpO2 ≥ 92% in room air. Additionally, NO at a dose of 85 ppm NO showed no difference compared to control for all efficacy endpoints, while 150 ppm NO showed statistical significance when compared to control.

We believe the entirety of data at 150-160 ppm NO in both adult and infant patient populations supports further development of LungFit® PRO in a pivotal study for patients hospitalized with viral pneumonia.

LungFit® GO for the treatment of Nontuberculous mycobacteria (NTM)

NTM lung infection is a rare and serious pulmonary disease associated with increased morbidity and mortality. Patients with NTM lung disease may experience a multitude of symptoms such as fever, weight loss, cough, lack of appetite, night sweats, blood in the sputum and fatigue. Patients with NTM lung disease, specifically *Mycobacterium abscessus* (*M.abscessus*) representing 20-25% of all NTM and other forms of NTM that are refractory to antibiotic therapy, frequently require lengthy and repeated hospital stays to manage their condition. There are no treatments specifically indicated for the treatment of *M. abscessus* lung disease in North America, Europe or Japan. There are approximately 50,000 to 90,000 people with NTM infections in the U.S. In Asia, the number of patients suffering from NTM surpasses what is seen in the U.S. There is one inhaled antibiotic approved for the treatment of refractory *Mycobacterium avium complex* ("MAC"). Current guideline-based approaches to treat NTM lung disease involve multi-drug regimens of antibiotics that may cause severe, long lasting side effects, and treatment can be as long as 18 months or more. Median survival for NTM MAC patients is approximately 13 years while median survival for patients with other variations of NTM is typically 4.6 years. The prevalence of human disease attributable to NTM has increased over the past two decades. In a study conducted between 2007 and 2016, researchers found that the prevalence of NTM in the U.S. is increasing at approximately 7.5% per year. *M. abscessus* treatment costs are estimated to be more than double that of MAC. In total, a 2015 publication from co-authors from several U.S. government departments stated annual cases in 2014 cost the U.S. healthcare system approximately $1.7 billion. For this indication, we believe U.S. sales potential to be greater than $1 billion and worldwide sales potential to be greater than $2.5 billion.

In December 2020 we began a 12-week, multi-center, open-label clinical trial in Australia and we plan to enroll approximately 20 adult patients with chronic refractory NTM lung disease. We received a grant of up to $2.17 million from the Cystic Fibrosis Foundation to fund this study and advance the clinical development of inhaled NO to treat NTM pulmonary disease. The trial is enrolling both cystic fibrosis ("CF") and non-CF patients infected with MAC or *M. abscessus*. The study consists of a run-in period followed by two treatment phases. The run-in period provides a baseline for the efficacy endpoints. The first treatment phase takes place over a two-week period and begins in the hospital setting where patients will be titrated from 150 ppm NO up to 250 ppm NO over several days. During this phase patients receive NO for 40 minutes, four times per day while MetHb levels are monitored. Patients are also trained to use LungFit® GO and subsequently discharged to complete the remaining portion of the two-week treatment period at their home at the highest tolerated NO concentration. For the second treatment phase, a 10-week maintenance phase, the administration is twice daily. The study is evaluating safety, quality of life, physical function, and bacterial load among other parameters.

We anticipate reporting interim data in the second half of calendar year 2021, likely at a scientific conference. We will release top-line results for the full data set approximately six months later. If the trial is successful, we would anticipate commencing a pivotal study in the first half of calendar year 2023.

Our program in chronic obstructive pulmonary disease ("COPD") is in the pre-clinical stage and will remain there, subject to obtaining additional financing.

Ultra-High Concentration NO in solid tumors

For our solid tumor program, we have released pre-clinical data at several medical/scientific conferences showing the promise of delivering NO at concentrations of 20,000 ppm – 200,000 ppm directly to tumors. Results showed that local tumor ablation with NO conveyed anti-tumor immunity to the host. In our most recent release of data, 8 of 11 mice treated with a single administration of 25,000 ppm NO over 5 minutes were resistant to a subsequent tumor challenge and 11 of 11 mice treated with 50,000 ppm NO were resistant to a subsequent tumor challenge. Pre-clinical work will continue throughout most of 2021 with a goal of receiving regulatory approval to initiate a first-in-human trial by the end of calendar year 2021.

Background and NO Mechanism of Action

NO is recognized as a vital molecule involved in many physiological and pathological processes. NO is naturally produced by the body's immune system to provide a first line of defense against invading pathogens. It is a powerful molecule with a short half-life of a few seconds in the blood, enabling it to be cleared rapidly from the body. NO has been shown to play a critical role in the function of several body systems. For example, as vasodilator of smooth muscles, NO enhances blood flow and circulation. In addition, NO is involved in regulation of a wound healing and immune responses to infection. The pharmacology, toxicity and other data for NO in humans is generally well known, and its use has been approved by the FDA as a vasodilator. The precise effect of inhaled NO is dependent on concentration, oxidation state and type of pathogen.

NO has multiple immunoregulatory and antimicrobial functions that are likely to be of relevance to inhaled NO therapy. *In vitro* studies suggest that NO possesses anti-microbial activity against common bacteria, gram positive and gram negative, as well as mycobacteria, fungi, yeast, parasites and helminths. It has the potential to eliminate multi-drug resistant strains of the above. Anti-viral activity covers respiratory viruses such as influenza, corona viruses, RSV and others. In healthy humans, NO has been shown to stimulate mucocilary clearance, and low levels of nasal NO correlate with impaired mucociliary function in the human upper airway. Unlike other inhaled drugs, NO is also a smooth muscle relaxant and avoids the concomitant bronchial constriction often associated with inhaled antibiotics and mucolytics. A potential benefit of these multiple mechanisms may be that in addition to treating lung infections in CF patients, this suggests that NO may be useful in directly treating the mucus caused by CF, which is the principal manifestation of the disease.

Nitric Oxide and Infection

NO possesses broad-spectrum anti-microbial activity acting against bacteria, fungi and viruses. NO is produced at high output as part of the innate immune response. NO and its by-products (for example, reactive nitrogen species, or RNS) are responsible for the process of killing microorganisms within white blood cells called macrophages and in organs such as the lungs and other mucolytic tissues.

More than a decade ago, several research groups showed that NO and RNS possess anti-viral activity and affect several viruses including coxsackievirus, RSV, influenza, severe acute respiratory syndrome, or SARS, coronavirus, rhinovirus, herpes simplex virus, Epstein-Barr virus, or EBV, and others. NO has also been shown to be useful in preventing bacterial growth on surfaces.

Continuous exposure to 150 ppm NO and above, especially in the lungs, may have side effects and cause damage to host cells. Intermittent exposure to NO in cycles retains NO anti-microbial activity both in vitro and in animal model of infection. Exposure of bacteria to concomitant 30-minute treatments with 160 ppm NO resulted in a significant reduction in bacterial load. A similar dose has been shown to reduce viruses (common influenza) by 30-100% in a canine kidney infection model. In vivo, in a pneumonia model in rats, inhaled 160 ppm NO, for 30 minutes, every 4 hours, resulted in significant reduction in bacteria counts in the lungs, without affecting the body's defense mechanisms, and without any other adverse effect. In addition, we believe a daily dose of 160 ppm of NO can treat bovine respiratory disease ("BRD") in cattle.

Importantly, several studies report synergy between NO and antibiotic drugs. Adjunctive treatment combining NO together with inhaled tobramycin antibiotics or other anti-microbial agents has been shown to greatly enhance the efficacy of the antibiotics in dispersing P. aeruginosa biofilms and to increase their ability to elicit anti-microbial activity. These studies suggest that adjuvant treatment combining NO with antibiotics might have a beneficial role by reducing bacterial infectivity, and therefore reduce the dependency on antibiotics.

Beyond Air Technology

We have developed the Beyond Air nitric oxide generator and delivery system which we call LungFit®, a novel and precise delivery system that uses NO generated from ambient air with a novel NO generator. Our system provides continuous monitoring and control of the gaseous content administered during intermittent and continuous NO inhalation treatments, as well as a precise and reliable monitoring system that is able to monitor patient status and alert medical staff to any adverse effects.

The LungFit® system is innovatively designed to provide patients with a gaseous dose of NO (ranging from 0.5 ppm up to 400 ppm) combined with ambient air. The gaseous blend is supplied to the patient via a ventilator for concentrations up to 80 ppm and a face mask, or similar apparatus, for concentrations above 80 ppm. LungFit® is designed to minimize the time that NO is mixed with oxygen and air. The system is also designed to continuously monitor inhaled NO concentration, NO_2 concentration and oxygen. A dedicated screen allows for monitoring of the gas mixture. Further, our product candidates resemble other inhalation systems, making them user friendly, with operation and maintenance that we believe will be immediately familiar to medical staff. Our LungFit® system has been manufactured at commercial scale with a contract manufacturer.

When programmed for lung infections, the LungFit®, is designed to specifically deliver a NO dosage of 150 ppm and higher. We believe that the LungFit® has a number of advantages over other NO formulation delivery systems. For example, it is:

- optimized to deliver 150 ppm and higher of NO, whereas existing NO delivery systems on the market consist of a maximum deliverable NO concentration of 80 ppm;
- equipped with a monitoring system that continuously monitors system parameters (e.g., NO, NO_2 and inhaled fraction of inspired oxygen ("FiO_2") concentrations);
- capable of providing constant flow of NO, which we believe allows it to adequately cover the surface area of the lung to eliminate bacteria, viruses, fungi and other microbes;
- programmable and able to deliver different dosage regimens for a wide range of lung infections;
- able to generate NO from ambient air, eliminating the need for the use of high-pressure cylinders;
- designed to be used by the patient, thus convenient and portable; and
- administered non-invasively through a facial mask, which has the potential to address severe infections in large, underserved chronic-care markets, such as CF and COPD.

We believe that our solution has the potential for a number of additional benefits and opportunities, as follows:

- The antimicrobial and multiple other properties of the NO molecule delivered to the lungs suggest the potential for application in a wide range of respiratory diseases. In contrast to the often arduous and slow drug discovery process for small molecules, proteins, peptides, etc., the use of NO in medicine is well-known, and therefore the identification of conditions where NO provides benefits has been, and we expect will continue to be, much simpler, quicker and less costly.
- The FDA approved the use of NO as an inhaled drug for the treatment of pulmonary hypertension in newborns in 1999. More than 20 years of clinical experience in the delivery, monitoring and understanding of NO in the clinical environment for vascular uses has been documented.
- NO is naturally produced by the immune system and acts as a first line of defense against infectious diseases. We believe therapeutic use of NO for viral and bacterial co-infections would potentially improve the success of antimicrobial and anti-viral treatments by mimicking the body's natural defense mechanism and thereby directly reduce viral infectivity, as well as antibiotic drug resistant bacteria.
- NO is used naturally by the body for vasodilation and we believe that the benefits to patients with various medical conditions will be seen via vasodilation when delivered with our system.

NitricGen License

On January 31, 2018, we announced that we entered into a definitive agreement to acquire a global, exclusive, perpetual, transferable license to the eNOGenerator and associated critical assets including intellectual property, know-how, trade secrets and confidential information (the "License") from NitricGen Inc. ("NitricGen"). The eNOGenerator is a novel and precise delivery system that uses NO generated from ambient air with a novel NO generator.

The Beyond Air LungFit® system, which incorporates the eNOGenerator, has been designated as a medical device by the FDA. The eNOGenerator can generate NO on demand for delivery to the lungs at concentrations ranging from 0.5 to 400 ppm. With the License, we expect that we will be able to target all conditions requiring NO at any concentration, regardless of the need for intermittent or continuous dosing.

Under the terms of the License, we agreed to pay NitricGen an aggregate of $2 million in up-front, clinical, and regulatory milestone payments, with the majority pertaining to regulatory milestones, as well as royalties on net sales of the delivery system containing the eNOGenerator at a percentage in the low-single digits. As partial consideration for the License, we issued to NitricGen warrants to purchase 100,000 shares of our common stock at an exercise price of $6.90 per share. To date, $200,000 has been paid for milestones that were earned. Upon FDA approval, the next milestone of $1,500,000 will be due to NitricGen and payable six months, thereafter.

Cystic Fibrosis Foundation Agreement

On February 10, 2021 we received a grant for up to $2.17 million from the CFF to advance the clinical development of high concentration NO for the treatment of nontuberculous mycobacteria pulmonary disease, which disproportionally affects CF patients. Under the terms of the agreement, the funding will be allocated to the ongoing LungFit® GO NTM pilot study. The Company has met the first milestone of $425,000 and has recorded a reimbursement receivable on the March 31, 2021 balance sheet. The reimbursement was recorded as an offset to research and development expenses for the year ended March 31, 2021 to the extent that reimbursable expenses were incurred, with the excess reimbursement included in accrued expenses as of March 31, 2021.

Strategies

Our objective is to build a leading medical device and biopharmaceutical company that develops and commercializes patented and proprietary products for the treatment of respiratory infections and diseases, with an initial focus on the treatment of PPHN, AVP, BRO, NTM and severe infections in COPD, and CF patients, among others. Additionally, we are exploring the effects of NO on solid tumors. If our clinical trials for our product candidates are successful, we expect to seek certification or marketing approval from the FDA and other worldwide authorities and notified regulatory bodies.

Our Clinical Results to Date

We have conducted several clinical trials to assess our ≥ 150 ppm NO inhalation-treatment in various indications. These trials include:

Date	Study	Indication	Primary	Results
2011	Pilot Safety (n=10)	All comers	Safety	No SAEs
2013 – 2014	POC double blind randomized (n=43)	Bronchiolitis (due to any virus)	Safety & Efficacy	No SAEs; 24 hour reduction in hospital length of stay
2013 – 2014	Pilot open label (n=9)	Cystic Fibrosis (CF)	Safety & Efficacy	No SAEs; Lowered bacterial load
2016	Compassionate use ISR (n=2)	NTM abscessus (CF)	Safety & Efficacy	No SAEs; clinical & surrogate endpoints improved
2017	Compassionate use National Institute of Health, US (n=1)	NTM abscessus (CF)	Safety & Efficacy	No SAEs; Improvements in clinical endpoints
2017	Pilot open label (n=9)	NTM abscessus	Safety & Efficacy	No SAEs; clinical & surrogate endpoints improved
2017-2018	Pilot; double blind randomized (n=68)	Bronchiolitis (due to any virus)	Safety & Efficacy	No SAEs; 27 hour reduction in hospital length of stay
2018	Compassionate use ISR (n=1)	NTM abscessus (CF)	Safety	No SAEs at 250 ppm NO dose
2019-2020	Pilot; double blind randomized (n=87)	Bronchiolitis (due to any virus)	Safety & Efficacy	NO SAEs; 150 ppm treatment showed statistically significant improvements in primary and key secondary endpoints compared to both 85 ppm and control

Cystic Fibrosis and NTM Clinical Development

In 2011, a prospective, open label, controlled, single-center pilot safety study was conducted on ten healthy adults between 20 and 62 years of age. The data were published in the Journal of Cystic Fibrosis in 2012. Subjects received 160 ppm NO for 30 minutes, five times a day, for five consecutive days via direct inhalation to the lungs using a prototype delivery system. The primary objective of the study was to determine the effect of inhaled 160 ppm NO on pulmonary function tests and characterize the relationship between high-concentration NO administration and MetHb – a form of hemoglobin that is a biproduct of NO and hemoglobin that cannot bind oxygen – and establish a MetHb safety threshold level to assess adverse events associated with the treatment. Secondary objectives of the study were to assess the changes in cytokine levels. Multiple safety markers were continuously monitored including: NO levels, NO_2 (a biproduct of NO and O_2 that can be toxic at high concentrations), FiO_2, as well as MetHb and oxygen saturation ("SaO_2"). Vital signs, lung function, blood chemistry (including nitrite/nitrates), hematology, prothrombin time, inflammatory cytokine/chemokines levels and endothelial activation (angiopoietin ratio) were also closely monitored. All individuals tolerated the NO formulation treatment courses well. No significant adverse events occurred. The maximum amount of air one can forcefully exhale in one second, known as forced expiratory volume in one second ("FEV1") and other lung function parameters, serum nitrites/nitrates, prothrombin, pro-inflammatory cytokine and chemokine levels did not differ between baseline and day five, while MetHb increased during the study period by an average of 0.9%, as expected. These data suggest that inhalation of 160 ppm NO for 30 minutes, five times a day, for five consecutive days is well tolerated in healthy individuals.

In 2014, we completed a pilot open label, multi-center study in nine CF patients (≥10 years old). Patients received intermittent (30 minutes, three times a day) inhalation of 160 ppm NO formulation, five days a week, over a two-week period. The study was performed in two centers, Soroka Medical Center and Schneider Children's Medical Center of Israel. The primary endpoints of the study were to determine the MetHb percentage, adverse events associated with inhaled NO and the percentage of subjects who prematurely discontinued the study due to adverse events ("AEs") and/or severe adverse events ("SAEs"), or for any other reason. AEs were reported by five (55.5%) subjects. There were no SAEs related to NO therapy, no treatment-related withdrawals due to AEs, and no deaths. AEs considered by the investigator as possibly or probably related to treatment were reported for two (22.2%) subjects. There were no AEs of MetHb elevation >5% or NO_2 elevation >5 ppm (study safety threshold of MetHb and NO_2, respectively). In total, seven cases of hemoptysis were reported in two subjects and all events were mild in severity. There was no cumulative effect of MetHb exposure during the study. The maximum MetHb level reported was 4.6%. Several secondary efficacy analyses were conducted in this study, and though the study was not powered for efficacy, results show various positive effects of the treatment regime. Bacterial and fungal sputum load analysis results were highly variable, though marked reductions of MSSA, Achromabacter, P. aeruginosa, and Aspergillus were seen in several subjects. These results suggest non-specific targeting of bacteria and fungi that commonly manifest in CF patients. In subjects with systemic inflammation (CRP >5 mg/mL) at baseline, CRP levels decreased over the treatment period, showing the effect of NO in the reduction of systemic inflammation. There were no statistically significant or clinically relevant changes in FEV1 over time, and lung function indices also remained relatively constant throughout the study duration.

In 2016, Rambam healthcare campus in Israel conducted a compassionate use treatment for two patients with CF who suffer from *M, abscessus* lung infections. The data were published in the Pediatric Infectious Disease Journal in 2017. The NO treatment regime, as well as the device for this treatment, was supplied by BA Ltd. our wholly owned subsidiary. Patients received intermittent 30-minute treatments of 160 ppm NO, with two different regimes including hospitalization (5 times a day) and ambulatory treatment (2-3 inhalations a day). Treatment was well tolerated with no evidence of any serious side effects. We observed significant improvement in sputum production (up to 5-10 time more sputum), and subjective improvement in the well-being of both patients. Significant reduction in systemic inflammation was observed in the first patient, as observed by reduction of CRP (C-reactive protein, a systemic inflammation marker that rises in response to inflammation) levels during treatment. In addition, the first patient had a 2 log (100-fold) reduction in *M. abscessus* during treatment (an effect that was lost after the treatment regime changed to ambulatory). The second patient showed a significant increase in the 6-minute walk ("6MW") test and the sputum culture became negative, which is consistent with eradication of *M. abscessus*. Further information is needed, but we believe these results suggest that the treatment of *M. abscessus* with high-concentration inhaled NO is effective.

In 2017, we treated one patient with CF who suffered from NTM infections (specifically, *M. abscessus*) under compassionate use in the United Sates at the National Heart, Lung and Blood Institute with our generator based NO delivery system. The patient saw improvements in 6MW, FEV1, most Quality of Life measures and had no SAEs. The bacteria was not eradicated. The patient requested to be treated again and this treatment was commenced in February 2018. A total of 38 treatments were administered over 8 days, 29 of them at a concentration of 240 ppm, with no SAEs believed to be related to NO reported.

Additionally in 2017, we completed a single-arm, open-label Pilot trial in nine patients with *M. abcessus* lung disease, who were refractory to standard-of-care. The patients were treated with inhaled NO at a concentration of 160 ppm for 30 minutes, in addition to treatment with standard-of-care. Our inhaled NO treatment was administered intermittently five times per day over a 14-day period, followed by a seven-day period with three treatments per day. The primary endpoint of safety, as measured by NO-related SAEs, over the 21-day treatment period was met with no SAEs reported. Secondary endpoints of a 6MW test FEV1, Quality of Life and *M. abscessus* load in sputum all trended positively. 6MW showed an increase of >40 meters at the end of treatment at day 21 versus baseline and an increase of >25 meters on day 81 (60 days after the cessation of therapy). The mean percentage change in FEV1 at day 21 and day 51 (30 days after the cessation of treatment) was > 3.5% with FEV1 returning to baseline at day 81 (60 days after the cessation of therapy). At day 81 (60 days after the cessation of therapy) bacterial load was 65% lower than baseline. 1 of 9 patients saw culture conversion. This study was published in the Journal of Cystic Fibrosis in 2019.

In 2018, an additional CF patient infected with *M. abscessus* was treated over a 4-week period with 76 of 84 treatments at 250 ppm NO in Israel at Soroka Medical Center. The patient saw improvements in 6MW, FEV1 and most Quality of Life measures. The bacteria was not eradicated. Importantly, there were no SAE's reported and all treatments were completed without incident.

BRO Clinical Development

In 2014, we completed a double blind, randomized Pilot study for infants with bronchiolitis (n=43) for which the data were published in the Pediatric Pulmonology Journal in 2017. The study was performed at Soroka University Medical Center in Israel. Forty-three infants between the ages of two to 12 months diagnosed with bronchiolitis were randomly assigned to either the treatment group or the control group. The treatment group comprised 21 subjects who received intermittent (30 minutes, five times a day) inhalation of 160 ppm NO formulation, in addition to supportive O_2 treatment for up to five days. The control group, 22 subjects, received ongoing inhalation of the supportive O_2 treatment. Primary endpoints included determination of the MetHb levels, adverse events associated with the inhaled NO formulation and proportion of subjects who prematurely discontinued the study. Baseline clinical score, indicating disease severity at screening, was similar between treatment groups (~8). Results were encouraging, with similar overall incidence of AEs between the treatment groups. Out of 43 patients, 39 (~90%) completed the study per protocol ("PP"), with similar percentages (90%) for both the control and the treatment groups, individually. Only one subject from the treatment group discontinued treatment due to an adverse event, namely – repeated MetHb levels above 5%. Adverse events were reported by 23 (53.5%) subjects overall, with ten (47.6%) subjects in the NO group reporting a total of 22 AEs, and 13 (59.1%) subjects in the control group reporting a total of 22 AEs. Serious adverse events were reported by four (19.0%) subjects in the NO group and four (18.2%) in the standard treatment group. There were no treatment-related SAEs in the NO treatment group.

In the NO group, six (28.6%) subjects had any MetHb measurement >5% during the study treatment period, and three of these subjects had more than one MetHb >5%. The maximum MetHb level was 5.6% in one subject in the NO group. There was no cumulative effect of MetHb exposure during the study. The MetHb levels in this study were defined to <5% as a safety measure, though previous findings have shown that higher levels (6.4%) are non-toxic in children. Secondary and exploratory analyses were performed, and results show positive impact of the treatment regime. In a subgroup of subjects that stayed at the hospital at least 24 hours (Length of Stay ("LOS") >24 hours), a statistically significant treatment benefit of NO versus standard treatment was demonstrated. Mean results for subjects with LOS > 24 hours show that LOS was shortened by approximately 34% in the NO group compared to the standard treatment group, with a one-day difference between the groups (PP, N=24). Time to normal oxygenation ((SaO2 of 92%) was shortened by approximately 44% (27.75 hours) in the NO group compared to the standard treatment group (PP, N=24). An 80% improvement in time to clinical score (indicating improvement in disease severity) and time to normal oxygenation (92%) was observed in favor of the NO group (PP, N=24).

In 2018 we completed a second pilot study in bronchiolitis in 6 centers in Israel. The data were published in Nature in 2020. The prospective, randomized, double-blind, controlled pilot study enrolled 67 patients, aged 0-12 months, who were hospitalized due to bronchiolitis. The patients received either standard of care ("SOC") (typically oxygen and hydration) or SOC plus inhaled NO at a concentration of 160 ppm for 30 minutes 5 times per day for up to 5 days. The primary endpoint of hospital LOS was met with a 26.7-hour reduction in hospital length of stay demonstrated (p=0.04). Secondary endpoints of time required to achieve a clinical score of 5 or less on the modified Tal score and time required to achieve oxygen saturation (SaO_2) of 92% or greater showed improvement versus the standard-of-care. There were no issues with NO_2 or MetHb and no SAEs were recorded.

In 2020 we completed a third pilot study in bronchiolitis in 8 centers in Israel and presented the data at CHEST Annual Meeting 2020. The prospective, randomized, double-blind, controlled pilot study enrolled 89 patients (ITT n=87), aged 0-12 months, who were hospitalized due to bronchiolitis. The patients were randomized 1:1:1 to receive either SOC (typically oxygen and hydration) or SOC plus inhaled NO at 85 ppm or SOC plus inhaled NO at 150 ppm for 40 minutes 4 times per day for up to 5 days. There were no SAEs related to NO therapy. Efficacy results are shown in the table below.

	150 ppm vs. 85 ppm Hazard Ratio (p-value)	150 ppm vs. SST Hazard Ratio (p-value)
Fit for Discharge	2.11 (0.041)	2.32 (0.049)
Hospital Length of Stay (LOS)	2.01 (0.046)	2.28 (0.043)
Oxygen Saturation of $\geq$ 92%	2.15 (0.056)	2.62 (0.039)

We plan to seek certification or regulatory approval for our current product candidates and, if approved, we expect they will be marketed as medical devices.

If we reach the commercialization stage, we expect that we will collaborate with companies outside the U.S. for all indications. We are still determining whether to attempt to collaborate for any indication in the U.S.

Our Pre-Clinical Results to Date

We have completed 4 separate toxicology studies in animals.

- **Rats**: 30 days of intermittent treatments with LungFit® at 400 ppm NO showed no observations (differences) between control rats and treated rats on observation during the treatment period prior to sacrifice and no observations on histopathology
- **Rats**: 12 weeks of intermittent treatments with LungFit® at 250 ppm NO showed no observations (differences) between control rats and treated rats on observation during the treatment period prior to sacrifice and no observations on histopathology
- **Dogs**: 12 weeks of intermittent treatments with LungFit® at 250 ppm NO showed no observations (differences) between control dogs and treated dogs on observation during the treatment period prior to sacrifice and no observations on histopathology
- **Rats:** Geno toxicology study of intermittent with LungFit® NO at 200 – 400 ppm showed a **non-genotoxic** response at all concentrations

Competition

The biotechnology, pharmaceutical and medical device industries are highly competitive. There are many pharmaceutical companies, biotechnology companies, medical device companies, public and private universities and research organizations actively engaged in the research and development of products that may be similar to our product candidates. We are aware of several companies currently developing and selling NO therapies for various indications such as pulmonary hypertension. For example, Mallinckrodt Pharmaceuticals ("Mallinckrodt") commercializes INOMAX® (nitric oxide) for inhalation, which is approved for use to treat newborns suffering from HRF-PPHN, in the U.S., Canada, Australia, Mexico and Japan. Praxair markets a generic version of the Mallinckrodt offering with their delivery system called NOxBOX®, acquired from Bedfont, in the United States. The Linde Group has marketing rights to INOMAX® in Europe. Air Liquide sells a similar product in Europe, called VasoKINOX™, together with their delivery platform called OptiKINOX™, for the treatment of pulmonary hypertension that occurs during or after heart surgery. In Europe, Bedfont Scientific Ltd. has a delivery system called NOxBOX® and Air Products PLC has a gas product called NOXAP®, each used in delivering inhaled NO formulations. Bellerophon Therapeutics is developing NO-based products for pulmonary arterial hypertension and pulmonary hypertension associated with COPD. VERO Biotech LLC (formerly known as Geno LLC) received FDA approval for their delivery system GENOSYL DS for PPHN in 2019. In addition, other companies may be developing generic NO formulation delivery systems for various dosages. Ceretec, Inc., a company affiliated with 12th Man Technologies Inc., recently obtained clearance from the FDA to market a NO gas product for use in membrane diffusing capacity testing in pulmonary function laboratories in the U.S. Novoteris, LLC previously received orphan drug designation from the FDA and the European Medicines Agency ("EMA") for the use of inhaled NO-based treatments in treating CF.

Our competitors, either alone or through their strategic partners, might have substantially greater name recognition and financial, technical, manufacturing, marketing and human resources than we do and greater experience and infrastructure in the research and clinical development of pharmaceutical products, obtaining FDA and other regulatory approvals of those products and commercializing those products around the world.

We have contracted with third-party contract manufacturers, Spartronics LLC ("Spartronics"), and Medisize Ireland Limited ("Medisize") who have completed a substantial portion of the commercial manufacturing process for our LungFit® PH system. In addition, we will be reliant on our partners for commercial manufacture of our systems for both clinical studies and commercial supply, if regulatory approval is received.

We own or have exclusively licensed patents, pending patent applications, know-how and trade secrets that relate to our NO generator, NO_2 filtration, delivery systems, devices configured for delivering NO to patients by inhalation, methods of exposing patients to inhalation of NO, and methods for treating subjects in need of NO inhalation.

In particular, we are party to a global, exclusive, transferable license agreement with NitricGen, Inc. for the eNOGenerator, its components, and all associated patents and know how related thereto. Additionally, we have a broad intellectual property portfolio directed to our product candidates and mode of delivery, monitoring parameters and methods of treating specific disease indications. Our intellectual property portfolio consists of issued patents and pending applications, which includes patents we acquired pursuant to the exercise of an option in 2017 granted to us by Pulmonox Technologies Corporation ("Pulmonox").

CareFusion Non-Exclusive License Agreement. In October 2013, we entered into a non-exclusive worldwide license agreement with CareFusion, whereby we licensed seven issued U.S. patents and corresponding foreign counterparts. Our intellectual property licensed from CareFusion, for which the earliest expiring patent term was 2019 and the last to expire is 2025. The term of the agreement extends through the life of the patents and may be terminated by either party with 60 days' prior written notice in the event of a breach of the agreement, and may be terminated unilaterally by CareFusion with 30 days' prior written notice in the event that we do not meet certain milestones. Pursuant to the agreement, we are required to pay CareFusion royalty payments of 5% of the net sales of a licensed product by the Company and an annual fee of $50,000, which is creditable against the royalty payments for the respective year.

Pulmonox Patents and Assets - Option to Acquire. On August 31, 2015, we entered into an agreement with Pulmonox (the "Option Agreement") whereby we acquired the option to purchase certain intellectual property assets, including Pulmonox's rights in 17 issued U.S. patents, including eight patents jointly owned with CareFusion which are directed to:

- devices and methods for delivering NO formulations to a patient at steady and alternating concentrations (80-400 ppm), including intermittent delivery of NO;
- a device and methods for treatment of surface infections; and
- use of NO as a mucolytic agent and for treatment and disinfection of biofilms.

We exercised the Option in January 2017, acquiring Pulmonox's rights in the patents described above. Upon exercise of the Option, we became obligated to make certain one-time development and sales milestone payments to Pulmonox, commencing with the date on which we receive regulatory approval for the commercial sale of the first product candidate qualifying under the agreement. These milestone payments are almost entirely sales-related and are capped at a total of $87 million across three separate and distinct indications that fall under the agreement with the majority of them, approximately $83 million, being sales-related based on cumulative sales milestones for each of the three products. In addition, the Company issued a fully vested warrant to purchase up to 178,570 shares of our common stock at an exercise price of $4.80 per share for each share of common stock. On May 10, 2018, we issued to Pulmonox, an additional fully vested warrant to purchase up to 29,763 shares of our common stock at an exercise price of $4.80 per share.

Patent Applications. We have filed over 35 US and foreign patents and patent applications, including Patent Corporation Treaty ("PCT") patent applications.

A PCT patent application is a filing under the Patent Cooperation Treaty to which the U.S. and a number of other countries are a party. It provides a unified procedure for filing a single patent application to protect inventions in those countries. A search with respect to the application is conducted by the International Searching Authority, accompanied by a written opinion regarding the patentability of the invention. A PCT application does not itself result in the grant of a patent, and the grant of patent is a prerogative of each national or regional authority where the PCT application is filed during national phase filings.

Government Regulation

U.S. Regulation. In the U.S., the FDA regulates drug and medical device products under the Federal Food, Drug, and Cosmetic Act ("FD&C Act - The Act"), and its implementing regulations. Our products have been designated as devices by the FDA and will be regulated by the Center for Devices and Radiological Health (CDRH). Given that currently approved NO products and delivery systems were approved either separately (NO drug approval and NO delivery systems cleared as devices) or as drug-device combinations in the United States, we expect our device to not only be reviewed by CDRH, but also have input from the Center for Drug Evaluation and Research ("CDER").

FDA Premarket Clearance and Approval Requirements for Medical Devices. Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, approval of a de novo application, or approval of a PMA application. Under the FFDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation (QSR) facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents.

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FFDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified, but are subject to FDA's premarket notification and clearance process in order to be commercially distributed. Our currently marketed product is a Class II device subject to 510(k) clearance.

510(k) Clearance Marketing Pathway. To obtain 510(k) clearance, a company must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to twelve months, but often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees for medical device establishments.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

PMA Approval Pathway. Class III devices require approval of a PMA before they can be marketed, although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA application, the manufacturer must demonstrate that the device is safe and effective, and the PMA application must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA application must also contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Following receipt of a PMA application, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FFDCA to complete its review of a PMA application, although in practice, the FDA's review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR. PMA devices are also subject to the payment of user fees.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA application constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). A PMA may include post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported the PMA or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness. None of our products are currently marketed pursuant to a PMA.

On November 10, 2020 we submitted a PMA application to the FDA for the use of LungFit® PH in PPHN.

De-Novo Pathway. Another pathway, known as de-novo down-classification also can be used for lower risk devices for which there is no existing product code or predicate device. The Food and Drug Administration Modernization Act of 1997 established the de-novo down-classification procedure as a new route to market for low to moderate risk medical devices that automatically require a PMA due to the absence of a predicate device. This procedure allows a manufacturer whose novel device automatically requires a PMA to request down-classification of its medical device (to allow clearance through the 510(k) pathway) on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Manufacturers can request de-novo down-classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a "not substantially equivalent" determination. Under this pathway, the FDA is required to classify the device within 120 days following receipt of the de-novo application. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed.

Clinical Trials. Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's IDE regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board (IRB) for each clinical site. The IRB is responsible for the initial and continuing review of the IDE study, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Post-market Regulation. After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of "off-label" uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FFDCA that may present a risk to health;

- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The manufacturing processes for medical devices are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. These requirements impose certain procedural and documentation requirements upon us and our third-party manufacturers related to the methods used in and the facilities and controls used for designing, manufacturing, packaging, labeling, storing, medical devices. As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. Following these inspections, the FDA may assert noncompliance with QSR requirements on a Form 483, which is a report of observations from an inspection, or by way of "untitled letters" or "warning letters" that could cause us or any third-party manufacturers to modify certain activities. A Form 483 notice, if issued at the conclusion of an FDA inspection, can list conditions the FDA investigators believe may have violated QSR or other FDA requirements. We cannot be certain that we or our present or any future third-party manufacturers or suppliers will be able to comply with QSR or other FDA regulatory requirements to the agency's satisfaction. Failure to comply with these obligations may lead to possible legal or regulatory enforcement action by the FDA.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing or delaying our requests for regulatory approvals or clearances of new products or modified products;
- withdrawing a PMA that has already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Advertising and Promotion. The FDA and other regulatory agencies closely regulate the post-approval marketing and promotion of medical devices, including standards and regulations for direct-to-consumer advertising, communications about unapproved uses, industry- sponsored scientific and educational activities and promotional activities involving the internet. Devices may be marketed only for the approved or cleared indications and in accordance with the provisions of the approved or cleared label.

Combination Products. A combination product is the combination of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are combined or mixed and produced as a single entity; packaged together in a single package or as a unit; or a drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

To determine which FDA center or centers will review a combination product candidate submission, companies may submit a request for assignment to the FDA. Those requests may be handled formally or informally. In some cases, jurisdiction may be determined informally based on FDA experience with similar products. However, informal jurisdictional determinations are not binding on the FDA. Companies also may submit a formal Request for Designation to the FDA Office of Combination Products. The Office of Combination Products will review the request and make its jurisdictional determination within 60 days of receiving a Request for Designation.

FDA will determine which center or centers within the FDA will review the product candidate and under what legal authority the product candidate will be reviewed. Depending on how the FDA views the product candidates that are developed, the FDA may have aspects of the product candidate reviewed by CBER, CDRH, or CDER, though one center will be designated as the center with primary jurisdiction, based on the product candidate's primary mode of action. The FDA determines the primary mode of action based on the single mode of action that provides the most important therapeutic action of the combination product candidate – the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product candidate. The review of such combination product candidates is often complex and time consuming, as the FDA may select the combination product candidate to be reviewed and regulated by one or multiple of the FDA centers identified above, which could affect the path to regulatory clearance or approval. Furthermore, the FDA may also require submission of separate applications to multiple centers.

The post-market requirements that apply to the cleared or approved product will largely be aligned with the agency center determined to have primary jurisdiction over the product candidate and that provided marketing authorization, but manufacturers must also comply with certain post-market requirements with respect to the constituent parts of combination products. In April 2019, FDA published a final guidance document entitled Compliance Policy for Combination Product Post-Marketing Safety Reporting, which is intended to assist manufacturers of combination products comply with reporting requirements applicable to such products.

After issuing marketing authorizations, the FDA has discretion in determining post-approval compliance requirements for combination products and could thus require, for example, compliance with certain current good manufacturing practices ("cGMP") requirements for drug components as well as QSR requirements for device components of a combination product. Other post-market requirements in the same vein as those described above for medical devices and drugs/biologics will also apply, depending on the application type and center overseeing regulation of the combination product, including:

- Other record-keeping requirements;
- Post-market adverse event and Medical Device Reporting requirements;
- Labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;
- Advertising and promotion requirements;
- Restrictions on sale, distribution or use of the product;
- Requirements for recalls being conducted and recall reporting;
- An order of repair, replacement or refund;
- Product tracking requirements; and
- Post-market surveillance or clinical trials.

Healthcare providers are permitted to prescribe approved devices for "off-label" uses—that is, uses not approved by the FDA and therefore not described in the product's labeling. These off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use. Thus, we may market our products, if approved by the FDA, only for their approved indications, but under certain conditions may engage in non-promotional, balanced communication regarding off-label uses. Failure to comply with applicable FDA requirements and restrictions in this area may subject us to adverse publicity and a variety of sanctions, which could harm our business and financial condition.

Coverage and Reimbursement. Coverage and reimbursement for medical devices in the U.S. is determined by third-party payors, including Medicare and Medicaid, commercial health insurers, and managed care organizations. Each payor has a unique process for determining whether to cover a device for a particular indication and how to set reimbursement rates for the device. A payor can decide to cover a device yet not provide adequate reimbursement to ensure access to the device. New devices often face significant uncertainty about coverage and reimbursement. Payors may require additional evidence, beyond the data required for FDA approval, to demonstrate that a device should be covered for a particular indication or that it should be reimbursed at a higher rate than other technologies. In addition, health care spending continues to be a concern for federal and state governments, as well as for commercial payors. Governments continue to debate methods of controlling health care costs, including reductions in reimbursement or additional controls on utilization of new technologies in Medicare and Medicaid, and commercial payors may similarly seek to limit spending on new devices. Restrictions on coverage and reimbursement could harm our future revenues and ability to realize an appropriate return on our investment.

Orphan Drug Designation and Exclusivity. Under the Orphan Drug Act, the FDA may grant orphan drug designation to products that are intended to treat rare diseases or conditions (i.e., those affecting fewer than 200,000 individuals in the U.S.), or diseases or conditions that affect more than 200,000 individuals in the U.S. but there is no reasonable expectation that the cost of developing and making the drug product would be recovered from sales in the U.S. Although orphan drug designation does not convey any advantage in the regulatory review and approval process, it can provide certain tax benefits and access to certain grants. Additionally, FDA user fees, which can be substantial, are waived for products that obtain orphan drug designation. Further, if a product with orphan drug designation subsequently receives FDA approval for the designated disease or condition, the product is generally granted seven years of orphan drug exclusivity, which (with certain limited exceptions) blocks for seven years FDA approval of another product with the same active ingredient for the same indication. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

Healthcare Fraud and Abuse Laws. In addition to the FDA's ongoing post-approval regulation of devices discussed above, manufacturers are also subject to several other types of laws and regulations, subject to differing enforcement regimes. In recent years, marketing and promotional activities regarding FDA-regulated products have come under intense scrutiny and have been the subject of enforcement action brought by the Department of Justice and the Office of Inspector General of the Department of Health and Human Services, as well as state authorities and even private individuals.

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and selection of medical devices for patients. Arrangements with third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations include the following:

- The federal health care program Anti-Kickback Statute ("AKS") prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical or device manufacturers, on the one hand, and prescribers, purchasers and formulary managers and others on the other. The term "remuneration" has been broadly interpreted to apply to anything of value including, for example, gifts, cash payments, donations, waivers of payment, ownership interests, and providing any item, service, or compensation for something other than fair market value. Liability under the AKS may be established without proving actual knowledge of the statute or specific intent to violate it. Although there are a number of statutory exceptions and regulatory safe harbors to the AKS protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration to those who prescribe, purchase, or recommend medical device products, including certain discounts, or engaging such individuals as consultants, advisors and speakers, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Moreover, there are no safe harbors for many common practices, such as educational grants and reimbursement support programs. Violations are punishable by up to 10 years in prison, criminal fines, administrative civil monetary penalties and exclusion from participation in federal healthcare programs. Any sales or marketing practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny under the AKS;

- the federal civil False Claims Act ("FCA") imposes liability on individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent, claims for payment of government funds, knowingly making, using, or causing to be made or used a false statement or record material to an obligation to pay money to the government, or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. A claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA. Actions under the FCA may be brought by the government or as a qui tam action by a private individual in the name of the government, who may also share in any monetary recovery. Qui tam actions are filed under seal and impose a mandatory duty on the U.S. Department of Justice to investigate such allegations. Manufacturers have faced liability under the FCA for providing inaccurate billing or coding information to customers or promoting a product off-label. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false or fraudulent claim or statement for violations, as well as exclusion from participation in federal healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations (collectively, HIPA), imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement or representation, or using any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items, or services;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided (in 2021) to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives.
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Several states have enacted legislation requiring medical device manufacturers to, among other things, establish marketing compliance programs; file periodic reports with the state, including reports on gifts and payments to individual health care providers; and/or register their sales representatives. Some states prohibit certain sales and marketing practices, including the provision of gifts, meals, or other items to health care providers.

Additionally, other laws such as the federal Lanham Act and similar state laws allow competitors and others to initiate litigation relating to advertising claims. If the Company sells its device outside the United States, it must comply with the Foreign Corrupt Practices Act ("FCPA") and local laws of other countries. FCPA is a complex patchwork of laws can change rapidly with relatively short notice.

Environmental Laws. Elements of our potential products may be classified as hazardous materials, subject to regulation by the Department of Transportation, the International Air Transportation Association, the International Maritime Organization, the Environmental Protection Agency and the Occupational Safety and Health Administration, which may impose various requirements pertaining to the way we manufacture, transport, store, handle and dispose of our products.

European Regulation of Medical Devices. In the European Economic Area ("EEA"), we expect our products to be regulated as a medical device product falling within the scope of EU MDR.

In the EEA, medical devices must currently comply with the General Safety and Performance Requirements laid down in Annex I to the EU MDR. Compliance with these requirements is a prerequisite to be able to affix the CE mark on products, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the General Safety and Performance Requirements of the EU MDR and obtain the right to affix the CE mark, medical devices manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Apart from low risk medical devices (Class I with no measuring function and which are not sterile), in relation to which the manufacturer may issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the General Safety and Performance Requirements, a conformity assessment procedure requires the intervention of a notified body, which is an organization designated by a Competent Authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the notified body would audit and examine the technical documentation and the quality system for the manufacture, design and final inspection of the medical devices. The notified body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the General Safety and Performance Requirements. This Certificate and the related conformity assessment process entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity. Notified bodies must be accredited by the EEA countries' accreditation bodies to conduct assessment procedures for medical devices in accordance with the EU MDR. There are currently a relatively small number of notified bodies that have been accredited to conduct these assessments. This may delay conformity assessment procedures in the future in the EU.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the General Safety and Performance Requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the Competent Authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent Ethics Committee. This process can be expensive and time-consuming.

The EU MDR repeals and replaces the EU Medical Devices Directive 93/42/EEC. Unlike directives, which must be implemented into the national laws of the EEA countries, the regulations is directly applicable, i.e., without the need for adoption of EEA country laws implementing them, in all countries and are intended to eliminate current differences in the regulation of medical devices among EEA countries. The EU MDR, among other things, establishes a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensures a high level of safety and health while supporting innovation. The EU MDR entered into application on 26 May 2020, and among others things:

- strengthens the rules on placing devices on the market and reinforce surveillance once they are available;
- establishes explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improves the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- sets up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU;
- strengthens rules for the assessment of certain high-risk devices which may have to undergo an additional check by experts before they are placed on the market.

Continuing Regulation. As in the U.S., manufacturers of medical devices are subject to comprehensive regulatory oversight by notified bodies and the competent authorities of the EEA countries. This oversight applies both before and after certification. It includes control of compliance with the EU MDR General Safety and Performance Requirements and post-market surveillance.

In the EEA, the advertising and promotion of our products will also be subject to EEA countries national laws implementing Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation of individual EEA countries governing the advertising and promotion of medical devices. EEA countries' legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. Violations of the rules governing the promotion of medical devices in the EEA could be penalized by administrative measures, fines and imprisonment.

Data Privacy Regulation. The collection and use of personal health data in the EEA is governed by the provisions of the Data Protection Directive. This Directive imposes a number of requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The Data Protection Directive also imposes strict rules on the transfer of personal data out of the EEA to the U.S. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of the EEA Member States may result in fines.

Orphan Designation and Exclusivity. In the European Union, the Committee for Medicinal Products for Human Use grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union Community and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the medicinal product.

In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Exceptional Circumstances/Conditional Approval. Orphan medicinal product or products for unmet medical needs may be eligible for EU approval under exceptional circumstances or with conditional approval. Approval under exceptional circumstances is applicable to orphan products and is used when an applicant is unable to provide comprehensive data on the efficacy and safety under normal conditions of use because the indication for which the product is intended is encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, when the present state of scientific knowledge does not allow comprehensive information to be provided, or when it is medically unethical to collect such information. Conditional marketing authorization is applicable to orphan medicinal products, medicinal products for seriously debilitating or life- threatening diseases or medicinal products to be used in emergency situations in response to recognized public threats. Conditional marketing authorization can be granted on the basis of less complete data than is normally required in order to meet unmet medical needs and in the interest of public health, provided the risk-benefit balance is positive, it is likely that the applicant will be able to provide the comprehensive clinical data, and unmet medical needs will be fulfilled.

Conditional marketing authorization is subject to certain specific obligations to be reviewed annually.

Other Regulations. We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Regulation in Israel. In order to conduct clinical testing on humans in the State of Israel, special authorization must first be obtained from the ethics committee and general manager of the institution in which the clinical studies are scheduled to be conducted, as required under the Guidelines for Clinical Trials in Human Subjects implemented pursuant to the Israeli Public Health Regulations (Clinical Trials in Human Subjects), as amended from time to time, and other applicable legislation. These regulations require authorization by the institutional ethics committee and general manager as well as from the Israeli Ministry of Health, except in certain circumstances, and in the case of genetic trials, special fertility trials and complex clinical trials, an additional authorization of the Ministry of Health's overseeing ethics committee. The institutional ethics committee must, among other things, evaluate the anticipated benefits that are likely to be derived from the project to determine if it justifies the risks and inconvenience to be inflicted on the human subjects, and the committee must ensure that adequate protection exists for the rights and safety of the participants as well as the accuracy of the information gathered in the course of the clinical testing. Since we perform a portion of the clinical studies on certain of our therapeutic candidates in Israel, we are required to obtain authorization from the ethics committee and general manager of each institution in which we intend to conduct our clinical trials, and in most cases, from the Israeli Ministry of Health.

Corporate History

We were incorporated on April 24, 2015. On June 25, 2019, our name was changed to Beyond Air, Inc. from AIT Therapeutics, Inc. We have the following wholly-owned subsidiaries:

Beyond Air Ltd. ("BA Ltd."), incorporated in Israel on May 1, 2011.

Advanced Inhalation Therapies ("AIT"), a wholly-owned subsidiary of BA Ltd., incorporated on August 29, 2014, in Delaware. AIT was dissolved on March 1, 2021.

Beyond Air Australia Pty Ltd., incorporated on December 17, 2019 in Australia.

Beyond Air Ireland Limited, incorporated on March 5, 2020 in Ireland.

Recent Developments

On January 23, 2019, we entered into an agreement for commercial rights (the "Circassia Agreement") with Circassia Limited and its affiliates (collectively, "Circassia") for PPHN and future related indications at concentrations of $\leq$80 ppm in the hospital setting in the United States and China. On December 18, 2019, the Company terminated the Circassia Agreement. Circassia contended that the termination was wrongful.

On May 25, 2021, we and Circassia Limited entered into a Settlement Agreement resolving all claims by and between both parties and mutually terminating the Circassia agreement disclosed in Note 10. Pursuant to the terms of the Settlement Agreement, we agreed to pay Circassia $10.5 million in three installments, the first being a payment of $2,500,000 to Circassia within fifteen (15) days following FDA approval of the LungFit® PH (the "Initial Payment Due Date"). Thereafter, the Company shall pay $3.5 million to Circassia on the first anniversary of the Initial Payment Due Date and $4.5 million on the second anniversary of the Initial Payment Due Date. Additionally, beginning in year three post-approval, Circassia will receive a quarterly royalty payment equal to 5% of LungFit® PH net sales in the US. This royalty will terminate once the aggregate payment reaches $6 million. This product candidate continues to be under FDA review.

Emerging Growth Company Status

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act enacted on April 5, 2012, referred to as the JOBS Act. For as long as we are an emerging growth company, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding advisory "say-on-pay" and "say-when-on-pay" votes on executive compensation and shareholder advisory votes on golden parachute compensation.

Under the JOBS Act, we will remain an emerging growth company until the earliest of:

- March 31, 2022;
- the last day of the fiscal year during which we have total annual gross revenues of $1.07 billion or more;
- the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt; and
- the date on which we are deemed to be a "large accelerated filer" under the Securities Exchange Act of 1934, as amended, referred to as the Exchange Act, (we would qualify as a large accelerated filer as of the first day of the first fiscal year after we (i) have more than $700 million in aggregate market value of outstanding common equity held by our non-affiliates as of the last day of our second fiscal quarter of our prior fiscal year and (ii) have been public for at least 12 months).

The JOBS Act also provides that an emerging growth company may utilize the extended transition period provided for complying with new or revised accounting standards. We have irrevocably elected to take advantage of this extended transition period. Because we will not be required to comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies, our financial statements may not be comparable to the financial statements of companies that comply with the effective dates of those accounting standards.

Available Information

We file electronically with the Securities and Exchange Commission (the "SEC") our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Exchange Act. We make available on our website at www.beyondair.net free of charge, copies of these reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Reports filed with the SEC may be viewed at www.sec.gov. The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

Human Capital

As of June 7, 2021, we had 45 total employees, all of whom were full time employees. None of our employees are represented by a labor union and we consider our employee relations to be good.

Our workforce is highly educated and diverse, which we believe is important for our continued success as a leading innovator in the medical device market. We employ a number of strategies to best enable us to attract, retain, and engage our team members. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, and incentivizing our management team and our clinical, scientific and other employees and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and motivate personnel through the granting of stock-based and cash-based compensation awards, in order to align our interests and the interests of our stockholders with those of our employees and consultants.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider carefully the risks described below, together with the other information included or incorporated by reference in this Annual Report. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Risks Related to Our Financial Position and Capital Requirements

We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future. We are a clinical-stage company. We have no approved products and have generated no revenue to date and may never generate revenue or achieve profitability.

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These are not the only risks we face. These risks include, among others, that:

- we are a development-stage medical device and biopharmaceutical company and have a limited operating history on which to assess our business, have incurred significant losses since our inception and incurred a net cash used in operating activities for the year ended March 31, 2021 of approximately $19.6M. As of March 31, 2021, we have an accumulated deficit of approximately $80.3 million and we anticipate to continue to incur significant losses for the foreseeable future;

- we are unable to predict the extent of future losses or when we will become profitable based on the sale of any product, if at all. Even if we succeed in developing and commercializing our product candidates, we may never generate revenue to sustain profitability;

- we do not have an approved FDA product in the market, and we expect that we will need to raise additional funding before we can expect to become profitable from sales of our products;

- we are heavily dependent upon the success of our product candidates, which are in various stages of clinical development, and we cannot provide any assurance that the FDA or other regulatory agencies will allow us to conduct further clinical trials;

- we are in the process of developing our proprietary NO delivery system, and unexpected delays will adversely impact the timing of our U.S.-based clinical trials and approvals;

- we might be unable to develop product candidates that will achieve commercial success in a timely and cost-effective manner, or ever;

- our competitors may develop or commercialize products faster or more successfully than us;

- because some of the target patient populations of our product candidates are small, we must be able to successfully identify patients and achieve a significant market share to maintain profitability and growth;

- our reliance on third parties to help conduct our pre-clinical studies, clinical trials and commercial scale manufacturing;

- we do not have any products certified or approved for sale by the FDA or any other regulatory agencies and notified bodies, and we cannot provide any assurance that any of our product candidates will receive regulatory approval;

- if we are unable to obtain and maintain effective intellectual property rights for our technologies, product candidates or any future product candidates, we may not be able to compete effectively in our markets; and

- our future success depends in part upon our ability to retain our executive and scientific teams, and to attract, retain and motivate other qualified personnel.

Because of the numerous risks and uncertainties associated with drug development and commercialization, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those expected or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

It is highly likely that we will need to raise additional capital to meet our business requirements in the future, and such capital raising may be costly or difficult to obtain, and could dilute current stockholders' ownership interests.

Our future capital requirements will depend on many factors, including the progress and results of our clinical trials, the timing and outcome of regulatory review of our product candidates, commercial manufacturing success, the number and development requirements of other product candidates that we pursue, and the costs of commercialization activities, including product marketing, sales, and distribution. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to reasonably estimate the amounts of additional capital outlays and operating expenditures that our business will require. It is likely that we will need to raise additional funds through public or private debt or equity financings to meet various objectives including, but not limited to:

- clinical trials for our product candidates;

- researching and developing new products;

- pursuing growth opportunities, including more rapid expansion;

- acquiring complementary businesses or technologies;

- making capital improvements to improve our infrastructure;

- hiring qualified management and key employees;

- responding to competitive pressures;

- complying with regulatory requirements; and

- maintaining compliance with applicable laws.

Any additional capital raised through the sale of equity or equity-linked securities may dilute our current stockholders' ownership in us and could also result in a decrease in the market price of our common stock. The terms of those securities issued by us in future capital transactions may be more favorable to new investors and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect.

Furthermore, any debt or equity financing that we may need may not be available on terms favorable to us, or at all.

Additionally, we may incur substantial costs in pursuing future capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we issue, such as convertible notes and warrants, which may adversely impact our financial condition.

If we are unable to obtain required additional capital, we may have to curtail our growth plans or cut back on existing business, and we may not be able to continue operating if we do not generate sufficient revenues from operations needed to stay in business.

Risks Related to the Discovery and Development of Our Product Candidates

We are heavily dependent on the success of our product candidates, which are in the early stages of clinical development. We cannot give any assurance that any of our product candidates will receive certification or regulatory approval, which is necessary before they can be commercialized.

To date, we have invested substantially all of our efforts and financial resources to design and develop our product candidates, including conducting clinical trials and providing general and administrative support for these operations. Our future success is dependent on our ability to successfully develop, obtain regulatory certification or approval for, and then successfully commercialize one or more product candidates. We currently generate no revenue from sales of any product, and we may never be able to develop or commercialize a marketable product.

Two of our product candidates are in the early stages of development and will require additional clinical development (and in some cases additional preclinical development), management of nonclinical, clinical and manufacturing activities, regulatory certification or approval, obtaining adequate manufacturing supply, building of a commercial organization and significant marketing efforts before we generate any revenue from product sales. To date, we have conducted 3 pilot clinical trials involving 198 patients with bronchiolitis (mainly caused by RSV) and a pilot clinical trial in nine patients with CF. In addition, Rambam healthcare campus in Israel conducted a compassionate treatment for two patients with CF who suffer from NTM infections (specifically M. abscessus). All of these trials were conducted outside the U.S. and were not conducted pursuant to an FDA IND. The results of these trials demonstrated improvements in various endpoints and clinical outcomes. The trials were small, however, and it is likely that the FDA will view them as not significant because of their size and scope. In addition, the delivery systems were different from the one that we intend to test and market, subject to FDA approval, in the U.S., further reducing the likelihood that FDA would view these test results as adequate or sufficient to support marketing applications. Two pilot clinical trials are ongoing, one in viral pneumonia and one in NTM lung infection. Both of these studies are using our LungFit® system (PRO and GO, respectively) and are being conducted outside the United States. Once completed, if the data are favorable, these trials would support our efforts towards obtaining FDA approval. We therefore intend to conduct larger clinical trials aiming for statistically and clinically significant favorable results, or we will not be able to obtain regulatory certification nor approval to market such product candidates. It may be years before a pivotal trial is initiated, if at all, for such product candidates. Before a medical device clinical trial can be undertaken in the U.S., the sponsor of the trial must submit an IDE application for a medical device and the FDA must permit the trial to go forward. We cannot assure that we will obtain such agency acquiescence in a timely manner, or at all.

In addition, we cannot be sure that we will be successful in completing the development of our NO Delivery System to the satisfaction of the FDA, which could lead to material delays in our ability to commence U.S.-based clinical trials, if at all. We are not permitted to market or promote any of our product candidates before we receive certification or regulatory approval from the FDA or comparable foreign regulatory authorities and notified bodies, and we may never receive such certification or regulatory approval for any of our product candidates.

We as a company have submitted our first marketing application for approval of our LungFit® PH product candidate to the FDA and approval is pending, but we can make no assurances as to what FDA shall decide or any other comparable foreign regulatory authorities and notified bodies where we are seeking regulatory approval; although in 2014 the FDA granted us orphan drug designation for the use of NO in the treatment of CF and in 2015, the EU also granted us orphan drug designation for the use of NO in the treatment of CF. We are no longer pursuing the drug regulatory pathway, so the orphan drug designation may have no application. We cannot be certain that any of our product candidates will be successful in clinical trials or receive certification or regulatory approval. Further, our product candidates may not receive certification or regulatory approval even if they are successful in clinical trials. If we do not receive certification or regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we do receive FDA approval for our LungFit® PH product candidate, the indications for which we are initially seeking approval are very narrow and this, as a result, may limit their commercial viability.

We generally plan to seek certification or regulatory approval to commercialize our product candidates in the U.S., the EU and in additional foreign countries. To obtain certification or regulatory approvals we must comply with the numerous and varying regulatory requirements of such countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing and distribution of our product candidates. Even if we are successful in obtaining marketing certification or regulatory approval in one jurisdiction, we cannot ensure that we will obtain certification or regulatory approval in any other jurisdictions. If we are unable to obtain clearance or approval for our product candidates in multiple jurisdictions, our revenue and results of operations would be negatively affected.

The success of our business may also depend upon our ability to identify, license or discover additional product candidates.

Although a substantial amount of our effort will focus on the continued clinical testing, potential certification, regulatory approval and commercialization of our existing product candidates, the success of our business may also depend upon our ability to identify, license or discover additional product candidates. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development for a number of reasons, including but not limited to the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in preclinical or clinical testing;
- our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the product candidates unmarketable or unlikely to receive marketing approval;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that such a product may become unreasonable to continue to develop;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, license or discover additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

The certification or regulatory approval processes of the FDA and comparable foreign regulatory authorities and notified bodies are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain certification or regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain certification or regulatory approval by the FDA or notified bodies in Europe is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors. In addition, certification or regulatory approval policies, regulations or the type and amount of clinical data necessary to gain certification or regulatory approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the certification or regulatory approval or the decision not to certify or approve an application. We have not obtained certification or regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain certification or regulatory approval.

The process required by the FDA before a new medical device may be marketed in the U.S. generally involves the following:

- completion of or reference to extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice ("GLP");
- submission to the FDA of a pre-IDE application, which the FDA authorizes before we may begin conducting human clinical trials, provided that the FDA does not object; the IDE must be updated annually;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the medical device candidate for each proposed indication; and
- submission to the FDA of a 510(k) or PMA, after completion of all pivotal clinical trials.

An IDE application is a request for authorization from the FDA to administer an investigational medical device to humans. We currently do not have any IDEs in effect.

Clinical trials involve the administration of the medical device to human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices ("GCPs") which include the requirement that all research subjects provide their informed consent for participation in any clinical trial. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IDE. Additionally, approval must also be obtained from each clinical trial site's Institutional Review Board ("IRB") before the trials may be initiated, and the IRB must monitor the study until completed and re-assess and approve the study at least annually. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

Clinical trials for medical devices are usually conducted in two phases. Pilot clinical trials are normally conducted in small groups of patients to assess safety, find the optimal dosing range and assess potential efficacy. After a successful pilot study or studies, the device is administered to a population of patients large enough to meet the requirements for regulatory approval. This size of trial is usually multi-center, controlled and potentially double-blind.

During the course of a clinical trial, we are required to inform the FDA and the IRB about adverse events associated with our product candidate. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee, or DSMB. This group reviews unblinded data from clinical trials and provides authorization for whether a trial may move forward at designated check points based on access to certain data from the study. We may also suspend or terminate a clinical trial based on evolving business objectives or competitive climates. Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational medical device information is submitted to the FDA in the form of an PMA requesting approval to market the product for one or more indications. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things.

Once the PMA submission has been accepted for filing, the FDA's goal is to review applications within six months of filing. However, the review process is often significantly extended by FDA requests for additional information or clarification as well as pandemic related delays. The FDA may refer the application to an advisory committee for review, evaluation, and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations.

An IDE is a request for authorization from the FDA to administer an investigational medical device to humans. We currently do not have any IDEs in effect.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical studies;
- we may be unable to demonstrate to the FDA or comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA may determine that the population studied in the clinical program was not sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical studies;
- the data collected from clinical studies of our product candidates may not be sufficient to support the submission of a PMA in the U.S. or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities and notified bodies may significantly change in a manner rendering our clinical data insufficient for certification or approval; and

This lengthy certification or regulatory approval process, as well as the unpredictability of the results of clinical studies, may result in our failing to obtain certification or regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.

Our business and eventual sale of our product candidates are subject to extensive regulatory requirements, including compliance with labelling, manufacturing and reporting controls. If we fail or are unable to timely obtain the necessary 510(k) clearances, de-novo authorizations, or premarket approval, or PMA, approvals for new products, or equivalent steps in third countries including the EEA, our ability to generate revenue could be materially harmed.

Our product candidates are classified as medical devices and are subject to extensive regulation in the United States by the FDA and other federal, state and local authorities and by comparable foreign regulatory authorities. The FDA can delay, limit or deny 510(k) clearance or PMA approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our systems are safe and effective for its intended use;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- the manufacturing process or facilities we use or contract to use may not meet applicable requirements; and
- disruptions at the FDA caused by funding shortages or global health concerns, including the COVID-19 pandemic.

The FDA may refuse our requests for 510(k) clearance, de-novo or PMA of new products, new intended uses or modifications to existing products.

From time to time, legislation is drafted and introduced in the United States that could significantly change the statutory provisions governing any regulatory approval or clearance that we receive in the United States. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our test kits under development or impact our ability to modify our currently approved or cleared test kits on a timely basis.

Our products are also subject to approval, certification and regulation by foreign regulatory and safety agencies. For example, the EU has adopted the EU MDR, which imposes stricter requirements for the marketing and sale of medical devices, including in the area of clinical evaluation requirements, quality systems and post-market surveillance. Complying with the requirements of the EU MDR may require us to incur significant expenditures. Failure to meet these requirements could adversely impact our business in the EEA and other regions that tie their product registrations to the EU requirements.

Once commercialized, modifications to our marketed products may require new 510(k) clearances or approval of PMA supplements, or equivalent steps in third counties including the EEA, or may require us to cease marketing or recall the modified products until certifications, clearances or regulatory approvals are obtained.

Modifications to any of our products once they are commercialized may require new regulatory approvals or clearances, including 510(k) clearances or approval of PMA supplements, or require us to recall or cease marketing the modified systems until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not affect safety or efficacy and does not represent a major change in its intended use, so that no new clearance or approval is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval of a PMA Supplement is required. We may make modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and/or seek new marketing authorizations and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

For example, if a manufacturer determines that a modification to a PMA approved device could affect its safety or effectiveness or would constitute a major change in its intended use, then the manufacturer must file for a new a new PMA or approval of a PMA supplement. Where we determine that modifications to our products require a new PMA approval, we may not be able to obtain those additional approvals for the modifications or additional indications in a timely manner, or at all. Obtaining new approvals can be a time-consuming process, and delays in obtaining required future approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

For those products sold in the EEA, we must notify our EU notified body if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. Obtaining certification can be a time-consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Medical device development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies and early clinical studies of our product candidates may not be predictive of the results of later-stage clinical studies. Product candidates that have shown promising results in early-stage clinical studies may still suffer significant setbacks in subsequent advanced clinical studies. There is a high failure rate for medical devices proceeding through clinical studies, and product candidates in later stages of clinical studies may fail to show the desired safety and efficacy traits despite having progressed satisfactorily through preclinical studies and initial clinical studies. A number of companies in the medical device and biopharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. We do not know whether any pivotal studies we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain certification or regulatory approval to market our product candidates. Nor do we know whether the FDA will permit us to proceed directly to pivotal trials without performing pilot trials in the U.S. using the same delivery system that we will seek approval by the agency.

If we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Once we obtain certification or marketing authorization for our product candidates, any product for which we obtain certification, clearance or approval, and the manufacturing processes, post-market surveillance, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight, requirements, and periodic inspections by the FDA and other domestic and foreign regulatory and notified bodies. We must comply with equivalent standards in third countries.

In particular, we and our suppliers are required to comply with FDA's QSR in the U.S. and other regulations enforced outside the United States which cover the manufacture of our products and the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of medical devices. Regulatory bodies, such as the FDA, and notified bodies enforce the QSR in the U.S. and other regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or PMA approval of new products or modified products;
- operating restrictions;
- withdrawal of 510(k) clearances on PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

In addition, we are required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. For example, the FDA has issued to us a post-market surveillance order under Section 522 of the FDCA which requires that we conduct a human factors study, as well as conduct a detailed analysis of adverse events and complaints from home users. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products in the EEA. We must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory clearances or approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

Once commercialized, we will be subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products.

The FDA and comparable foreign regulatory authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, will distract management from operating our business and may harm our reputation and financial results.

All manufacturers placing medical devices on the market in the EEA are legally bound to report to the relevant competent authorities (a) any serious incident involving devices made available on the EU market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting, and (b) any field safety corrective action in respect of devices made available on the EU market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the EU market, if the reason for the field safety corrective action is not limited to the device made available in the third country. Reports should be submitted through the electronic system set up and managed by the EU commission in collaboration with EEA countries. Report of serious incidents will be automatically transmitted to the competent authority of the EEA country in which the incident occurred and reports on field safety corrections actions will be automatically transmitted to the competent authority of the EEA country in which the field safety corrective action is being or is to be undertaken and the EEA country in which the manufacturer has its registered place of business.

Under the EU MDR, a 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person; (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health; or (c) a serious public health threat. A 'field safety corrective action' means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market.

Malfunction of our products could result in future voluntary corrective actions, such as recalls, including corrections, or customer notifications, or agency action, such as inspection or enforcement actions. If malfunctions do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions, in which case we may need to cease manufacture and distribution of the affected products, initiate voluntary recalls, and redesign the products. Regulatory authorities may also take actions against us, such as ordering recalls, imposing fines, or seizing the affected products. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Our product candidates may in the future be subject to product recalls that could harm our reputation, business and financial results.

Medical devices can experience performance problems in the field that require review and possible corrective action. The occurrence of component failures, manufacturing errors, software errors, design defects or labeling inadequacies affecting a medical device could lead to a government-mandated or voluntary recall by the device manufacturer, in particular when such deficiencies may endanger health. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. Product recalls may divert management attention and financial resources, expose us to product liability or other claims, harm our reputation with customers and adversely impact our business, financial condition and results of operations.

We may be subject to regulatory or enforcement actions if we engage in improper marketing or promotion of our product candidates.

Our educational and promotional activities and training methods must comply with FDA and other applicable laws, including the prohibition of the promotion of a medical device for a use that has not been cleared or approved by the FDA. Use of a device outside of its cleared or approved indications is known as "off-label" use. Physicians may use our products off-label in their professional medical judgment, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our educational and promotional activities or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of warning letters, untitled letters, fines, penalties, injunctions, or seizures, any of which could have an adverse impact on our reputation and financial results.

It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our educational and promotional activities or training methods to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged, and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. It is also possible that other federal, state or foreign enforcement authorities might take action, including, but not limited to, through a whistleblower action under the FCA, if they consider our business activities constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil or administrative penalties, treble damages, fines, disgorgement, exclusion from participation in government healthcare programs, reporting requirements and compliance oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

The advertising and promotion of our products in the EEA is subject to EEA countries' national laws implementing Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation of individual EEA country governing the advertising and promotion of medical devices. EEA country legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of any future products and to manufacture, market and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of planned or future products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay regulatory clearance or approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. For example, the recent change in administration may impact our business and industry. Any change in the laws or regulations that govern the clearance and approval processes relating to our current, planned and future products could make it more difficult and costly to obtain clearance or approval for new products or to produce, market and distribute existing products. Significant delays in receiving clearance or approval or the failure to receive clearance or approval for any new products would have an adverse effect on our ability to expand our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing clearance that we may have obtained and we may not achieve or sustain profitability.

In addition, on May 25, 2017, the new EU MDR entered into force for medical devices marketed in the EEA. Implementation of the EU MDR was delayed by one year due to the COVID-19 pandemic. Following its entry into application on May 26,2021, the EU MDR introduced substantial changes to the obligations with which medical device manufacturers must comply in the EEA. High risk medical devices are subject to additional scrutiny during the conformity assessment procedure. Specifically, the EU MDR repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the European Economic Area (EEA) Member States, the regulations is directly applicable, i.e., without the need for adoption of EEA country laws implementing them, in all EEA countries and are intended to eliminate current differences in regulation of medical devices among EEA countries. The EU MDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices to ensure a high level of safety and health while supporting innovation. The EU MDR entered into application on May 26, 2021 and among other things:

- strengthens the rules on placing devices on the market and reinforce surveillance once they are available;
- establishes explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improves the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- sets up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EEA; and
- strengthens rules for the assessment of certain high-risk devices which may have to undergo an additional check by experts before they are placed on the market.

The EU MDR imposes a number of new requirements on manufacturers of medical devices. Notified bodies need to be accredited by the EU Member States' accreditation bodies to conduct assessment procedures for medical devices in accordance with the Regulation. There are currently a relatively small number of notified bodies that have been accredited to conduct these assessments. This may delay conformity assessment procedures in the future in the EU. This may impact our activities in the EEA and the UK, the renewal of our existing CE Certificates of Conformity and conformity assessment related to future bodies.

Further, the EU MDR imposes increased compliance obligations for us to access the EEA market. Our failure to comply with applicable foreign regulatory requirements, including those administered by authorities of the EEA countries, could result in enforcement actions against us, including refusal, suspension, variation, or withdrawal of our CE Certificates of Conformity by our EU notified body, which could impair our ability to market products in the EEA in the future. Any changes to the membership of the EU, such as the recent departure of the United Kingdom (Brexit), may impact the regulatory requirements for the impacted countries and impair our business operations and our ability to market products in such countries.

Brexit, has created significant uncertainty concerning the future relationship between the UK and the EU. On 24 December 2020, the EU and UK reached an agreement in principle on the framework for their future relationship, the EU-UK Trade and Cooperation Agreement. The Agreement primarily focuses on ensuring free trade between the EU and the UK in relation to goods. The Agreement does not however, specifically address medical devices. The Agreement seeks to ensure that the parties ensure "regulatory cooperation". Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as a third country. Northern Ireland will, with regard to EU regulations, continue to follow the EU regulatory rules. In light of the fact that the CE marking process is set out in EU law, which no longer applies in the UK, the UK has devised a new route to market culminating in a UK Conformity Assessed (UKCA) mark to replace the CE mark. Northern Ireland will, however, continue to be covered by the regulations governing CE marks. As part of the Agreement, the EU and the UK have agreed to continue to recognize declarations of conformity based on a self-assessment in the other territory. Given the lack of comparable precedent to Brexit, it is unclear what the financial, regulatory, and legal implications of Brexit will be and how it will affect us. However, potentially changing regulatory schemes and tariffs engendered by Brexit may add additional complexity, cost and delays in marketing or selling our products in the United Kingdom.

We are working on NTM lung infection which is very rare.

NTM lung infection is a very rare disease and only a small number of people suffer from this condition. As a result of these small numbers, we may not be able to complete the study related to NTM or, even if approved, the device for that indication may never be profitable.

We are working on bronchiolitis in infants that usually is caused by the RSV virus.

RSV is a seasonal virus (only in the winter). In our trial, we are heavily dependent on the occurrence and the severity of this virus. Treating for RSV is highly reliant on the weather conditions in winter. The weather in the winter is not predictable. For example, if the winter is warm or short, or the RSV infection was not severe enough when we conducted our trial, or the length of stay in the hospital at the year that trial was conducted was different from previous seasons, then we might miss the season or the results can be significantly different between two seasons or between different countries or even between different sites.

We are working on PPHN which is a highly competitive market and certification or regulatory approval may not be easily obtained.

A delivery system with a generator of NO has never been approved anywhere in the world and this may cause significant delays in the approval process.

Clinical trials may be necessary to support future product submissions to the FDA. The clinical trial process is lengthy and expensive with uncertain outcomes, and often requires the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials will prevent us from commercializing any modified or new products and will adversely affect our business, operating results and prospects.

Initiating and completing clinical trials necessary to support any future PMAs, and additional safety and efficacy data beyond that typically required for a 510(k) clearance, for our possible future product candidates, will be time-consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials. The results of preclinical studies and clinical trials of our products conducted to date and ongoing or future studies and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials. Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

The initiation and completion of any of clinical studies may be prevented, delayed, or halted for numerous reasons. We may experience delays in our ongoing clinical trials for a number of reasons, which could adversely affect the costs, timing or successful completion of our clinical trials, including related to the following:

- we may be required to submit an IDE application to the FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and the FDA may reject our IDE application and notify us that we may not begin clinical trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators and/or an IRB, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;

- our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- we might have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;

- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;

- regulators, IRBs, or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;

- the cost of clinical trials may be greater than we anticipate;

- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;

- we may be unable to recruit a sufficient number of clinical trial sites;

- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;

- approval policies or regulations of the FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval;

- our current or future products may have undesirable side effects or other unexpected characteristics; and

- impacts of regional or global public health crises including the ongoing COVID-19 pandemic could adversely affect any clinical trials we are conducting or plan to conduct, including delays or difficulties in enrolling or onboarding patients, initiating clinical sites, or obtaining the requisite certification or regulatory approvals, interruption of key clinical trial activities, or supply chain disruptions that delay or make it more difficult or costly to obtain the supplies and materials we need for clinical trials.

Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of certification or regulatory approval of our product candidates.

Clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. Conducting successful clinical studies will require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators, support staff, and proximity of patients to clinical sites and able to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts.

We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with GCP requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval. Further, the FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays in the approval and attempted commercialization of our products or result in the failure of the clinical trial. In addition, despite considerable time and expense invested in our clinical trials, the FDA may not consider our data adequate to demonstrate safety and efficacy. Such increased costs and delays or failures could adversely affect our business, operating results and prospects.

Even if our products are approved or cleared in the United States and CE marked in the EEA, comparable regulatory authorities of additional foreign countries must also approve the manufacturing and marketing of our products in those countries. Approval and clearance procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States or the EEA, including additional preclinical studies or clinical trials. Any of these occurrences may harm our business, financial condition and prospects significantly.

In the EEA, we consider that our products would be classified as a medical device. However, competent regulatory authorities in EEA countries or notified bodies could disagree and consider our products to be a drug-delivery combination product composed of a medical device and a medicinal product. In the EEA, a drug-delivery systems can fall within the scope of the medical device legislation or the pharmaceutical legislation depending on their combination with the relevant medicinal substance.

If our device is considered as being intended to administer a medicinal product and our device and the medicinal product are placed on the market in such a way that they form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single integral product shall be governed by Directive 2001/83/EC and be subject to a marketing authorization. The medical device part of the drug-delivery combination product would not need to be CE marked. However, the relevant general safety and performance requirements set out in Annex I to the EU MDR would apply as far as the safety and performance of the device part of the single integral product are concerned. As a result, we would need to pursue a different regulatory pathways for placing our product on the EEA market which may lead to additional costs and time.

We may find it difficult to enroll patients in our clinical studies. Difficulty in enrolling patients could delay or prevent clinical studies of our product candidates.

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends in part on the speed at which we can recruit patients to participate in testing our product candidates, and we may experience delays in our clinical studies if we encounter difficulties in enrollment.

Some of the conditions for which we plan to evaluate our current product candidates are for rare diseases. For example, we estimate that 15,000 patients suffer from refractory NTM lung infection in the U.S. Accordingly, there is a limited patient pool from which to draw for clinical studies. Further, the eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study.

Additionally, the process of finding patients may prove costly. We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidate under study, particularly the toxicity of NO in certain doses, the availability and efficacy of competing therapies and clinical studies, the proximity and availability of clinical study sites for prospective patients and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining certification or regulatory approval of potential products will be delayed.

If we experience delays in the completion or termination of any clinical study of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented. In addition, any delays in completing our clinical studies will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of certification or regulatory approval of our product candidates.

We may encounter substantial delays in our clinical studies, or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, time consuming and uncertain as to outcome. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. Our clinical studies involve infants, children, and adults and, before we are permitted to enroll them in clinical trials, we must demonstrate that although the research may pose a risk to the subjects, there is a prospect of direct benefit to each patient. We must do so to the satisfaction of each research site's IRB. If we fail to adequately demonstrate this to the satisfaction of the relevant IRB, it will decline to approve the research, which could have significant adverse consequences for the Company.

A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of human clinical studies;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;

- delays in obtaining required IRB approval at each clinical study site;
- imposition of a clinical hold by regulatory agencies, after review of an IDE application, or equivalent application, or an inspection of our clinical study operations or study sites;
- delays in recruiting suitable patients to participate in our clinical studies;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's GPC requirements, or applicable regulatory guidelines in other countries;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in us deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs; and
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. We may also be required to conduct additional safety, efficacy and comparability studies before we will be allowed to start clinical studies. Clinical study delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their certification or regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive marketing label or the delay or denial of certification or regulatory approval by the FDA or other comparable foreign authorities. There is currently limited data regarding possible side effects for an antimicrobial dosage of NO treatments, such as our product candidates. Potential side effects of NO treatments may include high MetHb, NO_2 toxicity, nose bleeding and low blood pressure. Results of our studies may identify unacceptable severity and prevalence of these or other side effects. In such an event, our studies could be suspended or terminated, and the FDA or comparable foreign regulatory authorities or notified bodies could order us to cease further development of or deny approval of our product candidates for any or all targeted indications.

NO-related side effects could affect patient recruitment, the ability of enrolled patients to complete the study or result in potential product liability claims

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Even if we obtain certification or regulatory approval for our product candidates, we will still face extensive, ongoing regulatory requirements and review, and our products may face future development and regulatory difficulties.

The holder of an approved PMA or cleared 510(k) also is subject to obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the marketing application. Application holders must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling, or manufacturing process. Legal requirements have also been enacted to require disclosure of clinical trial results on publicly available databases.

In addition, manufacturers of FDA regulated products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with the FDA's QSR and, as applicable, cGMP regulations. Our relationships with healthcare providers, physicians and third-party payors must comply with FDA laws and regulations, the AKS, the FCA, HIPAA, various transparency laws, and similar state and foreign laws. GMPs regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Healthcare Act of 1992. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration and to low income patients of certain hospitals, additional laws and requirements apply. Our activities are also potentially subject to federal and state consumer protection and unfair competition laws. If we or our third-party collaborators fail to comply with applicable regulatory requirements, a regulatory agency may take any of the following actions:

- conduct an investigation into our practices and any alleged violation of law;
- issue warning letters or untitled letters asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw certification or regulatory approval;
- require that we suspend or terminate any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall; or
- exclude us from providing our products to those participating in government health care programs, such as Medicare and Medicaid, and refuse to allow us to enter into supply contracts, including government contracts.

The occurrence of any of the foregoing events or penalties may force us to expend significant amounts of time and money and may significantly inhibit our ability to bring to market or continue to market our products and generate revenue. Similar regulations apply in foreign jurisdictions.

Risks Related to our Reliance on Third Parties

We rely on third parties to conduct our preclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain certification or regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical and clinical studies, and we directly control only certain aspects of their activities, although from a regulatory perspective we are responsible for their actions. We are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with GCP, QSR and GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area ("EEA"), and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, study sites and other contractors. If we or any of our CROs or vendors fail to comply with applicable regulations, the clinical data generated in our clinical studies may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical studies before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical studies comply with GCP regulations. In addition, our clinical studies must be conducted with products that are produced under QSR regulations. Our failure to comply with these regulations may require us to repeat clinical studies, which would delay the certification or regulatory approval process, or have other adverse consequences.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical studies may be extended, delayed or terminated and we may not be able to obtain certification or regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a consequence, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which could materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We will rely on third parties to manufacture our NO generator and delivery system. Our business could be harmed if those third parties fail to provide us with sufficient quantities of our needed supplies, or fail to do so at acceptable quality levels or prices.

We do not currently have the infrastructure or capability internally to manufacture the components of our NO generator and delivery system, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We plan to rely on third parties for such supplies. There are a limited number of manufacturers who have the ability to produce our delivery system, and there may be a need to identify alternate manufacturers to prevent a possible disruption of our clinical studies. Any significant delay or discontinuity in the supply of these components could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates, which could harm our business and results of operations.

We and our collaborators and contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and have limited capacity.

All entities involved in the preparation of medical devices for clinical studies or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished medical device product approved for commercial sale or used in late-stage clinical studies must be manufactured in accordance with QSR. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We, our collaborators or our contract manufacturers must supply all necessary documentation in support of any marketing application on a timely basis and must adhere to GLP and QSR regulations enforced by the FDA and other regulatory agencies through their facilities inspection program. The facilities and quality systems of some or all of our collaborators and third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our collaborators and third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical study or commercial sales, or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. If we, our collaborators, or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA or other applicable regulatory authorities can impose regulatory sanctions including, among other things, refuse to approve a pending application for a new drug product, withdrawal of an approval, suspend production, suspend clinical studies, require a recall or suspension of production. As a result, our business, financial condition and results of operations may be materially harmed.

Additionally, if supply from one approved manufacturer is interrupted, an alternative manufacturer would need to be qualified through a PMA Supplement or Marketing Authorization Application amendment, or equivalent foreign regulatory filing, which could result in further delays. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical studies, regulatory submissions, required approvals or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical studies may be delayed or we could lose potential revenue.

If we encounter issues with our contract manufacturers or suppliers, we may need to qualify alternative manufacturers or suppliers, which could impair our ability to sufficiently and timely manufacture and supply LungFit® PH.

We currently depend on contract manufacturers and suppliers for LungFit® PH and its components. Although we could obtain each of these components from other third-party suppliers, we would need to qualify and obtain FDA approval for another contract manufacturer or supplier as an alternative source for each such component, which could be costly and cause significant delays. Each of our current commercial manufacturing and supply agreements include limitations on our ability to utilize alternative manufacturers or suppliers for these components above certain specified thresholds during the terms of the agreements, which impairs our ability to fully implement any future manufacturing strategies to prevent supply shortages or quality issues.

In addition, some of our suppliers and contract manufacturers, including Spartronics and Medisize conduct their manufacturing operations for us at a single facility. Unless and until we qualify additional facilities, we may face limitations in our ability to respond to manufacturing and supply issues. For example, if regulatory, manufacturing or other problems require one of these manufacturers or suppliers to discontinue production at their respective facility, or if the equipment used for the production of LungFit® PH in these facilities is significantly damaged or destroyed by fire, flood, earthquake, power loss or similar events, the ability of such manufacturer or supplier to provide components needed for LungFit® PH, or to manufacture LungFit® PH may be significantly impaired. In the event that these parties suffer a temporary or protracted loss of its facility or equipment, we would still be required to obtain FDA approval to qualify a new manufacturer or supplier, as applicable, as an alternate manufacturer or source for the respective component before any components manufactured by such manufacturer or by such supplier could be sold or used.

Any production shortfall that impairs the supply of LungFit® PH or any of these components could have a material adverse effect on our business, financial condition and results of operations and adversely affect our ability to satisfy demand for LungFit® PH, which could adversely affect our product sales and operating results materially.

We depend on third-party manufacturers, including sole source suppliers, to manufacture LungFit® PH and our product candidates and the materials we require for our clinical trials. We may not be able to maintain these relationships and could experience supply disruptions outside of our control.

We rely on a network of third-party manufacturers to manufacture and supply LungFit® PH for commercial sale and post-approval clinical trials, and our drug candidates for clinical trials and any commercial sales if they are approved. As a result of our reliance on these third-party manufacturers and suppliers, including sole source suppliers of certain components of LungFit® PH and our product candidates, we could be subject to significant supply disruptions. Our supply chain for sourcing raw materials and manufacturing drug product ready for distribution is a multi-step endeavor. Third-party contract manufacturers supply us with raw materials, and contract manufacturers in the United States convert these raw materials into drug substance and convert the drug substance into final dosage form. Establishing and managing this supply chain requires a significant financial commitment and the creation and maintenance of numerous third-party contractual relationships. Although we attempt to effectively manage the business relationships with companies in our supply chain, we do not have control over their operations.

We require a supply of LungFit® PH for sale in the United States, and we will require a supply of LungFit® PH for sale in international markets if we obtain marketing approvals outside of the United States. We currently rely, and expect to continue to rely, on sole source third-party manufacturers to produce starting materials, drug substance, and final drug product, and to package and label LungFit® PH and our product candidates. While we have identified and expect to qualify and engage back-up third party manufacturers as additional or alternative suppliers for the commercial supply of LungFit® PH, we currently do not have such arrangements in place. Moreover, some of these alternative manufacturers will have to be approved by the FDA before we can use them for manufacturing LungFit® ® PH. It is also possible that supplies of materials that cannot be second-sourced can be managed with inventory planning. There can be no assurance, however, that failure of any of our original sole source third party manufacturers to meet our commercial demands for LungFit® PH in a timely manner, or our failure to engage qualified additional or back-up suppliers for the commercial supply of LungFit® PH, would not have a material adverse effect on commercialization of LungFit™ and our business.

Supply disruptions may result from a number of factors, including shortages in product raw materials, labor or technical difficulties, regulatory inspections or restrictions, shipping or customs delays or any other performance failure by any third-party manufacturer on which we rely. Any supply disruptions could disrupt sales of LungFit® PH and/or the timing of our clinical trials, which could have a material adverse impact on our business. Furthermore, we may be required to modify our production methods to permit us to economically manufacture our drugs for sale and our drug candidates for clinical trials. These modifications may require us to re-evaluate our resources and the resources of our third-party manufacturers, which could result in abrupt changes in our production methods and supplies.

In the course of providing its services, a contract manufacturer may develop process technology related to the manufacture of our products or drug candidates that the manufacturer owns, either independently or jointly with us. This would increase our reliance on that manufacturer or require us to obtain a license from that manufacturer in order to have LungFit® PH or our drug candidates manufactured by other suppliers utilizing the same process.

The failure of our third party manufacturers to meet our commercial demands for LungFit® PH in a timely manner, or our failure to engage qualified additional or back-up suppliers for the commercial supply of LungFit® PH, would have a material adverse effect on our business, results of operations and financial position.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

Risks Related to Commercialization of Our Product Candidates

If the market opportunities for our product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

Our projections of both the number of people who have our target diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

We face intense competition and rapid technological change and the possibility that our competitors may discover, develop or commercialize therapies that are similar, more advanced or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our product candidates.

The biotechnology, pharmaceutical and medical device industries are highly competitive. There are many pharmaceutical companies, biotechnology companies, medical device companies, public and private universities and research organizations actively engaged in the research and development of products that may be similar to our product candidates. We are aware of several companies currently developing and selling NO therapies for various indications such as pulmonary hypertension. For example, Mallinckrodt commercializes INOMAX® (nitric oxide) for inhalation, which is approved for use to treat newborns suffering from HRF-PPHN, in the U.S., Canada, Australia, Mexico and Japan. Praxair markets a generic version of the Mallinckrodt offering with their delivery system called NOxBOX®, acquired from Bedfont, in the United States. The Linde Group has marketing rights to INOMAX® in Europe. Air Liquide sells a similar product in Europe, called VasoKINOX™, together with their delivery platform called OptiKINOX™, for the treatment of pulmonary hypertension that occurs during or after heart surgery. In Europe, Bedfont Scientific Ltd. has a delivery system called NOxBOX® and Air Products PLC has a gas product called NOXAP®, each used in delivering inhaled NO formulations. Bellerophon Therapeutics is developing NO-based products for pulmonary arterial hypertension and pulmonary hypertension associated with chronic obstructive pulmonary disease. VERO Biotech LLC (formerly known as Geno LLC) received FDA approval for their delivery system GENOSYL DS for PPHN in 2019. In addition, other companies may be developing generic NO formulation delivery systems for various dosages. Ceretec, Inc., a company affiliated with 12th Man Technologies Inc., recently obtained clearance from the FDA to market a NO gas product for use in membrane diffusing capacity testing in pulmonary function laboratories in the U.S. Novoteris, LLC previously received orphan drug designation from the FDA and the European Medicines Agency ("EMA") for the use of inhaled NO-based treatments in treating CF.

In addition to NO treatments currently available or under development, we also face competition from non-NO-based drugs and therapies. For example, the successful development of immunizations for bronchiolitis may render useless any product we develop for that indication. Also, antibiotic treatments for infections associated with CF and other underlying lung conditions may be preferred over any product that we develop. Even if we successfully develop our product candidates, and obtain approval for them, other treatments may be preferred and we may not be successful in commercializing our product candidates.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the medical device, biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain certification or regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop, or achieve earlier patent protection, certification or regulatory approval, product commercialization and market penetration than we do. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

We currently have a limited marketing and sales organization. If we are unable to fully establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

Although our employees may have sold other similar products in the past while employed at other companies, we as a company have no experience selling and marketing our product candidates and we currently have a limited marketing or sales organization. To successfully commercialize any products that may result from our development programs, we will need to further develop these capabilities, either on our own or with others. If our product candidates receive certification or regulatory approval, we intend to establish a more complete sales and marketing organization with technical expertise to commercialize our product candidates in the United States, which will be expensive, difficult and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products.

Further, given our lack of prior experience in marketing and selling medical device products, our initial estimate of the size of the required sales force may be materially more or less than the size of the sales force actually required to effectively commercialize our product candidates. As such, we may be required to hire substantially more sales representatives to adequately support the commercialization of our product candidates, or we may incur excess costs as a result of hiring more sales representatives than necessary. With respect to certain geographical markets, we may enter into collaborations with other entities to utilize their local marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If our future collaborators do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We may be competing with companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of our product candidates will depend in part on the medical community, patients and third-party payors accepting our product candidates as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the safety and efficacy of the product as demonstrated in clinical studies and potential advantages over competing treatments;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the clinical indications for which approval is granted;
- relative convenience and ease of administration;
- the cost of treatment, particularly in relation to competing treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage and reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical and clinical studies, market acceptance of the product will not be fully known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the product candidates may require significant resources and may never be successful. If our product candidates are approved but fail to achieve an adequate level of acceptance by physicians, patients, third-party payors and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The pricing, coverage and reimbursement of our product candidates, if approved, must be adequate to support our commercial infrastructure. Our per-patient prices must be sufficient to recover our development and manufacturing costs and potentially achieve profitability. Accordingly, the availability and adequacy of coverage and reimbursement by governmental and private payors are essential for most patients to be able to afford expensive treatments such as ours, assuming approval. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government authorities, private health insurers and other third-party payors. If coverage and reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the U.S., the principal decisions about coverage and reimbursement for new medical devices are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new device will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for products such as ours.

Outside the U.S., international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medical devices under such systems are substantially lower than in the U.S. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the U.S., the reimbursement for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the U.S. and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Cybersecurity risks and the failure to maintain the confidentiality, integrity, and availability of our computer hardware, software, and Internet applications and related tools and functions could result in harm to our business and/or subject us to costs, fines or lawsuits.

We rely on sophisticated information technology systems and network infrastructure to operate and manage our business. We also maintain personally identifiable information (PII) about our employees, and given the nature of our business, we have access to protected health information (PHI). Our business therefore depends on the continuous, effective, reliable, and secure operation of our computer hardware, software, networks, Internet servers, and related infrastructure. To the extent that our hardware or software malfunctions or access to our data by internal personnel, suppliers or customers through the Internet is interrupted or compromised, our business could suffer.

The integrity and protection of our customer, personnel, financial, research and development, and other confidential data is critical to our business, and our customers and employees have a high expectation that we will adequately protect their personal information. The regulatory environment governing information, security and privacy laws is increasingly demanding and continues to evolve and a number of states have adopted laws and regulations that may affect our privacy and data security practices regarding the use, disclosure and protection of PII. For example, California recently enacted legislation, the California Consumer Privacy Act, that, among other things, creates new individual privacy rights and imposes increased obligations on companies handling PII.

Although our computer and communications hardware is protected through physical and software safeguards, it is still vulnerable to system malfunction, computer viruses, malware and ransomware, and other cybersecurity threats such as phishing and social engineering attacks. These events could lead to the unauthorized access of our information technology systems and result in financial loss and the misappropriation or unauthorized disclosure of confidential information belonging to us, our employees, partners, customers, or our suppliers. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. If our information technology systems are compromised, we could be subject to fines, damages, litigation and enforcement actions, incur financial losses, suffer reputational damage, and lose trade secrets or other confidential information, each of which could significantly harm our business.

Healthcare legislative or regulatory reform measures, including government restrictions on pricing and reimbursement, may have a negative impact on our business and results of operations.

In the U.S., there have been and continue to be a number of legislative and regulatory changes and proposed changes to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act ("ACA") was enacted, which, among other things, substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. medical device industry. Some of the provisions of the ACA have been subject to judicial challenges as well as efforts to repeal, replace, or otherwise modify them or alter their interpretation or implementation. For example, the Tax Cuts and Jobs Act of 2017 ("Tax Act"), includes a provision that eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, commonly referred to as the "individual mandate," effective January 1, 2019. Currently, the Supreme Court is considering whether the ACA's individual mandate, post-repeal of its associated tax penalty, is unconstitutional, and, if so, whether the remaining provisions of the ACA are inseverable from the mandate. A ruling is expected by mid-2021 and could produce any of a number of results, including invalidation of the ACA in its entirety if there is a finding of inseverability. It is unclear how the ultimate decision in this case, or other efforts to repeal, replace or otherwise modify, or invalidate, the ACA or its implementing regulations, or portions thereof, will affect our business. Additional legislative changes, regulatory changes and judicial challenges related to the ACA remain possible. We cannot predict what effect further changes related to the ACA, including under the Biden administration, would have on our business.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the now-departed Trump administration proposed numerous prescription drug cost control measures. Similarly, the new Biden administration has made lowering prescription drug and medical device prices one of its priorities. The Biden administration has not yet proposed any specific plans, but we expect that these will be forthcoming in the near term. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Other examples of proposed changes include, but are not limited to, expanding post-approval requirements, changing the Orphan Drug Act, and restricting sales and promotional activities for pharmaceutical products.

We cannot be sure whether additional legislative changes will be enacted, or whether government regulations, guidance or interpretations will be changed, or what the impact of such changes would be on the marketing approvals, sales, pricing, or reimbursement of our drug candidates or products, if any, may be. We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

We are subject to additional federal and state laws and regulations relating to our business, and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

We are subject to additional health care regulation and enforcement by the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include the following:

- the federal health care program Anti-Kickback Statute, prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, or order or arranging for the purchase, lease or order of any good or service, for which payment may be made, in whole or in part, under federal health care programs such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical or device manufacturers, on the one hand, and prescribers, purchasers and formulary managers and others on the other. The term "remuneration" has been broadly interpreted to apply to anything of value including, for example, gifts, cash payments, donations, waivers of payment, ownership interests, and providing any item, service, or compensation for something other than fair market value. Liability under the AKS may be established without proving actual knowledge of the statute or specific intent to violate it. Although there are a number of statutory exceptions and regulatory safe harbors to the AKS protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration to those who prescribe, purchase, or recommend medical device products, including certain discounts, or engaging such individuals as consultants, advisors and speakers, may be subject to scrutiny if they do not fit squarely within an exception or safe harbor. Moreover, there are no safe harbors for many common practices, such as educational grants and reimbursement support programs;

- the federal civil False Claims Act that prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent, claims for payment of government funds, knowingly making, using or causing to be made or used a false statement or record material to an obligation to pay money to the government, or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. A claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA. Actions under the FCA may be

brought by the government or as a qui tam action by a private individual in the name of the government, who may also share in any monetary recovery. Qui tam actions are filed under seal and impose a mandatory duty on the U.S. Department of Justice to investigate such allegations. Manufacturers have faced liability under the FCA for providing inaccurate billing or coding information to customers or promoting a product off-label. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false or fraudulent claim or statement for violations, as well as exclusion from participation in federal healthcare programs;

- HIPA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement or representation, or using any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items, or services;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided (in 2021) to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers. Several states have enacted legislation requiring medical device manufacturers to, among other things, establish marketing compliance programs; file periodic reports with the state, including reports on gifts and payments to individual health care providers; and/or register their sales representatives. Some states prohibit certain sales and marketing practices, including the provision of gifts, meals, or other items to health care providers.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The scope and enforcement of these laws is uncertain and subject to change in the current environment of health care reform. We cannot predict the impact on our business of any changes in these laws. Federal or state regulatory authorities may challenge our current or future activities under these laws. Any such challenge, even if we are able to successfully defend against it, could have a material adverse effect on our reputation, business, results of operations, and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The use of any of our products could result in product liability or similar claims that could be expensive, damage our reputation and harm our business.

Our business exposes us to an inherent risk of potential product liability or similar claims. The medical device industry has historically been litigious, and we face financial exposure to product liability or similar claims if the use of any of our products were to cause or contribute to injury or death. There is also the possibility that defects in the design or manufacture of any of our products might necessitate a product recall. Although we plan to maintain product liability insurance, the coverage limits of these policies may not be adequate to cover future claims. In the future, we may be unable to maintain product liability insurance on acceptable terms or at reasonable costs and such insurance may not provide us with adequate coverage against potential liabilities. A product liability claim, regardless of merit or ultimate outcome, or any product recall could result in substantial costs to us, damage to our reputation, customer dissatisfaction and frustration and a substantial diversion of management attention. A successful claim brought against us in excess of, or outside of, our insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

If we fail to comply with applicable privacy, data protection and data security laws and regulations, we could face substantial penalties, liability and adverse publicity and our business, operations and financial condition could be adversely affected.

We are subject to various laws and regulations globally regarding privacy and data protection, including laws and regulations relating to the collection, storage, handling, use, disclosure, transfer and security of personal data. The restrictions under applicable privacy, data protection and data security laws and regulations that may affect our ability to operate include but are not limited to:

- HIPAA governs the use, disclosure, and security of protected health information by HIPAA "covered entities" and their "business associates." Covered entities are health plans, health care clearinghouses and health care providers that engage in specific types of electronic transactions. A business associate is any person or entity (other than members of a covered entity's workforce) that performs a service on behalf of a covered entity involving the use or disclosure of protected health information. Most healthcare providers who prescribe our products and from whom we obtain patient health information are subject to privacy and security requirements under HIPAA, as are we in certain circumstances. HHS (through the Office for Civil Rights) has direct enforcement authority against covered entities and business associates with regard to compliance with HIPAA regulations. We also could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting and/or conspiring to commit a violation of HIPAA. We are unable to predict whether our actions could be subject to prosecution in the event of an impermissible disclosure of health information to us;
- numerous U.S. federal and state laws and regulations, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure and protection of personal information. These laws may impose a number of compliance obligations on us, including requiring that we obtain consent before we collect, use, or disclose personal information, implement certain security protections to safeguard personal information, and notify individuals or regulators in the event of a breach;
- other countries also have, or are developing, laws governing the collection, use, disclosure and protection of personal information. The GDPR, for example, is an EU-wide regulation that imposes restrictions on the processing (e.g., collection, use, disclosure) of personal data and that also imposes strict restrictions on the transfer of personal data out of the EU to the US; and
- the legislative and regulatory landscape for privacy and data security continues to evolve, and there has been an increasing amount of focus on privacy and data security issues with the potential to affect our business. For example, the CCPA contains new disclosure obligations for businesses that collect personal information about California residents and affords those individuals new rights relating to their personal information that may affect our ability to use personal information. Other states, including Virginia, and the federal government, have considered and/or enacted similar privacy laws that could impose new obligations or limitations in areas affecting our business.

These privacy and data security laws and regulations could increase our cost of doing business, and failure to comply with these laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could materially and negatively affect our operating results and business. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws and regulations, the risks cannot be entirely eliminated. Any action against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal, state, and foreign privacy and data security laws and regulations may prove costly.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain effective patent rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our and our licensors' ability to obtain and maintain intellectual property protection in the U.S. and in other countries with respect to our proprietary technology and products.

We have sought to protect our proprietary position by filing patent applications in the U.S. and abroad related to our novel technologies and products that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of medical device, biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the U.S. or in other foreign countries. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, found unenforceable or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We have filed several patent applications directed to various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in certification or regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. In addition, some or all of our patent applications may not result in issued patents.

If we cannot obtain and maintain effective patent rights for our product candidates, we may not be able to compete effectively and our business and results of operations would be harmed.

Intellectual property rights of third parties could adversely affect our ability to commercialize our product candidates, and we might be required to litigate or obtain licenses from third parties in order to develop or market our product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

Given the number of companies developing various types of NO devices, it is difficult to conclusively assess our freedom to operate without infringing on third party rights. There are numerous companies that have pending patent applications and issued patents in the field of therapeutic NO delivery. Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our products or elements thereof, or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize products or our product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may be pending patent applications of which we are not aware, that if they result in issued patents, could be alleged to be infringed by our product candidates. If such an infringement claim should be brought and be successful, we may be required to pay substantial damages, be forced to abandon our product candidates or seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

It is also possible that we have failed to identify relevant third-party patents or applications. Patent applications in the U.S. and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidate or platform technology could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our product candidate or the use of our product candidate. Third party intellectual property right holders may also actively bring infringement claims against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in pursuing the development of and/or marketing our product candidate. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing our product candidate that is held to be infringing. We might, if possible, also be forced to redesign our product candidate so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Patent terms are limited and we may not be able to effectively protect our products and business.

Patents have a limited lifespan. In the U.S., the natural expiration of a patent is generally 20 years after it is filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited.

In addition, upon issuance in the U.S., the patent term may be extended based on certain delays caused by the applicant(s) or the U.S. Patent and Trademark Office ("USPTO"). Even if we obtain effective patent rights for our product candidates, we may not have sufficient patent terms or regulatory exclusivity to protect our products, and our business and results of operations would be adversely affected.

Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that we or our licensor were the first to make the invention claimed in our owned and licensed patents or pending applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming the other requirements for patentability are met, in the U.S. prior to March 15, 2013, the first to invent the claimed invention is entitled to the patent, while outside the U.S., the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act ("Leahy-Smith Act"), enacted on September 16, 2011, the U.S. has moved to a first to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the USPTO must still implement various regulations, the courts have yet to address these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

If we are unable to maintain effective proprietary rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

All of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology enter into confidentiality agreements and we expect they will assign all rights in their inventions to us pursuant to the terms of such agreements; however, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including with respect to NO delivery systems and formulations, including patent infringement lawsuits, interferences, oppositions and reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. We do not know whether there are any third-party patents that would impair our ability to commercialize these product candidates. We also cannot be sure that we have identified each and every patent and pending patent application in the U.S. and abroad that is relevant or necessary to the commercialization of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable.

Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently own and have in-licensed rights to intellectual property through licenses from third parties and under patents that we own, to develop our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and the rights to these formulations may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we sometimes collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development underwritten agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, we may have to abandon development of that program and our business and financial condition could suffer.

If we fail to comply with our obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are currently a party to intellectual property license agreements that are important to our business, and we may enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We may be involved in lawsuits or post-grant proceedings to protect or enforce our patents or the patents of our licensor, which could be expensive, time consuming and unsuccessful.

Competitors may infringe the patents of our licensor. If our licensing partner were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Pending patent applications may be subject to third-party pre-issuance submission of prior art to the USPTO, and any patents issuing thereon may become involved in derivation, reexamination, inter parties review, post grant review, interference proceedings or other patent office proceedings in the U.S. challenging our patent rights.

Proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensor. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development partnerships that would help us bring our product candidates to market.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in or right to compensation with respect to our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or claiming the right to compensation. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. To the extent that our employees have not effectively waived the right to compensation with respect to inventions that they helped create, they may be able to assert claims for compensation with respect to our future revenue may be successful. As a result, we may receive less revenue from future products if such claims are successful which in turn could impact our future profitability.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity. Therefore, obtaining and enforcing biotechnology patents is costly, time consuming and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S.

Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Our Business Operations

We manage our business through a small number of employees and key consultants.

As of March 31, 2021, we had a total of 41 full-time employees and a number of dedicated consultants, of whom work for us on a part-time basis. In addition, any of our employees and consultants may leave our company at any time, subject to certain notice periods. The loss of the services of any of our executive officers or any key employees or consultants would adversely affect our ability to execute our business plan and harm our operating results.

We do not currently carry “key person” insurance on the lives of members of management.

We will need to expand our organization and we may experience difficulties in recruiting needed additional employees and consultants, which could disrupt our operations.

As our development and commercialization plans and strategies develop and because we are so leanly staffed, we will need additional managerial, operational, sales, marketing, financial, legal and other resources. The competition for qualified personnel in the pharmaceutical life sciences field is intense. Due to this intense competition, we may be unable to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel.

Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the U.S., European Union or Israel.

Other than our operations that are located in the European Union and Israel (as further described below), we currently have limited international operations, but our business strategy incorporates potentially significant international expansion, particularly in anticipation of approval of our product candidates. We plan to maintain non-commercial infrastructure and conduct physician and patient association outreach activities, as well as clinical trials, outside of the U.S., European Union and Israel. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental certifications, approvals, permits and licenses;
- failure by us to obtain certification or regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits on our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- certain expenses including, among others, expenses for travel, translation and insurance; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the FCPA, its books and records provisions or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our results of operations.

We face business disruption and related risks resulting from the COVID-19 pandemic, which could have a material adverse effect on our business plan.

The development of our product candidates could be further disrupted and adversely affected by the ongoing COVID-19 pandemic. The spread of SARS CoV-2 resulted in the Director General of the World Health Organization declaring COVID-19 a pandemic on March 11, 2020. The Company has assessed the impact COVID-19 may have on the Company's business plans and its ability to conduct the preclinical studies and clinical trials as well as on the Company's reliance on third-party manufacturing and our supply chain. The Company experienced significant delays in the supply chain for LungFit® PH due to the redundancy in parts and suppliers with ventilator manufacturing which has since been remedied. However, there can be no assurance that the Company will be able to further avoid part or all of any impact from COVID-19 or its consequences. The extent to which the COVID-19 pandemic and global efforts to contain its spread may impact the Company's operations will depend on future developments.

We are dependent on information technology and our systems and infrastructure face certain risks, including from cybersecurity breaches and data leakage.

We rely to a large extent upon sophisticated information technology systems to operate our businesses, some of which are managed, hosted provided and/or used for third-parties or their vendors. We collect, store and transmit large amounts of confidential information (including personal information and pseudonymized information), and we deploy and operate an array of technical and procedural controls to maintain the confidentiality and integrity of such confidential information. A significant breakdown, invasion, corruption, destruction, interruption, or unavailability of critical information technology systems or infrastructure, by our workforce, others with authorized access to our systems or unauthorized persons could negatively impact operations. Hardware, software, or applications we develop or obtain from third parties may contain defects in design or manufacture or other supply chain problems that could unexpectedly compromise our information and network security.

The ever-increasing use and evolution of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our or our third-party providers' systems, portable media or storage devices. We could also experience a business interruption, theft of confidential information or reputational damage from industrial espionage attacks, malware or other cyber-attacks (including ransomware), which may compromise our system infrastructure or lead to data leakage, either internally or at our third-party providers. While we have invested in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. Any such interruption or breach of our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us. In addition, as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, with new and constantly changing requirements applicable to our business, compliance with those requirements could also result in additional costs.

Risks Related to the Ownership of our Common Stock

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for (A) any derivative action or proceeding brought on behalf of us; (B) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; (C) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our Amended and Restated Certificate of Incorporation or our Bylaws; or (D) any action asserting a claim against us governed by the internal affairs doctrine. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. In addition, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Securities Act or any other claim for which the federal and state courts have concurrent jurisdiction.

The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Recent trading in our common stock has been volatile and may continue to be volatile in the future.

The stock market in general has experienced extreme price and volume fluctuations. The market prices of the securities of biotechnology and specialty pharmaceutical companies, particularly companies like ours without product revenues and earnings, have been highly volatile and may continue to be highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies.

The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- announcements of technological innovations or new products by us or our competitors;
- announcement of FDA approval, disapproval or delay of approval of our product candidates or other product-related actions;
- developments involving our discovery efforts and clinical studies;

● developments or disputes concerning patents or proprietary rights, including announcements of infringement, interference or other litigation against us or our potential licensees;

● developments involving our efforts to commercialize our products, including developments impacting the timing of commercialization;

● announcements concerning our competitors, or the biotechnology, pharmaceutical or drug delivery industry in general;

● public concerns as to the safety or efficacy of our product candidates or our competitors' products;

● changes in government regulation of the pharmaceutical or medical industry;

● changes in the reimbursement policies of third party insurance companies or government agencies;

● actual or anticipated fluctuations in our operating results;

● changes in financial estimates or recommendations by securities analysts;

● developments involving corporate collaborators, if any;

● changes in accounting principles; and

● the loss of any of our key scientific or management personnel. In the past, securities class action litigation has often been brought against companies that experience volatility in the market price of their securities. Whether or not meritorious, litigation brought against us could result in substantial costs and a diversion of management's attention and resources, which could adversely affect our business, operating results and financial condition.

We cannot assure you that our stock price and volume will remain at current levels in which case investors may sustain large losses.

In addition, the stock market in general, and the stocks of small-cap biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in these "Risk Factors," could have a dramatic and material adverse impact on the market price of our common stock.

Antidilution provisions in certain of our outstanding warrants may affect the interests of our common stockholders.

The warrants we issued in our January 2017 and March 2017 financing transactions, or the 2017 Warrants, contain price protection provisions that could be triggered by our issuance of common stock in the future, if the offering price for any such future issuance is less than the then-applicable warrant exercise price. The 2017 Warrants had an original exercise price of $6.90 per share. As a result of our February 2018 financing transaction, we adjusted the exercise price down to $4.25 per share pursuant to the terms of the 2017 Warrants. As of result of the December 2019 equity offering, we adjusted the exercise price down to $3.66 per share pursuant to the terms of the 2017 Warrants. As June 7, 2021 there are 3,053,103 2017 warrants outstanding at a current exercise price of $3.66 per share.

On March 16, 2018, Empery Asset Master, Ltd., Empery Tax Efficient, LP and Empery Tax Efficient II, LP, (collectively, "Empery"), filed a complaint in the Supreme Court of the State of New York (the "NY Supreme Court"), relating to the notice of adjustment of both the exercise price of and the number of warrant shares issuable under warrants issued to Empery in January 2017 (the "Empery Suit"). The Empery Suit alleges that, as a result of certain circumstances in connection with our February 2018 offering, the 166,672 warrants issued to Empery in January 2017 provide for adjustments to both the exercise price of the warrants and the number of warrant shares issuable upon such exercise. Empery seeks monetary damages and declaratory relief under theories of breach of contract or contract reformation.

While we believe that we have complied with the applicable protective features of the 2017 Warrants and properly adjusted the exercise price, if Empery were to prevail on all claims, the new adjusted total number of warrant shares could be as follows: 319,967 warrant shares for Empery Asset Master, Ltd., 159,869 warrant shares for Empery Tax Efficient, LP and 252,672 warrant shares for Empery Tax Efficient II, LP, and the exercise price could be reduced from $3.66 to $1.57 per share. On March 9, 2020, we filed a motion for summary judgment, which was denied by order of the Ny Supreme Court entered on August 20, 2020, except for the second claim for relief for declaratory judgment which was dismissed as moot. On October 1, 2020, the Company filed a Notice of Appeal and appeal of the NY Supreme Court's denial of summary judgment remains pending. Trial of this matter was conducted from April 19, 2021 to April 21, 2021, and a decision was reserved pending post-trial briefing of various issues, to be fully submitted by June 30, 2021.

While we asserted at trial and continue to asset several meritorious defenses against the claims, the ultimate resolution of the matter, if unfavorable, could result in a material loss.

Anti-takeover provisions in our amended and restated certificate of incorporation and our amended and restated bylaws, as well as provisions of Delaware law, might discourage, delay or prevent a change in control of our company or changes in our Board of Directors or management and, therefore, depress the trading price of our common stock.

Our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law contain provisions that may depress the market price of our common stock by acting to discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove members of our Board of Directors or our management. Our corporate governance documents include provisions:

- providing that directors may be removed by stockholders with or without cause;
- limiting the ability of our stockholders to call and bring business before special meetings and to take action by written consent in lieu of a meeting;
- requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our Board of Directors;
- authorizing blank check preferred stock, which could be issued with voting, liquidation, dividend and other rights superior to our common stock; and
- limiting the liability of, and providing indemnification to, our directors and officers.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock from engaging in certain business combinations with us. Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

Risks Related to Employee Matters

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately, to disclose unauthorized activities to us or to comply with our code of business conduct and ethics. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, false claims, inappropriate promotion, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Employee litigation and unfavorable publicity could negatively affect our future business.

Our employees may, from time to time, bring lawsuits against us regarding injury, creating a hostile work place, discrimination, wage and hour disputes, sexual harassment, or other employment issues. In recent years there has been an increase in the number of discrimination and harassment claims generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these claims have had a significant negative impact on some businesses. Certain companies that have faced employment- or harassment-related lawsuits have had to terminate management or other key personnel, and have suffered reputational harm that has negatively impacted their business. If we were to face any employment-related claims, our business could be negatively affected.

Under applicable employment laws, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.

We generally enter into non-competition agreements with our employees and certain key consultants. These agreements prohibit our employees and certain key consultants, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period of time. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work and it may be difficult for us to restrict our competitors from benefitting from the expertise our former employees or consultants developed while working for us. For example, Israeli courts have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or the protection of its intellectual property. If we cannot demonstrate that such interests will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees or consultants and our ability to remain competitive may be diminished.

General Risk Factors

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our research, development candidates, investigational medicines, and the diseases our development candidates and investigational medicines are being developed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, subjects may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our development candidates and investigational medicines. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business.

Unfavorable U.S. or global economic conditions could adversely affect our business, financial condition, or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and financial markets, including by the current COVID-19 pandemic, or any other health epidemic. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the most recent global financial crisis, could result in a variety of risks to our business, including weakened demand for our investigational medicines and our ability to raise additional capital when needed on favorable terms, if at all. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third-party payors or our collaborators. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our executive office is located at 825 East Gate Boulevard, Suite 320, Garden City, New York 11530 under a lease that expires in June 2023. We also lease office space at 12 Eli Horovitz Street, Rehovot, 7414002 Israel and that lease expired on March 2021. The Company has a research and development facility in Madison, Wisconsin under a lease that expires on May 2026. We plan on moving to our executive office in July 2021 to 900 Stewart Avenue, Suite 310, Garden, City, NY 11530 under a lease that expires in June 2031.

ITEM 3. LEGAL PROCEEDINGS

On March 16, 2018, Empery, filed a complaint in the NY Supreme Court, relating to the notice of adjustment of both the exercise price of and the number of warrant shares issuable under warrants issued to Empery in January 2017. The Empery Suit alleges that, as a result of certain circumstances in connection with our February 2018 offering, the 166,672 warrants issued to Empery in January 2017 provide for adjustments to both the exercise price of the warrants and the number of warrant shares issuable upon such exercise. Empery seeks monetary damages and declaratory relief under theories of breach of contract or contract reformation.

While we believe that we have complied with the applicable protective features of the 2017 Warrants and properly adjusted the exercise price, if Empery were to prevail on all claims, the new adjusted total number of warrant shares could be as follows: 319,967 warrant shares for Empery Asset Master, Ltd., 159,869 warrant shares for Empery Tax Efficient, LP and 252,672 warrant shares for Empery Tax Efficient II, LP, and the exercise price could be reduced from $3.66 to $1.57 per share. On March 9, 2020, we filed a motion for summary judgment, which was denied by order of the NY Supreme Court entered on August 20, 2020, except for the second claim for relief for declaratory judgment which was dismissed as moot. On October 1, 2020, the Company filed a Notice of Appeal and appeal of the NY Supreme Court's denial of summary judgment remains pending. Trial of this matter was conducted from April 19, 2021 to April 21, 2021, and a decision was reserved pending post-trial briefing of various issues, to be fully submitted by June 30, 2021.

While we asserted at trial and continue to asset several meritorious defenses against the claims, the ultimate resolution of the matter, if unfavorable, could result in a material loss to us.

In addition to Empery, there are 1,139,220 2017 Warrants outstanding held by investors who did not participate in the February 2018 financing transaction. Any further adjustments to the 2017 Warrants pursuant to their antidilution provisions may result in additional dilution to our stockholders and may adversely affect the market price of our common stock. The antidilution provisions may also limit our ability to obtain additional financing on terms favorable to us.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock has been listed under the symbol "XAIR" on the Nasdaq Capital Market since May 7, 2019. From August 28, 2018 until May 6, 2019, our common stock was quoted on the OTC Pink.

Stockholders

As of June 7, 2021, there were approximately 102 holders of record for shares of our common stock. This does not reflect beneficial stockholders who held their common stock in "street" or nominee name through brokerage firms.

Securities Authorized for Issuance Under Equity Compensation Plans

Information regarding securities authorized for issuance under the Company's equity compensation plans is contained in Part III, Item 12 of this Annual Report.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future.

Unregistered Sales of Equity Securities

(a) Sales of Unregistered Securities

None.

(b) Use of Proceeds

None.

(c) Issuer Purchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

Not required for smaller reporting companies.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with "our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Item 1A "Risk Factors."

Introduction

We are a clinical-stage medical device and biopharmaceutical company developing the "LungFit® system, which is capable of generating NO from ambient air. The LungFit® platform can generate NO up to 400 parts per million ("ppm") for delivery to a patient's lungs directly or via a ventilator. LungFit® can deliver NO either continuously or for a fixed amount of time at various flow rates and has the ability to either titrate dose on demand or maintain a constant dose. We believe that LungFit® can be used to treat patients on ventilators that require NO, as well as patients with chronic or acute severe lung infections via delivery through a breathing mask or similar apparatus. Furthermore, we believe that there is a high unmet medical need for patients suffering from certain severe lung infections that the LungFit® platform can potentially address. Our current areas of focus with LungFit® is PPHN, AVP including COVID-19, BRO and NTM lung infection. Our current product candidates will be subject to premarket reviews and approvals by the FDA, as well as similar regulatory agencies in other countries or regions. If approved, our system will be marketed as a medical device in the United States.

On November 10, 2020, we submitted a PMA application to the FDA for the use of LungFit® PH in PPHN. There is a standard 180-day review process that starts upon FDA acknowledgement of submission, though due to the ongoing COVID-19 pandemic, we anticipate an FDA response towards the end of the third calendar quarter of calendar year 2021. We also expect to receive CE mark under the MDR in the European Union around the end of calendar year 2021. We also expect to make certain regulatory filings outside of the U.S. this year. If regulatory approvals are obtained, we anticipate a product launch in the U.S. in 2021 and globally in 2022

COVID-19

The development of our product candidates could be further disrupted and adversely affected by the ongoing COVID-19 pandemic. The spread of SARS CoV-2 resulted in the Director General of the World Health Organization declaring COVID-19 a pandemic on March 11, 2020. We have assessed the impact COVID-19 may have on our business plans and our ability to conduct the preclinical studies and clinical trials as well as on our reliance on third-party manufacturing and our supply chain. We experienced significant delays in the supply chain for LungFit® PH. Estimated clinical trial completion in NTM is delayed 9-12 months and trials in BRO are delayed from the fourth quarter calendar year 2020 to fourth quarter calendar year 2022. There can be no assurance that we will be able to further avoid part or all of any impact from COVID-19 or its consequences. The extent to which the COVID-19 pandemic and global efforts to contain its spread may impact our operations will depend on future developments.

Financial Operations Overview

Critical Accounting Estimates and Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses for the reporting period. Actual results could differ from those estimates. On an ongoing basis, we evaluate our significant estimates and assumptions including expense recognition and accrual assumptions under consulting and clinical trial agreements, stock-based compensation, impairment assessments, accounting for licensed rights to use technologies and other long-lived assets and the determination of valuation allowance requirements on deferred tax attributes.

Research and Development

Research and development expenses are charged to the statement of operations as incurred. Research and development expenses include salaries, benefits, stock-based compensation and costs incurred by outside laboratories, manufacturers, clinical research organizations, consultants, and accredited facilities in connection with clinical trials and preclinical studies. Research and development expenses are partially offset by the benefit of tax incentive payments for qualified research and development expenditures from the Australian tax authority ("AU Tax Rebates"). We do not record AU Tax Rebates until payment is received due to the uncertainty of receipt. To date, we have not received any AU Tax Rebates.

Stock-Based Compensation

We measure the cost of employee and non-employee services received in exchange for an award of equity instruments based on the grant date fair value of the award. Fair value for restricted stock awards is valued using the closing price of our common stock on the date of grant. The grant date fair value is recognized over the period during which an employee and non-employee is required to provide service in exchange for the award – the requisite service period. The grant date fair value of employee share options is estimated using the Black-Scholes option pricing model. The risk-free interest rate assumptions were based upon the observed interest rates appropriate for the expected term of the equity instruments. The expected dividend yield was assumed to be zero as we have not paid any dividends since our inception and do not anticipate paying dividends in the foreseeable future. Due to our limited trading history, we utilize an implied volatility based on an aggregate of guideline companies. In 2020, we began to incorporate and weight our historical volatility with our peer group in order to obtain expected volatility. The peer companies selected have similar characteristics, including industry and market capitalization. We routinely review our calculation of volatility based on our life cycle, our peer group, and other factors. We use the simplified method to estimate the expected term.

Licensed Right to Use Technology

Licensed right to use technology that is considered platform technology with alternative future uses is recorded as an intangible asset and is being amortized on a straight-line method over its estimated useful life, determined to be thirteen years.

Income Taxes

We account for income taxes using the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in the tax rate is recognized in income or expense in the period that the change is effective. Tax benefits are recognized when it is probable that the deduction will be sustained. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will either expire before we are able to realize the benefit, or that future deductibility is uncertain. As of March 31, 2021 and 2020, we recorded a valuation allowance to the full extent of our net deferred tax assets since the likelihood of realization of the benefit does not meet the more likely than not threshold.

We file U.S. Federal, various state, and International income tax returns. Uncertain tax positions are reviewed on an ongoing basis and are adjusted in light of changing facts and circumstances. Such adjustment is reflected in the tax provision when appropriate**.** We will recognize interest and penalties, if any, related to unrecognized tax benefits in income taxes in the statements of operations. Tax years 2017 through 2021 remain open to examination by federal and state tax jurisdictions. We file tax returns in Israel for which tax years 2015 through 2021 remain open. In addition, we file tax returns in Ireland and Australia and the tax year 2020 remains open.

COMMITMENTS AND CONTINGENCIES

License Agreements

On October 22, 2013, the Company entered into a patent license agreement (the "CareFusion Agreement") with SensorMedics Corporation, a subsidiary of CareFusion Corp. ("CareFusion"), pursuant to which the Company agreed to pay to CareFusion a non-refundable upfront fee of $150,000 that is credited against future royalty payments, and is obligated to pay 5% royalties of any licensed product net sales, but at least $50,000 per annum during the term of the agreement. As of March 31, 2021, the Company has not paid any royalties to CareFusion since the Company has not received any revenues from the technology associated with the license under the CareFusion Agreement. The term of the CareFusion Agreement extends through the life of applicable patents and may be terminated by either party with 60 days' prior written notice in the event of a breach of the CareFusion Agreement, and may be terminated unilaterally by CareFusion with 30 days' prior written notice in the event that the

In August 2015, BA Ltd. entered into the Option Agreement with Pulmonox whereby BA Ltd. acquired the option to purchase certain intellectual property assets and rights (the "Option") on September 7, 2016 for $25,000. On January 13, 2017, we exercised the Option and paid $500,000 to Pulmonox. We become obligated to make certain one-time development and sales milestone payments to Pulmonox, commencing with the date on which we receive regulatory approval for the commercial sale of the first product candidate qualifying under the Option Agreement. These milestone payments are capped at a total of $87 million across three separate and distinct indications that fall under the agreement, with the majority of them, approximately $83 million, being sales-related based on cumulative sales milestones for each of the three products.

On January 31, 2018, we entered into the NitricGen Agreement to acquire a global, exclusive, transferable license and associated assets including intellectual property, know-how, trade secrets and confidential information from NitricGen related to the LungFit® We acquired the licensing right to use the technology and agreed to pay NitricGen a total of $2 million in future payments based upon achieving certain milestones, as defined in the NitricGen Agreement, and royalties on sales of the LungFit® We paid NitricGen $100,000 upon the execution of the NitricGen Agreement, $100,000 upon achieving the next milestone and issued to NitricGen 100,000 warrants to purchase our common stock valued at $295,000 upon executing the NitricGen Agreement. The remaining future milestone payments are $1,800,000, of which $1,500,000 is due six months after the first approval of the LungFit® by the FDA or the EMA.

Contingencies

On March 16, 2018, Empery filed a complaint in NY Supreme Court, relating to the notice of adjustment of both the exercise price of and the number of warrant shares issuable under warrants issued to Empery in January 2017. The Empery Suit alleges that, as a result of certain circumstances in connection with our February 2018 offering, the 166,672 warrants issued to Empery in January 2017 provide for adjustments to both the exercise price of the warrants and the number of warrant shares issuable upon such exercise. Empery seeks monetary damages and declaratory relief under theories of breach of contract or contract reformation.

While the Company believes that it has complied with the applicable protective features of the 2017 Warrants and properly adjusted the exercise price, if Empery were to prevail on all claims, the new adjusted total number of warrant shares could be as follows: 319,967 warrant shares for Empery Asset Master, Ltd., 159,869 warrant shares for Empery Tax Efficient, LP and 252,672 warrant shares for Empery Tax Efficient II, LP, and the exercise price could be reduced from $3.66 to $1.57 per share. On March 9, 2020, we filed a motion for summary judgment, which was denied by order of the NY Supreme Court entered on August 20, 2020, except for the second claim for relief for declaratory judgment which was dismissed as moot. On October 1, 2020, we filed a Notice of Appeal and appeal of the NY Supreme Court's denial of summary judgment remains pending. Trial of this matter was conducted from April 19, 2021 to April 21, 2021, and decision was reserved pending post-trial briefing of various issues, to be fully submitted by June 30, 2021.

While we asserted at trial and continues to asset several meritorious defenses against the claims, the ultimate resolution of the matter, if unfavorable, could result in a material loss to us.

In addition to Empery, there are 1,139,220 2017 Warrants outstanding held by investors who did not participate in the February 2018 financing transaction. Any further adjustments to these 2017 Warrants pursuant to their antidilution provisions may result in additional dilution to the interests of our stockholders and may adversely affect the market price of our common stock. The antidilution provisions may also limit our ability to obtain additional financing on terms favorable to us.

On May 25, 2021, the Company and Circassia Limited entered into a Settlement Agreement resolving all claims by and between both parties and mutually terminating the Circassia agreement disclosed in Note 10. Pursuant to the terms of the Settlement Agreement, the Company agreed to pay Circassia $10.5 million in three installments, the first being a payment of $2,500,000 to on the Initial Payment Due Date. Thereafter, the Company shall pay $3.5 million to Circassia on the first anniversary of the Initial Payment Due Date and $4.5 million on the second anniversary of the Initial Payment Due Date. Additionally, beginning in year three post-approval, Circassia will receive a quarterly royalty payment equal to 5% of LungFit® PH net sales in the US. This royalty will terminate once the aggregate payment reaches $6 million. This product candidate continues to be under FDA review.

Results of Operations

	Year Ended March 31, 2021	Year Ended March 31, 2020
License revenue	$ 873,190	$ 1,390,104
Operating expenses		
Research and development	(12,618,349)	(10,648,920)
General and administrative	(10,468,341)	(8,883,119)
Loss from Operations	(22,213,500)	(18,141,935)
Other income (expense)		
Realized and unrealized loss from marketable securities	-	(2,075,602)
Dividend and interest income	16,901	115,716
Interest expense and financing expense	(641,626)	(30,543)
Foreign exchange loss (gain)	(36,506)	35,560
Total other loss	(661,231)	(1,954,869)
Net loss before income taxes	(22,874,731)	(20,096,804)
Benefit for income taxes	-	154,300
Net loss	$ (22,874,731)	$ (19,942,504)
Deemed dividend from warrant modification	-	(522,478)
Net loss attributed to common stockholder	$ (22,874,731)	$ (20,464,982)
Net loss per share – basic and diluted	$ (1.27)	$ (1.78)

Weighted average number of shares of common stock outstanding – basic and diluted	18,005,226	11,506,212

Comparison of the year ended March 31, 2021 to the year ended March 31, 2020

License Revenue

On January 23, 2019 we entered into the Circassia Agreement for PPHN and future related indications at concentrations of < 80 ppm in the hospital setting in the United States. License revenue for the year ended March 31, 2021 was $873,190 as compared to $1,390,104 for the year ended March 31, 2020. The decrease of $516,914 was primarily due to delays in the PMA process, thus more revenue was recognized during the year ended March 31, 2020. A greater percentage of cost to complete the performance obligation associated with license revenue was incurred during the year ended March 31, 2020. As of March 31, 2021, there was no performance obligation remaining. As of March 31, 2021 and 2020, deferred revenue was $0 and $873,190, respectively. On December 18, 2019, we terminated the Circassia Agreement pursuant to which we had granted Circassia an exclusive royalty-bearing license to distribute, market and sell our NO generator and delivery system in the United States and China. On May 25, 2021 we reached a settlement agreement with Circassia whereby we retain all rights to LungFit®.

Research and Development

Research and development for the year ended March 31, 2021 were $12,618,349, as compared to $10,648,920 for the year ended March 31, 2020. The increase of $1,969,429 was attributed primarily to an increase in the development of the LungFit® System for PPHN, an increase in pre-clinical studies initiation for NTM open-label clinical trial and acute viral pneumonia clinical trial. In addition, there was an increase in salaries and employee benefits and an increase in stock-based compensation. This was offset by the completion of animal toxicology studies.

General and Administrative Expenses

General and administrative expense for the year ended March 31, 2021 and 2020 were $10,468,341 and $8,883,119, respectively. The increase of $1,585,522 was attributed primarily to an increase in salaries and employee benefits and an increase of insurance expense.

Net Loss Attributed to Common Stockholders

Net loss attributed to common stockholders for the year ended March 31, 2021, was $22,874,731 or $1.27 per share, basic and diluted. As a result of the foregoing, our net loss attributed to common stockholders for the year ended March 31, 2020, was $20,464,982 or $1.78 per share, basic and diluted.

Liquidity and Capital Resources

We have not generated any revenue from the sale of products, and we do not expect to generate revenue from sale of our products until certification or regulatory approval is received for our product candidates. We had an operating cash flow decrease of $19.6 million for the year ended March 31, 2021 and we have experienced an accumulated loss of $80.5 million since inception through March 31, 2021. As of March 31, 2021, we had cash, cash equivalents and restricted cash of $35.3 million. We believe that our cash, cash equivalents and restricted cash as of March 31, 2021 will enable us to fund our operating expenses and capital expenditure requirements into the third fiscal quarter of 2022.

Our future capital needs and the adequacy of its available funds beyond one year from the date of filing these financial statements will depend on many factors, including, but not necessarily limited to, the cost and time necessary for the development, clinical studies and certification or regulatory approval of our other medical devices, indications as well as the commercial success of our first product candidates that receive marketing approval by the FDA. We may be required to raise additional funds through sale of equity or debt securities or through strategic collaborations and/or licensing agreements in order to fund operations until we are able to generate enough product or royalty revenues, if any. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could have a material adverse effect on our strategic objectives, results of operations and financial condition.

There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all.

On March 17, 2020, we entered into a facility agreement with certain lenders ("Facility Agreement") pursuant to which the lenders shall loan to up to $25,000,000 in five tranches of $5,000,000 per tranche at our option, provided however that we may only utilize tranches three through five following FDA approval of LungFit® PH. The loan(s) are unsecured with an interest rate of 10% per annum which is paid quarterly and may be prepaid with certain prepayment penalties. The effective interest rate for this loan is 13.3% per year. Each tranche shall be repaid in installments commencing June 15, 2023 with all remaining amounts outstanding under any tranche due on March 17, 2025. We drew down on the first tranche of $5,000,000.

On April 2, 2020, we entered an At-The-Market Equity Offering Sales Agreement with SunTrust Robinson Humphrey, Inc. and Oppenheimer & Co. (the "ATM"). Under the ATM, we may sell shares of our common stock having aggregate sales proceeds of up to $50 million, from time to time and at various prices. If shares of our common stock are sold, there is a three percent fee paid to the sales agent. As of March 31, 2021, there was a balance of approximately $38 million available under the ATM.

On May 14, 2020, we entered into a $40 million stock purchase agreement (the "New Stock Purchase Agreement") with Lincoln Park Capital Fund, LLC ("LPC"), which replaced the former $20 million purchase agreement with LPC, dated August 10, 2018. The New Stock Purchase Agreement provides for the issuance of up to $40 million of our common stock, which we may sell from time to time in our sole discretion, to LPC over the next 36 months, subject to the conditions and limitations in the New Stock Purchase Agreement. As of March 31, 2021, there was a balance of approximately $29.3 million available under the New Stock Purchase Agreement.

Our ability to continue to operate beyond twelve months from the filing of this Form 10-K will be largely dependent upon the approval of our PMA for the PPHN medical device, the expected timing and commercial acceptance of the launch this device, as well as obtaining partners in other parts of the world, and raising additional funds to finance our activities until we are generating cash flow from operations. Further, there are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of our other product candidates.

There are numerous risks and uncertainties associated with the development of our NO delivery system and we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates.

Our future capital requirements will depend on many factors, including:

- the effects of the COVID-19 pandemic on our business, the medical community and the global economy;
- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the costs of commercializing the LungFit® system, if approved;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the costs and timing of obtaining certification or regulatory approval for our product candidates;
- the costs of filing, prosecuting, enforcing and defending patent claims and other intellectual property rights;
- the costs of, and timing for, strengthening our manufacturing agreements for production of sufficient clinical quantities of our product candidate;
- the potential costs of contracting with third parties to provide marketing and distribution services for us or for building such capacities internally;
- the costs of acquiring or undertaking the development and commercialization efforts for additional, future therapeutic applications of our product candidate;
- the magnitude of our general and administrative expenses; and
- any cost that we may incur under current and future in-and out-licensing arrangements relating to our product candidate.

Cash Flows

Below is a summary of the statements of cash flows for the years ended March 31, 2021 and 2020.

	For The Year Ended March 31, 2021	For The Year Ended March 31, 2020
Net cash provided by (used in):		
Operating activities	$ (19,639,376)	$ (15,250,049)
Investing activities	$ (890,407)	$ 4,423,433
Financing activities	$ 30,332,379	$ 34,934,590
Net increase in cash, cash equivalents and restricted cash	$ 9,802,596	$ 24,107,974

Comparison between March 31, 2021 and March 31, 2020

For the year ended March 31, 2021, net cash used by operating activities was $19,639,376 which was primarily due to our net loss of $22,874,731, an increase in grant receivable, other current assets prepaid expenses, as well as a net decrease in accounts payable and deferred revenue of $2,784,107, partially offset by an increase in accrued expenses of $707,401 and non-cash expenses of $5,312,061. For the year ended March 31, 2020, net cash used by operating activities was $15,250,049 which was due primarily to our net loss of $19,942,504, a decrease in other current assets, prepaid expenses, accrued expenses and deferred revenue of $2,221,604 and was offset by an increase in unrealized and realized loss from the sale of marketable securities of $2,075,602 an increase in accounts payable of $1,091,557 and non-cash expense of $3,746,900.

Investing Activities

For the year ended March 31, 2021, cash used in investing activities was $890,407 which was from purchase of property and equipment. For the year ended March 31, 2020, cash provided by investing activities was $4,423,433 which was from the net proceeds from the sale of marketable securities of $4,467,064 and the purchase of property and equipment of $43,631.

Financing Activities

For the year ended March 31, 2021, net cash provided by financing activities was $30,332,379 which was primarily from the net proceeds from New Stock Purchase Agreement, the net proceeds from the ATM Equity Offering and from the exercise from the issuance of common stock for warrants and options. For the year ended March 31, 2020, net cash provided by financing activities was $34,934,590 which was primarily due to net proceeds from an underwritten offering, net proceeds from a private placement, net proceeds from the former $20 million purchase agreement with LPC, dated August 10, 2018, and from the net proceeds from the issuance of common stock from warrant exercises and options.

Contractual Obligations

The following tables sets forth our contractual obligations for the next five years and thereafter for the year ended March 31, 2021:

	2022	2023	2024	2025	2026	Thereafter	Total
Rent	$ 266,200	$ 328,400	$ 286,800	$ 277,500	$ 284,600	$ 1,328,600	$ 2,772,100
Long-term loan	-	-	2,000,000	3,000,000	-	-	5,000,000
Loan	556,500	-		-	-	-	556,500
Total	$ 822,700	$ 328,400	$ 2,286,800	$ 3,277,500	$ 284,600	$ 1,328,600	$ 8,328,600

ITEM 7A. Quantitative and Qualitative Disclosure about Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of foreign currency exchange rates.

Foreign Currency Exchange Risk

Our results of operations and cash flow are subject to fluctuations due to changes in foreign currency exchange rates. Certain of our expenses are denominated in New Israeli Shekels, or NIS, Euro and the Australian Dollar. Our results of operations and cash flow are, therefore, subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates. We do not hedge our foreign currency exchange risk. In the future, we may enter into formal currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from significant changes in such fluctuations.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements together with the report of our independent registered public accounting firm, required to be filed pursuant to this Item 8 are appended to this Annual Report. An index of those consolidated financial statements is found in Item 15 of this Annual Report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

We performed an evaluation of the effectiveness of our disclosure controls and procedures that are designed to ensure that information required to be disclosed in this Annual Report and filed with the SEC is recorded, processed, summarized and reported timely within the time period specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act, is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. There can be no assurance that our disclosure controls and procedures will detect or uncover all failures of persons within our company to disclose information otherwise required to be set forth in our reports. Nevertheless, our disclosure controls and procedures are designed to provide reasonable assurance of achieving the desired control objectives. Based on our evaluation, our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer) have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15(d)-15(e) of the Exchange Act) were effective at such reasonable assurance level as of March 31, 2021.

(b) Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, with the participation of our Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer), conducted an evaluation of the effectiveness of our internal control over financial reporting as of March 31, 2021, based on the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on this evaluation, management concluded that our internal control over financial reporting was effective as of March 31, 2021.

(c) Attestation Report of Registered Public Accounting Firm

This report does not include an attestation report of our registered public accounting firm as we are not an accelerated filer or a large accelerated filer.

(d) Changes in Internal Controls over Financial Reporting

There were no other changes in our internal control over financial reporting that occurred during the year ended March 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

The table below sets forth the name, age and position of each of our directors and executive officers and as of the date of this Annual Report on Form 10-K.

Name	Age	Position
Steven A. Lisi	50	Chief Executive Officer and Chairman of the Board of Directors
Amir Avniel	47	President, Chief Operating Officer and Director
Douglas Beck, CPA	60	Chief Financial Officer
Ron Bentsur	53	Director
Erick J. Lucera	54	Director
Yoori Lee	48	Director
Dr. William Forbes	59	Director
Robert F. Carey	62	Director

Steven A. Lisi, Chief Executive Officer and Chairman of the Board

Steven Lisi has served on our Board of Directors since January 13, 2017, and has served on the Board of Directors of BA Ltd., our wholly-owned subsidiary, since June 2016. Mr. Lisi has served as our Chief Executive Officer since June 14, 2017. Mr. Lisi was previously Senior Vice President of Business and Corporate Development at Avadel Technologies (AVDL), where he was instrumental in restructuring the company and transforming it from $100 million in enterprise value to $1 billion in three years. Mr. Lisi raised $121 million in equity, led the sale of Avadel's contract manufacturing facility, rationalized the product pipeline, refocused the business development effort, transformed the investor base and established Avadel's presence in Ireland. Prior to his position with Avadel, Mr. Lisi spent 18 years investing in healthcare companies on a global basis at Mehta and Isaly (now OrbiMed), SAC Capital (portfolio manager), Millennium Partners (portfolio manager), Panacea Asset Management (co-owner) and Deerfield Management (Partner). Mr. Lisi serves on the Board of Mico Innovations, a next generation coronary and neurovascular stent company. Mr. Lisi received his Master's in International Business from Pepperdine University.

Our Board of Directors believes that Mr. Lisi's experience and perspective as our Chief Executive Officer, as well as his depth of operating and senior management experience and specific skills in the areas of general operations and financial operations, provide him with the qualifications and skills to serve as a director.

Amir Avniel, President, Chief Operating Officer and Director

Amir Avniel has served on BA Ltd.'s Board since 2011 and became BA Ltd.'s Chief Executive Officer in August 2014. He has served on our Board and served as our Chief Executive Officer from January 13, 2017 to June 14, 2017. He has more than ten years of management experience in the biotechnology industry. From 2013 through 2014, Mr. Avniel served as Strategy and Business Development of A.B. Seeds, a wholly owned subsidiary of Monsanto Company. Mr. Avniel served as the Chief Executive Officer of Rosetta Green Ltd. from 2010 through 2013 and led Rosetta Green in its acquisition by Monsanto. He also served as the president and the Chief Executive Officer of Rosetta Genomics from 2006 to 2009, and Mr. Avniel is a named inventor in over 20 patent applications. He studied computer science at the Academic College of Tel Aviv - Jaffa Israel and earned a Bachelor's degree in Social Sciences and Humanities - from Open University in Israel. Prior to his academic studies, he served as an officer in the Israel Defense Force, where he was awarded four commendations for excellence.

Our Board of Directors believes that Mr. Avniel's experience and perspective as our President and Chief Operating Officer, as well as his depth of operating and senior management experience in the biotechnology industry, provide him with the qualifications and skills to serve as a director.

Douglas Beck, CPA, Chief Financial Officer

Douglas Beck has been our Chief Financial Officer since November 1, 2018. He was the Chief Financial officer of JLM Couture Inc, from February 2016 until October 31, 2018, and was the Chief Financial Officer of Relmada Therapeutics, Inc. from December 2013 to December 2015. In addition, Mr. Beck serves on the New York State Society of CPAs Chief Financial Officer and SEC committee. Mr. Beck is a graduate of Fairleigh Dickinson University and is a licensed certified public accountant in New York.

Ron Bentsur, Director

Ron Bentsur joined BA Ltd. in August 2015 and serves as a director. Mr. Bentsur has served as Chief Executive Officer and Director of UroGen Pharma, Ltd. since August 2015. From 2009 through April 2015, Mr. Bentsur served as Chief Executive Officer and Director of Keryx Biopharmaceuticals, Inc. Mr. Bentsur's tenure as CEO of Keryx Biopharmaceuticals culminated in the September 2014 FDA approval of Auryxia ™ (ferric citrate) and its December 2014 U.S. launch. Prior to joining Keryx Biopharmaceuticals, Inc., from 2006 to 2009, Mr. Bentsur served as Chief Executive Officer of XTL Biopharmaceuticals, Ltd. Prior to that, Mr. Bentsur served as Vice President Finance and Chief Financial Officer of Keryx Biopharmaceuticals, Inc., as Director of Technology Investment Banking at Leumi Underwriters, where he was responsible for all technology and biotechnology private placement and advisory transactions, and as a New York City-based investment banker, primarily at ING Barings Furman Selz. Mr. Bentsur holds a B.A. in Economics and Business Administration with distinction from the Hebrew University of Jerusalem and an M.B.A., magna cum laude, from New York University's Stern Graduate School of Business. Mr. Bentsur also serves as Director of Stemline Therapeutics, Inc.

Our Board of Directors believes that Mr. Bentsur's experience and perspective advising our company and other life sciences companies, as well as his depth of operating and senior management experience in the biopharma industry, provide him with the qualifications and skills to serve as a director.

Yoori Lee, Director

Yoori Lee joined Beyond Air's Board of Directors in January 2018. She has served as Co-founder and President of Trio Health Advisory Group, Inc. since 2013. Trio Health's mission is to improve the quality of care in patient outcomes through coordinating the efforts of all patient care stakeholders. Prior to Trio Health, Ms. Lee spent over 15 years at Leerink Partners LLC, a leading healthcare investment bank, where she was Managing Director, and Director of MEDACorp Services. Additionally, she helped found the MEDACorp network, a cadre of experts including more than 35,000 healthcare professionals in diverse areas of practice such as clinical medicine, biomedical research, regulatory affairs, public policy, healthcare administration and healthcare information technology.

Our Board of Directors believes that Ms. Lee's experience and perspective advising our company as well as her experience with Leerink Partners LLC and MEDACorp. provide her with the qualifications and skills to serve as a director.

Dr. William Forbes, Director

Dr. William Forbes joined Beyond Air's board of Director in August 2018. He brings to the Beyond Air Board more than 30 years of pharmaceutical product development experience and, working with health authorities in the US and Europe, has contributed to numerous marketing approvals spanning a diverse range of therapeutic areas. Dr. Forbes currently serves as the Chief Development Officer of Trevi Therapeutics, a clinical-stage pharmaceutical company focused on serious neurologically mediated diseases. Prior to joining Trevi, Dr. Forbes was at Salix Pharmaceuticals as the Chief Development Officer and also Head of Medical and R&D. Prior to Salix, Dr. Forbes spent 15 years in Clinical Development & Regulatory Affairs and Clinical Research at a number of global pharmaceutical companies.

Our Board of Directors believes that Dr. Forbes' experience and perspective advising our company, as well as his depth of operating and senior management experience in our industry, provide him with the qualifications and skills to serve as a director.

Robert F. Carey

Robert Carey joined Beyond Air's Board of Directors in February 2019. He has an extensive track record of accomplishment within the biopharmaceutical and healthcare investment banking industry. He has assisted biotech and specialty pharma companies raise more than $10 billion in initial public offerings, follow-on offerings, debt offerings, and private placements. He has served as a financial advisor on mergers, acquisitions, and strategic alliance transactions with a total deal value of more than $10 billion. In 2020, Mr. Carey co-founded and served as President and Chief Operating Officer of ACELYRIN, INC., a biopharmaceutical company that will invest in, develop and commercialize life-changing drug therapies. Mr. Carey previously served as Executive Vice President and Chief Business Officer at Horizon Therapeutics plc from March 2014 to September 2019, during which Horizon Therapeutics deployed in excess of $3.5 billion to acquire or license eight commercial products and three products in development and grew net sales from $74 million in 2013 to approximately $1.2 billion in 2018, a compound annual growth rate of 75%. Before Horizon, he spent more than 11 years as Managing Director and Head of the Life Sciences Investment Banking Group at JMP Securities. Mr. Carey was also Managing Director in the healthcare groups at Dresdner Kleinwort Wasserstein and Vector Securities. He received his B.B.A. in Accounting from the University of Notre Dame. Mr. Carey currently serves on the Board of Sangamo Therapeutics, Inc. and Hawthorne Race Course, Inc.

Our Board of Directors believes that Mr. Carey's experience and perspective advising the Company and other life sciences companies in connections with financings and strategic transactions, as well as his depth of operating and senior management experience in our industry, provide him with the qualifications and skills to serve as a director.

Erick J. Lucera, Director

Erick J. Lucera joined our Board of Directors in August 2017 and serves on our audit committee. He was appointed Chief Financial Officer for AVEO Oncology (Nasdaq: AVEO), a Nasdaq traded biopharmaceutical company focused on targeted medicines for oncology and other unmet medical needs in 2020. Mr. Lucera was the Chief Financial Officer of Valeritas Holdings, Inc., a U.S. Nasdaq traded commercial stage company developing new technology for diabetes, from 2016 to 2019. Mr. Lucera served as Chief Financial Officer, Treasurer and Secretary of Viventia Bio from 2015 to 2016. From 2012 to 2015, he was Vice President, Corporate Development at Aratana Therapeutics, a veterinary biopharmaceutical company. While at Aratana, he helped grow the company's product pipeline through a series of acquisitions and in licensing transactions financed through five public and private offerings of nearly $250 million. Before his career as a healthcare company executive, Mr. Lucera spent over 15 years in investment management as a healthcare analyst at Eaton Vance, the portfolio manager of the Triathlon Life Sciences Fund at Intrepid Capital and as head of the healthcare research team at Independence Investments. He holds a Certificate in Public Health from Harvard University, an MS in quantitative finance from Boston College, an MBA from Indiana University Bloomington, and a BS in accounting from the University of Delaware. Mr. Lucera has obtained CFA, CMA, and CPA designations.

Our Board of Directors believes that Mr. Lucera's experience and perspective advising the Company and other life sciences companies on strategic transactions and financings, as well as his depth of operating and senior management experience in our industry, provide him with the qualifications and skills to serve as a director.

Term of Office of Directors

Our directors are elected at each annual meeting of stockholders for a term of one year. Each director shall serve until his successor is duly elected and qualified or until his earlier death, resignation or removal.

Family Relationships

There are no family relationships among any of our current or former directors or executive officers.

Involvement in Certain Legal Proceedings

Erick J. Lucera was the Chief Financial Officer of Valeritas Holdings, Inc. until January 3, 2020. On February 9, 2020, Valeritas Holdings, Inc. filed a voluntary petition for bankruptcy protection under Chapter 11 of Title 11 of the U.S. Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware in order to facilitate its sale to a Denmark-based biotechnology company. The plan of liquidation was approved on June 8, 2020 and became effective on June 30, 2020.

Except as set forth above, none of our directors, executive officers, significant employees, promoters or control persons has been involved in any legal proceeding in the past ten years that would require disclosure under Item 401(f) of Regulation S-K promulgated under the Securities Act.

Board Committees

Our Board of Directors has established three standing committees: the audit committee, the compensation committee and the nominating committee. The current members of our audit committee are Erick Lucera, Ron Bentsur and Robert F. Carey with Erick Lucera serving as chairperson. The current members of our compensation committee are Yoori Lee, Erick J. Lucera, and Ron Bentsur with Yoori Lee serving as chairperson. The current members of our nominating committee are Erick Lucera, Yoori Lee and Dr. William Forbes.

Our Board of Directors has determined that Erick Lucera, Ron Bentsur and Robert F. Carey meet the additional test for independence for audit committee members imposed by Securities and Exchange Commission ("SEC") regulations and Section 5605(c)(2)(A) of the NASDAQ Stock Market listing rules and that Erick J. Lucera, Yoori Lee and Ari Raved meet the additional test for independence for compensation committee members imposed by Section 5605(d)(2)(A) of the NASDAQ Stock Market listing rules.

Audit Committee

The primary purpose of our audit committee is to assist the Board of Directors in the oversight of the integrity of our accounting and financial reporting process, the audits of our consolidated financial statements, and our compliance with legal and regulatory requirements. Our audit committee met four times during the year ended March 31, 2021. The functions of our audit committee include, among other things:

- hiring the independent registered public accounting firm to conduct the annual audit of our consolidated financial statements and monitoring its independence and performance;
- reviewing and approving the planned scope of the annual audit and the results of the annual audit;
- pre-approving all audit services and permissible non-audit services provided by our independent registered public accounting firm;
- reviewing the significant accounting and reporting principles to understand their impact on our consolidated financial statements;
- reviewing our internal financial, operating and accounting controls with management, our independent registered public accounting firm and our internal audit provider;
- reviewing with management and our independent registered public accounting firm, as appropriate, our financial reports, earnings announcements and our compliance with legal and regulatory requirements;
- periodically reviewing and discussing with management the effectiveness and adequacy of our system of internal controls;
- in consultation with management and the independent auditors, reviewing the integrity of our financial reporting process and adequacy of disclosure controls;

- reviewing potential conflicts of interest under and violations of our code of conduct;
- establishing procedures for the treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters and confidential submissions by our employees of concerns regarding questionable accounting or auditing matters;
- reviewing and approving related-party transactions; and
- reviewing and evaluating, at least annually, our audit committee's charter.

With respect to reviewing and approving related-party transactions, our audit committee will review related-party transactions for potential conflicts of interests or other improprieties. Under SEC rules, related-party transactions are those transactions to which we are or may be a party in which the amount involved exceeds the lesser of $120,000 or 1% of total assets, and in which any of our directors or executive officers or any other related person had or will have a direct or indirect material interest, excluding, among other things, compensation arrangements with respect to employment and Board of Directors membership. Our audit committee could approve a related-party transaction if it determines that the transaction is in our best interests. Our directors are required to disclose to this committee or the full Board of Directors any potential conflict of interest, or personal interest in a transaction that our Board of Directors is considering. Our executive officers are required to disclose any related-party transaction to the audit committee. We also poll our directors on an annual basis with respect to related-party transactions and their service as an officer or director of other entities. Any director involved in a related-party transaction that is being reviewed or approved must recuse himself or herself from participation in any related deliberation or decision. Whenever possible, the transaction should be approved in advance and if not approved in advance, must be submitted for ratification as promptly as practical.

The financial literacy requirements of the SEC require that each member of our audit committee be able to read and understand fundamental financial statements. In addition, at least one member of our audit committee must qualify as an audit committee financial expert, as defined in Item 407(d)(5) of Regulation S-K promulgated under the Securities Act, and have financial sophistication in accordance with the NASDAQ Stock Market listing rules. Our Board of Directors has determined that Erick Lucera qualifies as an audit committee financial expert.

Both our independent registered public accounting firm and management periodically will meet privately with our audit committee.

Compensation Committee

The primary purpose of our compensation committee is to assist our Board of Directors in exercising its responsibilities relating to compensation of our executive officers and employees and to administer our equity compensation and other benefit plans. In carrying out these responsibilities, this committee reviews all components of executive officer and employee compensation for consistency with its compensation philosophy, as in effect from time to time. The functions of our compensation committee include, among other things:

- designing and implementing competitive compensation, retention and severance policies to attract and retain key personnel;
- reviewing and formulating policy and determining the compensation of our Chief Executive Officer, our other executive officers and certain employees;
- reviewing and recommending to our Board of Directors the compensation of our non-employee directors;
- reviewing and evaluating our compensation risk policies and procedures;
- administering our equity incentive plans and granting equity awards to our employees, consultants and directors under these plans;
- administering our performance bonus plans and granting bonus opportunities to our employees, consultants and non-employee directors under these plans;

- if required from time to time, preparing the analysis or reports on executive officer compensation required to be included in our annual proxy statement;
- engaging compensation consultants or other advisors it deems appropriate to assist with its duties; and
- reviewing and evaluating, at least annually, our compensation committee's charter.

The compensation committee retains sole authority to hire any compensation consultant, approve such consultant's compensation, determine the nature and scope of its services, evaluate its performance, and terminate its engagement.

The compensation committee will review our compensation policies and practices for all employees, including our named executive officers, as they relate to risk management practices and risk-taking incentives to assess and determine that there are no risks arising from these policies and practices that are reasonably likely to have a material adverse effect on us.

Nominating committee

The primary purpose of our nominating committee is to assist our Board of Directors in promoting the best interest of our company and our stockholders through the implementation of sound corporate governance principles and practices. The functions of our nominating committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our Board of Directors;
- determining the minimum qualifications for service on our Board of Directors;
- developing and recommending to our Board of Directors an annual self-evaluation process for our Board of Directors and overseeing the annual self-evaluation process;
- developing, as appropriate, a set of corporate governance principles, and reviewing and recommending to our Board of Directors any changes to such principles; and
- periodically reviewing and evaluating our nominating committee's charter.

Director Candidates

Our Board of Directors has a critical role in guiding our strategic direction and overseeing the management of our business, and accordingly, we seek to attract and retain highly qualified directors who have sufficient time to engage in the activities of our Board of Directors and to understand and enhance their knowledge of our industry and business plans. In evaluating the suitability of individual candidates, the Board, in approving (and, in the case of vacancies, appointing) such candidates, may take into account many factors, including: personal and professional integrity, ethics and values; experience in corporate management, such as serving as an officer or former officer of a publicly held company; strong finance experience; experience relevant to our industry; experience as a board member or executive officer of another publicly held company; relevant academic expertise or other proficiency in an area of our operations; diversity of expertise and experience in substantive matters pertaining to our business relative to other board members; diversity of background and perspective, including, but not limited to, with respect to age, gender, race, place of residence and specialized experience; practical and mature business judgment, including, but not limited to, the ability to make independent analytical inquiries; and any other relevant qualifications, attributes or skills. The Board evaluates each individual in the context of the Board as a whole, with the objective of assembling a group that can best perpetuate the success of the business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas.

Stockholder Communications

Although we do not have a formal policy regarding stockholder communications with our Board of Directors, stockholders may communicate with our Board of Directors, or any individual director on our Board of Directors, by writing to us at the address of our principal executive offices, addressing the communication to the attention of our Chief Executive Officer, and specifying the Board of Directors or, if applicable, the individual member thereof as the intended recipient of the communication.

Board Leadership Structure and Role in Risk Oversight

The Board of Directors does not have a formal policy on whether or not the roles of Chairman of the Board and Chief Executive Officer should be separate and believes that it should retain the flexibility to make this determination in the manner it believes will provide the most appropriate leadership for our company from time to time. Currently, Steven A. Lisi serves as Chairman of the Board and Chief Executive Officer, working closely with former CEO and present COO and President, Amir Avniel. We do not have a lead independent director. Mr. Lisi sets the strategic direction for the company and provides day-to-day leadership. As Chairman of the Board of Directors, Mr. Lisi further oversees the agenda for board meetings in collaboration with the other board members. Our Board believes that it is in the best interest of the company and its stockholders for Mr. Lisi to serve in both roles at this time given his knowledge of our company and industry. We believe that this structure provides appropriate leadership and oversight of the company and facilitates effective functioning of both management and our Board of Directors. Our Board of Directors will continue to reassess the structure to determine what is in the best interests of the Company and stockholders.

The Board of Directors oversees our exposure to risk through its interaction with management and receipt from management of periodic reports outlining matters related to financial, operational, regulatory, legal and strategic risks. Risk assessment and oversight are an integral part of our governance and management processes. Our Board of Directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the risks facing us. Throughout the year, senior management reviews these risks with the Board of Directors at regular board meetings as part of management presentations that focus on particular business functions, operations or strategies and presents the steps taken by management to mitigate or eliminate such risks.

Code of Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all our directors, officers (including our Chief Executive Officer, Chief Financial Officer and any person performing similar functions) and employees. We have made our Code of Ethics available on our website at www.beyondair.net under "*Investors—Governance—Governance Documents*". We intend to disclose any future amendments to, or waivers from, our Code of Business Conduct and Ethics within four business days of the waiver or amendment through a website posting or by filing a Current Report on Form 8-K with the SEC.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than 10% of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Executive officers, directors and greater than 10% stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

SEC regulations require us to identify in this Annual Report anyone who filed a required report late during the most recent fiscal year. To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations that no other reports were required, during the year ended March 31, 2021, all of our officers, directors and greater than 10% beneficial owners have complied with Section 16(a) filing requirements on a timely basis, other than as set forth below:

Filer	Number of Late Reports	Number of Transactions not Reported Timely
Robert Carey	One Form 4	One
Steven Lisi	Two Form 4s	Two
William Forbes	One Form 3 and one Form 4	One
Yoori Lee	One Form 4	One
Amir Avniel	Two Form 4s	Two
Douglas Beck	Three Form 4s	Three

ITEM 11. EXECUTIVE COMPENSATION

Executive Compensation

The information required by this Item is set forth under the captions "Executive Officers," "Executive Compensation," and "Corporate Governance—Director Compensation" in our definitive proxy statement for our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of March 31, 2021, and is incorporated into this Annual Report by reference

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is set forth under the captions "Executive Officers," "Executive Compensation," and "Corporate Governance—Director Compensation" in our definitive proxy statement for our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days of March 31, 2021, and is incorporated into this Annual Report on Form 10-K by reference

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Transactions with Related Persons

We describe below transactions and series of similar transactions, since April 1, 2019, to which we were a party or will be a party, in which, with respect to reviewing and approving related-party transactions, our audit committee will review related-party transactions for potential conflicts of interests or other improprieties. Under SEC rules, related-party transactions are those transactions to which we are or may be a party in which the amount involved exceeds the lesser of $120,000 or 1% of total assets, and in which any of our directors or executive officers or any other related person had or will have a direct or indirect material interest, excluding, among other things, compensation arrangements with respect to employment and Board of Directors membership. Our audit committee could approve a related-party transaction if it determines that the transaction is in our best interests. Our directors are required to disclose to this committee or the full Board of Directors any potential conflict of interest, or personal interest in a transaction that our Board of Directors is considering. Our executive officers are required to disclose any related-party transaction to the audit committee. We also poll our directors on an annual basis with respect to related-party transactions and their service as an officer or director of other entities. Any director involved in a related-party transaction that is being reviewed or approved must recuse himself or herself from participation in any related deliberation or decision. Whenever possible, the transaction should be approved in advance and if not approved in advance, must be submitted for ratification as promptly as practical.

Purchases of Our Securities

On June 3, 2019, Steven Lisi, our Chief Executive Officer and Chairman, purchased 58,252 shares of our common stock from us at a purchase price of $5.15 per share, or $300,000. On December 12, 2019, Mr. Lisi purchased 190,437 shares of our common stock from us at a purchase price of $3.66 per share, or $697,000.

Director Independence

Our Board of Directors has determined that each of Ron Bentsur, Erick Lucera, Yoori Lee, William Forbes and Robert F. Carey is independent within the meaning of Rule 5605(a)(2) of the Nasdaq Listing Rules and the rules and regulations promulgated by the SEC. In making its independence determinations, the Board of Directors sought to identify and analyze all of the facts and circumstances related to any relationship between a director, his immediate family and our company and our affiliates and did not rely on categorical standards other than those contained in the Nasdaq rule referenced above.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Audit Fees

The aggregate fees billed for the fiscal years ended March 31, 2021 and 2020 for professional services rendered by Friedman LLP for the audit of our annual financial statements provided by Friedman LLP in connection with statutory and regulatory filings or engagements for this fiscal period were as follows:

	Year Ended March 31, 2021	Year Ended March 31, 2020
Audit Fees	$ 150,600	$ 207,250
Audit Related Fees	$ -	$ -
Tax Fees	$ -	$ -
All Other Fees	$ -	$ -
Total	**$ 150,600**	**$ 207,250**

In the above table, "audit fees" are fees billed by our independent registered public accounting firm for services provided in auditing our annual financial statements for the subject year. Audit fees also include professional services performed for filing of our registration statement on Form S-1 and S-3 for equity offerings, Form S-8 for shares of our common stock underlying our 2013 Equity Incentive Option Plan and for the resale of certain shares of our common stock and other filings. "Audit-related fees" are fees not included in audit fees that are billed by the independent registered public accounting firm for assurance and related services that are reasonably related to the performance of the audit review of our financial statements. "Tax fees" are fees billed by the independent registered public accounting firm for professional services rendered for tax compliance, tax advice and tax planning. "All other fees" are fees billed by the independent registered public accounting firm for products and services not included in the foregoing categories.

Policy on Pre-Approval by Audit Committee of Services Performed by Independent Auditors

The audit committee pre-approves all services provided by our independent registered public accounting firm. All of the above services and fees were reviewed and approved by the audit committee before the respective services were rendered.

The Board of Directors has considered the nature and amount of fees billed by Friedman and believes that the provision of services for activities unrelated to the audit, if any, is compatible with maintaining each such auditor's independence.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

1. Financial Statements.

See Index to Consolidated Financial Statements on page F-1.

2. Finance Statement Schedules.

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. Exhibits

2.1	Agreement and Plan of Merger and Reorganization, dated as of December 29, 2016, by and among AIT Therapeutics, Inc. and Advanced Inhalation Therapies Ltd., filed as Exhibit 2.1 to our Current Report on Form 8-K, as amended and filed with the SEC on March 15, 2017 and incorporated herein by reference.
2.2	First Amendment to Agreement and Plan of Merger and Reorganization, dated as of January 12, 2017, by and among AIT Therapeutics, Inc. and Advanced Inhalation Therapies Ltd., filed as Exhibit 2.2 to our Current Report on Form 8-K, as amended and filed with the SEC on March 15, 2017 and incorporated herein by reference.
2.3	Merger Completion Certificate, dated as of December 29, 2016, by and among Red Maple Ltd. and Advance Inhalation (AIT) Ltd., filed as Exhibit 2.3 to our Current Report on Form 8-K, as amended and filed with the SEC on March 15, 2017 and incorporated herein by reference.
3.1	Amended and Restated Certificate of Incorporation of AIT Therapeutics, Inc., dated as of January 9, 2017, filed as Exhibit 3.1 to our Current Report on Form 8-K, as amended and filed with the SEC on March 15, 2017 and incorporated herein by reference.
3.2	Amended and Restated Bylaws of AIT Therapeutics, Inc. filed as Exhibit 3.2 to our Current Report on Form 8-K, as amended and filed with the SEC on March 15, 2017 and incorporated herein by reference.
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation, dated as of June 25, 2019, filed as Exhibit 3.3 to our Annual Report on Form 10-K filed with the SEC on June 28, 2019 and incorporated herein by reference.
4.1	Form of Common Stock Certificate, filed as Exhibit 4.1 to our Current Report on Form 8-K, as filed with the SEC on March 15, 2017 and incorporated herein by reference.
4.2	Form of Warrant to Purchase Common Stock, by and among AIT Therapeutics, Inc. and the Holders party thereto, filed as Exhibit 10.3 to our Current Report on Form 8-K, as filed with the SEC on March 15, 2017 and incorporated herein by reference.
4.3	Form of Warrant to Purchase Common Stock, by and among AIT Therapeutics, Inc. and the Holders party thereto, filed as Exhibit 4.1 to our Current Report on Form 8-K, as filed with the SEC on April 4, 2017 and incorporated herein by reference.
4.4	Form of Warrant to Purchase Common Stock, by and among AIT Therapeutics, Inc. and the Holders party thereto, filed as Exhibit 4.1 to our Current Report on Form 8-K, as filed with the SEC on February 22, 2018 and incorporated herein by reference.
4.5	Form of Warrant to Purchase Common Stock, by and among Beyond Air, Inc. and the Holders party thereto, filed as Exhibit 4.1 to our Current Report on Form 8-K, as filed on March 20, 2020 and incorporated herein by reference

10.1	Amended and Restated Agreement for the Transfer and Assumption of Obligations Under the Securities Purchase and Registration Rights Agreements, dated as of January 12, 2017, by and among AIT Therapeutics, Inc. and Advanced Inhalation Therapies Ltd., filed as Exhibit 10.1 to our Current Report on Form 8-K, as amended and filed with the SEC on March 15, 2017 and incorporated herein by reference.
10.2	Securities Purchase and Registration Rights Agreement, by and among Advanced Inhalation Therapies Ltd. and the Investors party thereto, filed as Exhibit 10.2 to our Current Report on Form 8-K, as amended and filed with the SEC on March 15, 2017 and incorporated herein by reference.
10.3	License Agreement, dated as of November 1, 2011, by and between Advanced Inhalation Therapies Ltd. and The UBC, filed as Exhibit 10.10 to our Current Report on Form 8-K, as amended and filed with the SEC on March 15, 2017 and incorporated herein by reference.
10.4^	Non-Exclusive Patent License Agreement, dated as of October 22, 2013, by and between Advanced Inhalation Therapies Ltd. and SensorMedics Corporation, filed as Exhibit 10.9 to our Current Report on Form 8-K. as filed with the SEC on January 20, 2017 Registration Statement on Form S-1(File No. 333-216287), and incorporated herein by reference.
10.5	Option Agreement, dated as of August 31, 2015, by and between Advanced Inhalation Therapies Ltd. and Pulmonox Technologies Corporation, filed as Exhibit 10.13 to our Current Report on Form 8-K, as amended and filed with the SEC on March 15, 2017 and incorporated herein by reference.
10.6	Tenth Amendment to Option Agreement, dated as of December 31, 2016, by and between Advanced Inhalation Therapies Ltd. and Pulmonox Technologies Corporation, filed as Exhibit 10.14 to our Current Report on Form 8-K, as amended and filed with the SEC on March 15, 2017 and incorporated herein by reference.
10.7+	Employment Agreement, dated as of June 24, 2016, by and between Advanced Inhalation Therapies Ltd. and Steven Lisi, filed as Exhibit 10.15 to our Current Report on Form 8-K, as amended and filed with the SEC on March 15, 2017 and incorporated herein by reference.
10.8+	Employment Agreement, dated as of October 1, 2014, by and between Advanced Inhalation Therapies Ltd. and Amir Avniel, filed as Exhibit 10.17 to our Registration Statement on Form S-1 (File No. 333-216287), and incorporated herein by reference.
10.9+	Employment Agreement, dated as of September 17, 2015, by and between Advanced Inhalation Therapies Ltd. and Amir Avniel, filed as Exhibit 10.18 to our Registration Statement on Form S-1 (File No. 333-216287), and incorporated herein by reference.
10.10+	Waiver of the back salary, dated as of October 31, 2016, by and between Advanced inhalation Therapies Ltd. and Amir Avniel, filed as Exhibit 10.19 to our Registration Statement on Form S-1 (File No. 333-216287), and incorporated herein by reference.
10.11	Stock Purchase and Registration Rights Agreement, dated March 31, 2017, by and among the Company and the Investors party thereto, filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on April 4, 2017 and incorporated herein by reference.
10.12	Form of Subscription Agreement, dated March 31, 2017, by and among the Company and the Investors party thereto, filed as Exhibit 10.2 to our Current Report on Form 8-K, filed with the SEC on April 4, 2017 and incorporated herein by reference.
10.15	Securities Purchase Agreement, dated as of August 10, 2018, by and between AIT Therapeutics, Inc. and Lincoln Park Capital Fund, LLC., filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on August 13, 2018 and incorporated herein by reference.
10.16	Registration Rights Agreement, dated as of August 10, 2018, by and between AIT Therapeutics, Inc. and Lincoln Park Capital Fund, LLC, filed as Exhibit 10.2 to our Current Report on Form 8-K, filed with the SEC on August 13, 2018 and incorporated herein by reference.
10.17+	Offer letter between AIT Therapeutics, Inc. and Douglas J. Beck, filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on November 1, 2018 and incorporated herein by reference.
10.18	Form of Subscription Agreement, dated as of June 3, 2019, by and among AIT Therapeutics, Inc. and the Purchasers party thereto, filed as Exhibit 10.1 to our Current Report on Form 8-K, as filed with the SEC on June 7, 2019 and incorporated herein by reference.

10.19*	License, Development and Commercialization Agreement, dated January 23, 2019, by and between AIT Therapeutics, Inc. and Circassia Limited, filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q on February 14, 2019 and incorporated herein by reference.
10.21	Form of Purchase Agreement with U.S. Investors, filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on December 10, 2019 and incorporated herein by reference.
10.22	Form of Purchase Agreement with Foreign Investors, filed as Exhibit 10.2 to our Current Report on Form 8-K, filed with the SEC on December 10, 2019 and incorporated herein by reference.
10.23	Facility Agreement, dated March 17, 2020, filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on March 17, 2020 and incorporated herein by reference.
10.24	At-The-Market Equity Offering Sales Agreement, dated April 2, 2020, by and among the Company, SunTrust Robinson Humphrey, Inc. and Oppenheimer & Co., filed as Exhibit 1.1 to our Current Report on Form 8-K, filed with the SEC on April 3, 2020 and incorporated herein by reference.
10.25	Purchase Agreement, dated May 14, 2020, by and between Beyond Air, Inc. and Lincoln Park Capital Fund, LLC, filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on May 14, 2020 and incorporated herein by reference.
10.26	Registration Rights Agreement, dated May 14, 2020, by and between Beyond Air, Inc. and Lincoln Park Capital Fund, LLC, filed as Exhibit 4.1 to our Current Report on Form 8-K, filed with the SEC on May 14, 2020 and incorporated herein by reference.
10.27*	Supply Agreement, dated as of August 6, 2020, by and between Beyond Air, Inc. and Spartronics Watertown, LLC, filed as Exhibit 10.1 to our Current Report on Form 8-K, as filed with the SEC on August 12, 2020 and incorporated herein by reference.
10.28*	Manufacture and Supply Agreement, dated as of July 30, 2020, by and between Beyond Air, Inc. and Medisize Ireland Limited, filed as Exhibit 10.1 to our Current Report on Form 8-K, as filed with the SEC on August 18, 2020 and incorporated herein by reference.
10.29+	Beyond Air, Inc. Third Amended and Restated 2013 Equity Incentive Plan (included in Appendix A to our Definitive Proxy Statement filed on January 22, 2021 and incorporated herein by reference).
10.30+	Beyond Air, Inc. 2021 Employee Stock Purchase Plan, filed as Exhibit 10.2 to our Current Report on Form 8-K, as filed with the SEC on March 9, 2021 and incorporated herein by reference.
21.1**	List of subsidiaries of Beyond Air, Inc.
23.1**	Consent of Friedman LLP
31.1***	Rule 13a-14(a) / 15d-14(a) Certification of Principal Executive Officer
31.2***	Rule 13a-14(a) / 15d-14(a) Certification of Principal Financial Officer
32.1***	Section 1350 Certification of Principal Executive Officer
32.2***	Section 1350 Certification of Principal Financial Officer
101.INS	XBRL Instance
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ Management contract or compensation plan arrangement

* Pursuant to Item 601(b)(10) of Regulation S-K, portions of this exhibit have been omitted as the registrant has determined that the omitted information (i) is not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

** Filed herewith

*** Furnished herewith.

Item 16. Form 10-K Summary

Information with respect to this item is not required and has been omitted at the Company's option.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: June 10, 2021

BEYOND AIR, INC.

By: */s/ Steven Lisi*
Steven Lisi
Chairman and Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Name	Title	Date
/s/ Steven Lisi Steven Lisi	Chairman and Chief Executive Officer (Principal Executive Officer)	June 10, 2021
/s/ Douglas Beck Douglas Beck	Chief Financial Officer (Principal Financial Officer) (and Principal Accounting Officer)	June 10, 2021
/s/ Amir Avniel Amir Avniel	Chief Operating Officer, President and Director	June 10, 2021
/s/ Erick Lucera Erick Lucera	Director	June 10, 2021
/s/ Yoori Lee Yoori Lee	Director	June 10, 2021
/s/ William Forbes William Forbes	Director	June 10,2021
/s/ Ron Bentsur Ron Bentsur	Director	June 10,2021
/s/ Robert Carey Robert Carey	Director	June 10, 2021

BEYOND AIR, INC. AND ITS SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

AS OF MARCH 31, 2021

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Beyond Air, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Beyond Air, Inc. and Subsidiaries (the "Company") as of March 31, 2021 and 2020, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years in the two-year period ended March 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of March 31, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the two-year period ended March 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provides a reasonable basis for our opinion.

/s/ Friedman LLP

We have served as the Company's auditor since 2019.

East Hanover, New Jersey
June 10, 2021

BEYOND AIR, INC. AND ITS SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	March 31, 2021	March 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 34,630,682	$ 19,829,275
Restricted cash	637,025	5,635,836
Grant receivable	425,000	-
Other current assets and prepaid expenses	1,530,096	1,149,806
Total current assets	37,222,803	26,681,917
Licensed right to use technology	374,686	412,763
Right-of-use lease assets	1,860,885	195,727
Property and equipment, net	928,842	211,337
Other assets	137,880	-
TOTAL ASSETS	$ 40,525,096	$ 27,434,744
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,324,988	$ 2,256,229
Accrued expenses	1,804,938	1,097,534
Deferred revenue	-	873,190
Stock to be issued to a vendor	-	240,000
Operating lease liability	113,141	69,342
Loan payable	556,514	335,358
Total current liabilities	3,799,581	4,871,653
Operating lease liability	1,789,461	131,581
Long-term loan, net	4,472,201	4,339,065
Total liabilities	10,061,243	9,342,299
Commitments and contingencies		
Stockholders' 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, 21,828,244 and 16,056,360 shares issued and outstanding as of March 31, 2021 and 2020, respectively	2,183	1,606
Treasury stock	(25,000)	(25,000)
Additional paid-in capital	110,948,477	75,702,915
Accumulated deficit	(80,461,807)	(57,587,076)
Total stockholders' equity	30,463,853	18,092,445
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 40,525,096	$ 27,434,744

The accompanying notes are an integral part of these consolidated financial statements

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

	Year Ended March 31, 2021	Year Ended March 31, 2020
License revenue	$ 873,190	$ 1,390,104
Operating expenses		
Research and development	(12,618,349)	(10,648,920)
General and administrative	(10,468,341)	(8,883,119)
Loss from Operations	(22,213,500)	(18,141,935)
Other income (expense)		
Realized and unrealized loss from marketable securities	-	(2,075,602)
Dividend and interest income	16,901	115,716
Interest and finance expense	(641,626)	(30,543)
Foreign exchange loss (gain)	(36,506)	35,560
Total other loss	(661,231)	(1,954,869)
Net loss before income taxes	(22,874,731)	(20,096,804)
Benefit for income taxes	-	154,300
Net loss	$ (22,874,731)	$ (19,942,504)
Deemed dividend from warrant modification	-	(522,478)
Net loss attributed to common stockholder	$ (22,874,731)	$ (20,464,982)
Net loss per share – basic and diluted	$ (1.27)	$ (1.78)
Weighted average number of shares of common stock outstanding – basic and diluted	18,005,226	11,506,212

The accompanying notes are an integral part of these consolidated financial statements

BEYOND AIR, INC. AND ITS SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEAR ENDED MARCH 31, 2020

	Common Stock		Treasury	Additional Paid-in	Accumulated	Total Stockholders'
	Number	Amount	Stock	Capital	Deficit	Equity
Balance as of April 1, 2019	8,714,815	$ 871	$ (25,000)	$ 41,693,578	$ (37,644,572)	$ 4,024,877
Issuance of common stock pursuant to an underwritten offering and a private placement, net	3,152,985	315	-	10,169,028	-	10,169,343
Issuance of common stock pursuant to Purchase Agreement, net	1,420,000	142	-	7,744,870	-	7,745,012
Incremental value of warrants due to a modification	-	-	-	522,478	-	522,478
Deemed dividend due to a warrant modification	-	-	-	(522,478)	-	(522,478)
Issuance of common stock pursuant to a private placement, net	1,583,743	159	-	7,839,336	-	7,839,495
Warrant issued with debt issuance	-	-	-	594,979	-	594,979
Issuance of common stock upon exercise of options	58,662	6	-	210,644	-	210,650
Issuance of common stock upon the exercise of warrants	985,694	99	-	3,968,845	-	3,968,944
Issuance of common stock upon cashless excise of warrants	73,461	7	-	(7)	-	-
Vested restricted stock	67,000	7		(7)	-	-
Stock-based compensation	-	-	-	3,481,649	-	3,481,649
Net loss	-	-	-	-	(19,942,504)	(19,942,504)
Balance as of March 31, 2020	16,056,360	$ 1,606	$ (25,000)	$ 75,702,915	$ (57,587,076)	$ 18,092,445

BEYOND AIR, INC. AND ITS SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEAR ENDED MARCH 31, 2021

	Common Stock		Treasury	Additional Paid-in	Accumulated	Total Stockholders'
	Number	Amount	Stock	Capital	Deficit	Equity
Balance as of April 1, 2020	16,056,360	$ 1,606	$ (25,000)	$ 75,702,915	$ (57,587,076)	$ 18,092,445
At The Market Equity Offering stock issuance of common stock, net	1,961,201	196	-	11,855,260	-	11,855,456
Issuance of common stock pursuant to a Purchase Agreement, net	1,975,511	198	-	11,582,991	-	11,583,189
Issuance of common stock upon the exercise of warrants	1,583,028	158	-	6,671,873	-	6,672,031
Issuance of common stock upon cashless excise of warrants	65,204	7	-	(7)	-	-
Issuance of common stock upon exercise of options	2,340	-	-	545	-	545
Issuance of common stock to investor relations firm	30,000	3	-	242,097	-	242,100
Vested restricted stock	154,600	15		(15)		-
Stock-based compensation	-	-	-	4,892,818	-	4,892,818
Net loss	-	-	-	-	(22,874,731)	(22,874,731)
Balance as of March 31, 2021	21,828,244	$ 2,183	$ (25,000)	$ 110,948,477	$ (80,461,807)	$ 30,463,853

The accompanying notes are an integral part of these consolidated financial statements

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

	For The Year Ended March 31, 2021	For The Year Ended March 31, 2020
Cash flows from operating activities		
Net loss	$ (22,874,731)	$ (19,942,504)
Adjustments to reconcile net loss used in provided by operating activities		
Depreciation and amortization	210,979	159,403
Stock-based compensation	4,894,918	3,577,649
Operating lease expense	38,365	5,196
Realized and unrealized loss on marketable securities sold	-	2,075,602
Gain on cancellation of operating lease	(1,843)	-
Foreign currency adjustment	36,506	-
Amortization of debt issuance cost and deferred financing fees	133,136	4,652
Changes in:		
Grant receivable	(425,000)	-
Other current assets and prepaid expenses	(518,170)	(361,395)
Accounts payable	(967,747)	1,091,557
Accrued expenses	707,401	(470,105)
Deferred revenue	(873,190)	(1,390,104)
Net cash used in operating activities	(19,639,376)	(15,250,049)
Cash flows from investing activities		
Investment in available for sale marketable equitable securities	-	(37,320,235)
Proceeds from redemption of marketable securities	-	41,787,299
Purchase of property and equipment	(890,407)	(43,631)
Net cash (used in) provided by investing activities	(890,407)	4,423,433
Cash flows from financing activities		
Issuance of common stock in connection with a Purchase Agreement with Lincoln Park, At The Market Equity Offering, private placement, net, exercise of warrants and stock options	30,111,223	29,933,444
Proceeds from Facility Agreement	-	5,000,000
Proceeds from loan	625,250	375,570
Payment of loan	(404,094)	(303,806)
Payment of debt issuance costs	-	(70,618)
Net cash provided by financing activities	30,332,379	34,934,590
Increase in cash, cash equivalents and restricted cash	9,802,596	24,107,974
Cash, cash equivalents and restricted cash at beginning of period	25,465,111	1,357,137
Cash, cash equivalents and restricted cash at end of period	$ 35,267,707	$ 25,465,111
Supplemental disclosure of non-cash financing and investing activities:		
Right-of-use lease assets	$ 1,777,192	$ 258,605
Operating lease liability	$ 1,777,192	$ 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
Supplemental disclosure of cash flow items:		
Interest paid	$ 508,490	$ 23,112
Income taxes paid	$ -	$ -

The accompanying notes are an integral part of these consolidated financial statements

NOTE 1 ORGANIZATION AND BUSINESS

We were incorporated on April 24, 2015. On June 25, 2019, our name was changed to Beyond Air, Inc. from AIT Therapeutics, Inc. We have the following wholly-owned subsidiaries:

Beyond Air Ltd. ("BA Ltd.") incorporated in Israel on May 1, 2011.

Advanced Inhalation Therapies ("AIT"), a wholly-owned subsidiary of BA Ltd., incorporated on August 29, 2014, in Delaware. AIT was dissolved on March 1, 2021.

Beyond Air Australia Pty Ltd., incorporated on December 17, 2019 in Australia.

Beyond Air Ireland Limited, incorporated on March 5, 2020 in Ireland.

We are a clinical-stage medical device and biopharmaceutical company developing a nitric oxide ("NO") generator and delivery system (the "LungFit® system") that is capable of generating NO from ambient air. The LungFit® platform can generate NO up to 400 parts per million ("ppm") for delivery to a patient's lungs directly or via a ventilator. LungFit® can deliver NO either continuously or for a fixed amount of time at various flow rates and has the ability to either titrate dose on demand or maintain a constant dose. We believe that LungFit® can be used to treat patients on ventilators that require NO, as well as patients with chronic or acute severe lung infections via delivery through a breathing mask or similar apparatus. Furthermore, we believe that there is a high unmet medical need for patients suffering from certain severe lung infections that the LungFit® platform can potentially address. Our current areas of focus with LungFit® are PPHN, AVP including COVID-19, BRO and NTM lung infection. Our current product candidates will be subject to premarket reviews and approvals by the FDA, as well as similar regulatory agencies in other countries or regions. If approved, our system will be marketed as a medical device in the United States.

NOTE 2 SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

These consolidated financial statements include the accounts of the Company and the accounts of its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation of the accompanying financial statements.

Use of Estimates

The preparation of consolidated financial statements in conformity with generally accepted accounting principles in the United States ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses for the reporting period. Actual results could differ from those estimates.

On an ongoing basis, the Company evaluates its significant estimates and assumptions including expense recognition and accrual assumptions under consulting and clinical trial agreements, stock-based compensation, impairment assessments, warrant fair value, and the determination of valuation allowance requirements on deferred tax attributes.

Liquidity Risks and Uncertainties

The Company has incurred operating losses in each year since inception. For the year ended March 31, 2021, the Company used $19.6 million in cash to fund operating activities and has accumulated losses of $80.5 million. However, the Company has cash, cash equivalents and restricted cash of approximately $35.3 million as of March 31, 2021. Management estimates that based on the current business plan, such cash and equivalents will be sufficient to fund its operations for at least one year from the date of filing these financial statements.

The Company's future capital needs and the adequacy of its available funds beyond one year from the date of filing these financial statements will depend on many factors, including, but not necessarily limited to, the cost and time necessary for the development, clinical studies and certification or regulatory approval of the Company's product candidates, as well as the commercial success of the Company's product candidates that receive market approval by the FDA. The Company may be required to raise additional funds through sale of equity or debt securities or through strategic collaboration and/or licensing agreements in order to fund operations until it is able to generate enough product or royalty revenues, if any. Such financing may not be available on acceptable terms, or at all, and the Company's failure to raise capital when needed could have a material adverse effect its strategic objectives, results of operations and financial condition.

The Company's access to capital and liquidity currently includes the following:

a) an At-The-Market Equity Offering Sales Agreement (the "ATM") for $50 million of which $37,989,544 remains as of March 31, 2021, see Note 5.

b) a $25 million unsecured loan with certain lenders pursuant to the Facility Agreement (as defined below). The Company has drawn down the first of five tranches of $5 million and has the ability to draw down an additional $5 million tranche at any time prior March 17, 2022 as well as the ability to draw down the remaining $15 million in three subsequent tranches after FDA approval of LungFit® PH, see Note 12.

c) a $40 million stock purchase agreement (the "New Stock Purchase Agreement") of which $29,269,991 remains available as of March 31, 2021 with Lincoln Park Capital Fund, LLC ("LPC"), which replaced the former $20 million purchase agreement with LPC, dated August 10, 2018. The New Stock Purchase Agreement provides for issuances through May 2023 at the Company's discretion, see Note 5.

Other Risks and Uncertainties

The Company is subject to risks common to medical device companies including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, product liability, and the uncertainty of new medical device market acceptance and financing. The Company is dependent on third party suppliers and manufacturers which, in some cases are single-source including two third-party contract manufacturers who have completed a substantial portion of the commercial manufacturing process for our LungFit® PH system.

There can be no assurance that the Company's product will be accepted in the marketplace, nor can there be any assurance that any future products can be developed or manufactured at an acceptable cost and with appropriate performance characteristics, or that such products will be successfully marketed, if at all.

NOTE 2 SIGNIFICANT ACCOUNTING POLICIES (continued)

The Company's products require approval or clearance from the FDA prior to commencing commercial sales in the United States. There can be no assurance that the Company's products will receive all of the required approvals or clearances. Approvals or clearances are also required in foreign jurisdictions in which the Company may license or sell its products. If the Company is denied such approvals or clearances or such approvals or clearances are delayed, it may have a material adverse impact on the Company's results of operations, financial position and liquidity.

The development of the Company's product candidates could be further disrupted and adversely affected by the ongoing COVID-19 pandemic. The spread of SARS CoV-2 resulted in the Director General of the World Health Organization declaring COVID-19 a pandemic on March 11, 2020. The Company has assessed the impact COVID-19 may have on the Company's business plans and its ability to conduct the preclinical studies and clinical trials as well as on the Company's reliance on third-party manufacturing and our supply chain. The Company experienced significant delays in the supply chain for LungFit®. However, there can be no assurance that the Company will be able to further avoid part or all of any impact from COVID-19 or its consequences. The extent to which the COVID-19 pandemic and global efforts to contain its spread may impact the Company's operations will depend on future developments.

Cash and Cash Equivalents and Concentration of Credit Risk

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase and an investment in a U.S. government money market fund to be cash equivalents. The Company maintains its cash and cash equivalents in highly rated financial institutions in Israel, Ireland and the U.S., the balances of which, at times, may exceed federally insured limits.

The Company has no off-balance-sheet concentration of credit risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

As of March 31, 2021 and 2020 restricted cash consisted of $619,000 designated for a contract manufacturer. This cash is expected to be used for material and parts that require a long lead time. As of March 31, 2020, restricted cash also included $5,000,000 of cash in an escrow account from who were a part of the lenders long-term debt transaction.

The following table is the reconciliation of the presentation and disclosure of financial instruments as shown on the Company's consolidated statements of cash flows:

	March 31, 2021	March 31, 2020
Cash and cash equivalents	$ 34,630,682	$ 19,829,275
Restricted cash	637,025	5,635,836
Total	$ 35,267,707	$ 25,465,111

NOTE 2 SIGNIFICANT ACCOUNTING POLICIES (continued)

Revenue Recognition

The Company recognizes revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligation(s) in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) we satisfy the performance obligation(s). At contract inception, the Company assesses the goods or services promised within each contract, assesses whether each promised good or service is distinct, and identifies those that are performance obligations.

The Company uses judgment to determine: a) the number of performance obligations based on the determination under step (ii) above and whether those performance obligations are distinct from other performance obligations in the contract; b) the transaction price under step (iii) above; and c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above. The Company uses judgment to determine whether milestones or other variable consideration, except for royalties, should be included in the transaction price. The transaction price is allocated to each performance obligation on an estimated stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under contract are satisfied. Where a portion of non-refundable up-front fees or other payments received are allocated to continuing performance obligations under the terms of a license arrangement, they are recorded as contract liabilities and recognized as revenue when (or as) the underlying performance obligation is satisfied.

Grant receivable

Under a collaboration arrangement with the Cystic Fibrosis Foundation, grant milestones are achieved subject to certain performance steps and requirements under a development program. Grant milestones are recorded as reimbursements against the applicable portion of the Company's research and development expenses. Such reimbursements are reflected as a reduction of research and development expenses in the Company's consolidated statements of operations, as the performing research and development services for reimbursement is not considered to be an ongoing component or central to the Company's operations.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and managed its business as one segment.

Research and Development

Research and development expenses are charged to the statement of operations as incurred. Research and development expenses include salaries, benefits, stock-based compensation and costs incurred by outside laboratories, manufacturers, clinical research organizations, consultants, and accredited facilities in connection with clinical trials and preclinical studies Research and development expenses are partially offset by the benefit of tax incentive payments for qualified research and development expenditures from the Australian tax authority ("AU Tax Rebates"). The Company does not record AU Tax Rebates until payment is received due to the uncertainty of receipt. To date, the Company has not received any AU Tax Rebates.

NOTE 2 SIGNIFICANT ACCOUNTING POLICIES (continued)

Foreign Exchange Transactions

The Company's subsidiaries have operations in Israel, Ireland, and in Australia. The Company's operations are in the United States and the U.S. dollar is the currency of the primary economic environment in which the Company operates and expects to continue to operate in the foreseeable future. The Company translated its non-U.S. operations' assets and liabilities denominated in foreign currencies into U.S. dollars at current rates of exchange as of the balance sheet date and income and expense items at the average exchange rate for the reporting period. Translation adjustments resulting from exchange rate fluctuations as of March 31, 2021 and 2020 were not material. Gains or losses from foreign currency transactions are included in other income (expense) in the statement of operations as foreign currency exchange gain/(loss).

Stock-Based Compensation

The Company measures the cost of employee and non-employee services received in exchange for an award of equity instruments based on the grant date fair value of the award. Fair value for restricted stock awards is valued using the closing price of the Company's common stock on the date of grant. The grant date fair value is recognized over the period during which an employee and non-employee is required to provide service in exchange for the award – the requisite service period. The grant date fair value of is estimated using the Black-Scholes option pricing model. The risk-free interest rate assumptions were based upon the observed interest rates appropriate for the expected term of the equity instruments. The expected dividend yield was assumed to be zero as the Company has not paid any dividends since its inception and does not anticipate paying dividends in the foreseeable future. Due to the Company's limited trading history, the Company utilizes weighting of its historical volatility and the implied volatility based on an aggregate of guideline companies. The Company uses the simplified method to estimate the expected term.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and accumulated amortization. Depreciation and amortization is calculated using the straight-line method over the estimated useful life of the assets as follows:

Computer equipment	Three years
Furniture and fixtures	Seven years
Clinical and medical equipment	Five or Fifteen years
Leasehold improvements	Shorter of term of lease or estimated useful life of the asset

Licensed Right to Use Technology

Licensed right to use technology that is considered platform technology with alternative future uses is recorded as an intangible asset and is amortized on a straight-line method over its estimated useful life, determined to be thirteen years. See Note 15.

The expected amortization expense for the next five years and thereafter is as follows for the year ended March 31,:

2022	$	38,077
2023		38,077
2024		38,077
2025		38,077
2026		38,077
Thereafter		184,301
Total	$	374,686

Long-Lived Assets

The Company assess the impairment of long-lived assets on an ongoing basis and whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors the Company considers that could trigger an impairment review include the following:

- significant underperformance relative to expected historical or projected future operating results,
- significant changes in the manner of the Company's use of the acquired assets or the strategy for its overall business,
- significant negative regulatory or economic trends, and
- significant technological changes, which would render the platform technology, equipment, and manufacturing processes obsolete.

NOTE 2 SIGNIFICANT ACCOUNTING POLICIES (continued)

Recoverability of assets that will continue to be used in the Company's operations is measured by comparing the carrying value to the future net undiscounted cash flows expected to be generated by the asset or asset group. Future undiscounted cash flows include estimates of future revenues, driven by market growth rates, and estimated future costs. There were no events during the reporting periods that were deemed to be a triggering event that would require an impairment assessment.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in the tax rate is recognized in income or expense in the period that the change is effective. Tax benefits are recognized when it is probable that the deduction will be sustained. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will either expire before the Company is able to realize the benefit, or that future deductibility is uncertain. As of March 31, 2021, and 2020, the Company recorded a valuation allowance to the full extent of the Company's net deferred tax assets since the likelihood of realization of the benefit does not meet the more likely than not threshold.

The Company files U.S. federal, various state, and international income tax returns. Uncertain tax positions are reviewed on an ongoing basis and are adjusted in light of changing facts and circumstances. Such adjustment is reflected in the tax provision when appropriate**.** The Company will recognize interest and penalties, if any, related to unrecognized tax benefits in income taxes in the statements of operations. Tax years 2017 through 2021 remain open to examination by federal and state tax jurisdictions. The Company files tax returns in Israel for which tax years 2015 through 2021 remain open. In addition, the Company files tax returns in Ireland and Australia and the tax year 2020 and 2021 remains open.

Net Income (Loss) Per Share

Basic and diluted net loss per share attributable to common stockholders is computed by dividing the net loss and deemed dividend from a warrant modification to common stockholders by the weighted average number of shares of common stock outstanding for the period. The dilutive effect of outstanding options, warrants, restricted stock and other stock-based compensation awards is reflected in diluted net income (loss) per share by application of the treasury stock method. The calculation of diluted net income (loss) attributed to common stockholders per share excludes all anti-dilutive shares of common stock. For periods in which the Company has reported net losses, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, because such shares of common stock are not assumed to have been issued if their effect is anti-dilutive, see Note 9.

Recently Issued Accounting Standards Adopted

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-15, "Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract (a consensus of the FASB Emerging Issues Task Force)" ("ASU 2018-15"). The amendments in ASU 2018-15 align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). As permitted by ASU 2018-15, the Company early-adopted this standard on a prospective basis, during the year ended March 31, 2021. The adoption did not have a material impact on the consolidated financial statements.

NOTE 2 SIGNIFICANT ACCOUNTING POLICIES (continued)

Recently Issued Accounting Standards Not Yet Adopted

In December 2019, the FASB issued ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes" ("ASU 2019-12") as part of its initiative to reduce complexity in the accounting standards. ASU 2019-12 eliminates certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The standard also clarifies and simplifies other aspects of the accounting for income taxes. ASU 2019-12 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021. Early adoption is permitted. The Company does not anticipate the adoption of this guidance to have a material impact on its consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06," Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity" ("ASU 2020-06"), which simplifies accounting for convertible instruments by removing major separation models required under current U.S. GAAP. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and it also simplifies the diluted earnings per share calculation in certain areas. ASU 2020-06 is effective for the Company on December 1, 2022, Early adoption is permitted, but no earlier than December 1, 2021. The Company is currently evaluating the impact of ASU 2020-06 on its consolidated financial statements and related disclosures.

NOTE 3 FAIR VALUE MEASUREMENT

The Company's financial instruments primarily include cash, cash equivalents, restricted cash, accounts payable, loan, loan payable and the Facility Agreement. Due to the short-term nature of these financial instruments, the carrying amounts of these assets and liabilities approximate their fair value. Long-term debt approximates fair value due to the prevailing market conditions for similar debt with remaining maturity and terms.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value. A fair value hierarchy has been established for valuation inputs that gives the highest priority to quoted prices in active markets for identical assets or liabilities and the lowest priority to unobservable inputs. The fair value hierarchy is as follows:

Level 1 - quoted prices in active markets for identical assets or liabilities;

Level 2 - inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; or

Level 3 - unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

NOTE 4 PROPERTY AND EQUIPMENT

Property and equipment consist of the following:

	March 31, 2021	March 31, 2020
Clinical and medical equipment	$ 1,074,353	$ 357,795
Computer equipment	152,052	73,982
Furniture and fixtures	133,170	53,895
Leasehold improvements	21,840	5,336
	1,381,415	491,008
Accumulated depreciation and amortization	(452,573)	(279,671)
	$ 928,842	$ 211,337

Depreciation and amortization expense for the years ended March 31, 2021 and 2020 was $172,902 and $77,166, respectively.

NOTE 5 STOCKHOLDERS' EQUITY

On August 10, 2018 the Company entered into a Purchase Agreement with Lincoln Park Financial Corporation ("LPC"). The Company may sell and issue LPC and LPC is obligated to purchase up to $20 million in value of shares of common stock from time to time over three years. On May 14, 2020, the Company entered into the New Stock Purchase Agreement, which replaced the former $20 million purchase agreement with LPC. The New Stock Purchase Agreement provides for the issuance of up to $40 million of the Company's common stock which the Company may sell from time to time in its sole discretion to LPC over 36 months, provided that the closing price of the Company's common stock is not below $0.25 per share and subject to certain other conditions and limitations set forth in the New Stock Purchase Agreement. Under both the new and former agreement, for the years ended March 31, 2021 and March 31, 2020, the Company received net proceeds of $11,583,189 and $7,745,012, respectively, from the sale of 1,975,511 and 1,420,000 shares of common stock, respectively. As of March 31, 2021, there was $29,269,991 available under the New Stock Purchase Agreement.

On April 2, 2020, the Company entered into the ATM. Under the ATM, the Company may sell shares of its common stock having aggregate sales proceeds of up to $50 million from time to time and at various prices, subject to the conditions and limitations in the sales agreement. If shares of the Company's common stock are sold, there is a three percent fee paid to the sales agent. For the year ended March 31, 2021, the Company received net proceeds of $11,855,456 from the sale 1,961,201 shares of the Company's common stock. As of March 31, 2021, there was $37,989,544 available under the ATM.

On June 3, 2019, the Company entered into a stock purchase agreement with investors for the issuance of 1,583,743 shares of common stock. The Company raised net proceeds of $7,839,495. The Company's CEO participated in this offering and invested $300,000 and received 58,253 shares of common stock, or $5.15 per share. In addition, certain directors and employees invested $610,000 for an aggregate of 118,254 shares of common stock, at a purchase price of $5.15 per share.

On December 12, 2019, the Company closed on an underwritten offering (the "2019 Offering") and concurrent private placement of 3,152,985 shares of common stock at $3.66 per share for net proceeds of $10,169,343. The shares of common stock issued in the 2019 Offering were registered under the Company's shelf registration statement on Form S-3. 532,786 shares of common stock were sold in a private placement and subsequently registered under a registration statement on Form S-1 that was declared effective on January 23, 2020. In addition, the Company's CEO invested $699,999 and received 190,437 shares of common stock at $3.66 per share. In addition, certain employees participated in this offering by investing $475,000 and receiving 129,781 shares of common stock at $3.66 per share.

NOTE 5 STOCKHOLDERS' EQUITY (continued)

Stock to be Issued to a Vendor

As of March 31, 2020, the Company was obligated to issue 30,000 shares of common stock to a vendor for services related to investor relations. The fair value of the liability as of March 31, 2020 was $240,000. In May 2020, 30,000 shares were issued at the fair value of $242,100. Such amount was transferred to stockholders' equity.

Issuance of Restricted Shares

During the quarter ended December 31, 2020 and March 31, 2021, restricted stock was issued to officers, employees and consultants. The fair value for the restricted stock awards was valued at the closing price of the Company's common stock on the date of grant. Restricted stock vests annually over five years. Stock based compensation related to these stock issuances for the years ended March 31, 2021 and 2020 was $1,349,178 and $895,040, respectively. A summary of the change in warrants options for the years ended March 31, 2020 and 2021 is as follows:

	Number Of Shares	Weighted Average Grant Date Fair Value
Unvested as of April 1, 2019	340,000	$ 4.62
Granted	390,000	5.23
Vested	(67,000)	4.62
Forfeited	(16,200)	4.65
Unvested as of April 1, 2020	646,800	4.99
Granted	62,000	5.81
Vested	(154,600)	5.02
Unvested as of March 31, 2021	554,200	$ 5.07

Stock Option Plans

The Company's Third Amended and Restated 2013 Equity Incentive Plan (the "2013 Plan") allows for awards to officers, directors, employees, and consultants of stock options, restricted stock units and restricted shares of the Company's common stock. The vesting terms of the options issued under the 2013 Plan are generally four years and expires in ten years from the grant date. The 2013 Plan has 5,600,000 shares authorized for issuance which includes. On January 9, 2021, the Company's Board of Directors approved an amendment to the 2013 Plan to increase the number of shares in the 2013 Plan by 1,500,000, which was approved by the Company's stockholders at the 2021 annual stockholder meeting on March 4, 2021. As of March 31, 2021, 502,797 shares were available under the 2013 Plan.

A summary of the change in options for the year ended March 31, 2020 and 2021 is as follows:

	Number Of Options	Weighted Average Exercise Price - Options	Weighted Average Remaining Contractual Life-Options	Aggregate Intrinsic Value
Options outstanding as of April 1, 2020	2,375,812	$ 4.48	9.2	$ 7,952,643
Granted	815,000	5.51		
Exercise	(58,662)	3.59		
Forfeited	(78,561)	4.03	-	
Options outstanding as of March 31, 2020	3,053,589	4.77	8.4	$ 9,878,264
Granted	1,132,500	5.41		
Exercise	(2,340)	0.23		
Forfeited	(6,250)	4.80	-	
Outstanding as of March 31, 2021	4,177,499	$ 4.91	8.4	$ 2,609,100
Exercisable as of March 31, 2021	1,751,474	$ 4.59	7.4	$ 2,427,500

NOTE 5 STOCKHOLDERS' EQUITY (continued)

As of March 31, 2021, the Company had unrecognized stock-based compensation expense of approximately $7.63 million which is expected to be expensed over the weighted average remaining service period of 3.1 years. For the year ended March 31, 2021 and March 31, 2020, the weighted average fair value of options granted was $5.38 and $4.03 per share, respectively. The following was utilized to calculate the fair value of options on the date of grant:

	March 31, 2021	March 31, 2020
Risk -free interest rate	0.6 - 1.1%	0.5% - 3.2%
Expected volatility	91.3 - 91.8%	80.7 - 87.5%
Dividend yield	0%	0%
Expected terms (in years)	6.25	5-10

The following summarizes the components of stock-based compensation expense which included stock options and restricted stock for the years ended March 31, 2021 and March 31, 2020:

	Year Ended March 31,	
	2021	2020
Research and development	$ 2,012,579	$ 687,674
General and administrative	2,882,339	2,889,975
Total	$ 4,894,918	$ 3,577,649

On March 4, 2021, the stockholders approved the 2021 Employee Stock Purchase Plan "ESPP". The purpose of the ESSP is to encourage and to enable eligible employees of the Company, through after-tax payroll deductions, to acquire proprietary interests in the Company through the purchase and ownership of shares of Stock. The EPPP is intended to benefit the Company and its stockholders by (a) incentivizing participants to contribute to the success of the Company and to operate and manage the Company's business in a manner that will provide for the Company's long-term growth and profitability and that will benefit its stockholders and other important stakeholders and (b) encouraging participants to remain in the employ of the Company. As of March 31, 2021, no shares were issued under the ESPP.

Warrants

A modification of the exercise price to the January 2017 and March 2017 investor warrants from $4.25 per share to $3.66 per share was triggered by the 2019 offering described above. As a result, the Company recognized the incremental value of $522,478 as a deemed dividend in the March 31, 2020 reporting period using the Black-Scholes pricing model with the following assumptions:

Expected term in years	2.2
Volatility	87%
Dividend yield	0.0%
Risk-free interest rate	0.7%

A summary of the Company's outstanding warrants as of March 31, 2021 are as follows:

Warrant Holders	Number Of Warrants	Exercise Price	Date of Expiration
January 2017 offering – investors	2,977,232	$ 3.66	January 2022 (a)
March 2017 offering – investors	68,330	$ 3.66	March 2022 (a)
March 2017 offering - placement agent	7,541	$ 3.66	March 2022 (a)
Third-party license agreement	208,333	$ 4.80	January 2024
March 2020 loan (see Note 12)	172,187	$ 7.26	March 2025
Total	3,433,623		

(a) These warrants have down round protection.

NOTE 5 STOCKHOLDERS' EQUITY (continued)

For the year ended March 31, 2021 and 2020, 1,583,028 and 985,694 warrants were exercised into common shares from the proceeds of $6,672,031 and $3,968,944 respectively. For the year ended March 31 2021 and 2020, warrant holders exercised 165,405 and 156,154 warrant shares on a cashless basis for 65,204 and 73,461 shares of common stock, respectively.

NOTE 6 OTHER CURRENT ASSETS PREPAID EXPENSES

A summary of current assets and prepaid expenses is as follows:

	March 31, 2021	March 31, 2020
Research and development	$ 271,727	$ 266,510
Insurance	971,140	471,182
Professional	-	156,259
Value added tax receivable	41,272	124,127
Other	245,957	131,728
Total	$ 1,530,096	$ 1,149,806

NOTE 7 ACCRUED EXPENSES

A summary of the accrued expenses is as follows:

	March 31, 2021	March 31, 2020
Research and development	$ 584,802	$ 484,756
Professional fees	708,800	476,638
Employee salaries and benefits	269,787	71,066
Other	241,549	65,074
Total	$ 1,804,938	$ 1,097,534

NOTE 8 LEASES

On April 1, 2019, the Company early adopted ASU No. 2016-02, Leases (Topic 842), as amended ("ASU 2016-02"), which generally requires lessees to recognize operating and financing lease liabilities and corresponding right-of-use assets on the balance sheet and to provide enhanced disclosures surrounding the amount, timing and uncertainty of cash flows arising from leasing arrangements. During the year ended March 31, 2021, the Company entered into two new leases and cancelled a lease, which resulted in the recognition of operating lease liabilities and right-of-use assets of same amount of $1,777,192. The cancellation of the lease resulted in a derecognition of operating lease liabilities and right-of-use assets of $19,329 and $17,486, respectively. As a result of the cancellation, the Company recorded a gain of $1,843. The right-of use assets and operating lease liability are as follows:

	March 31, 2021	March 31, 2020
Right-of-use assets	$ 1,860,885	$ 195,727
Operating lease liability short-term	$ 113,141	$ 69,342
Operating lease liability long-term	1,789,461	131,581
Total	$ 1,902,602	$ 200,923

Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as prepaid or accrued rent. The interest rate implicit in the Company's leases is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. Operating lease expense is recognized on a straight-line basis over the lease term and is included in general and administrative and research development expenses. The Company has other operating lease agreements with commitments of less than one year or that are not significant. The Company elected the practical expedient option and as such these lease payments are expensed as incurred.

Other Information For The Year Ended March 31, 2021	
Cash paid for amounts included in the measurement of lease liabilities:	
Cash paid	$ 104,041
Right-of-use assets obtained in exchange for new operating lease liabilities:	-
Weighted-average remaining lease term — operating leases	9.1 years
Weighted-average discount rate — operating leases	8.3%

Maturity of Lease Liabilities	**Operating Leases**
Payments remaining for the year ended March 31:	
2022	$ 266,193
2023	328,475
2024	286,786
2025	277,451
2026	284,590
Thereafter	1,328,640
Total lease payments	2,772,135
Less: interest	(869,533)
Present value of lease liabilities	$ 1,902,602

NOTE 9 BASIC AND DILUTED NET INCOME (LOSS) PER SHARE OF COMMON STOCK

The following potentially dilutive securities were not included in the calculation of diluted net income (loss) per share attributable to common stockholders because their effect would have been anti-dilutive for the periods presented:

	March 31, 2021	March 31, 2020
Common stock warrants	3,433,623	5,173,724
Common stock options	4,177,499	3,053,589
Restricted shares	554,200	646,800
Total	8,165,322	8,874,113

NOTE 10 LICENSE AGREEMENT

On January 23, 2019, the Company entered into the Circassia Agreement with Circassia for PPHN and future related indications at concentrations of $\leq$ 80 ppm in the hospital setting in the United States and China. On December 18, 2019, the Company terminated the Circassia Agreement, see Note 15.

This contract consisted of five performance obligations with only the following two obligations required prior to the termination of the License Agreement:

- Performance Obligation 1: non-exclusive transfer of functional intellectual property rights to Circassia, which includes:

  the consummation of the Circassia Agreement, which included significant pre-agreement negotiation and product specification, and

NOTE 10 LICENSE AGREEMENT (continued)

the successful completion of the pre-submission meeting with the FDA. At this meeting, the FDA reinforced its assessment of the LungFit® PH as a medical device and the requirements for approval.

- Performance Obligation 2: ongoing support associated with the PMA submission and regulatory approval by the FDA. This also includes development activities including manufacturing readiness process ahead of such approval.

During the three months ended March 31, 2019, the Company met the first two milestones under the license agreement and received 17,572,815 shares of common stock valued at $9,987,295. This consideration was allocated to the first two performance obligations; one being the transfer of the intellectual property to Circassia, which was recognized at a point in time and was valued at $7,116,232 and the other being the ongoing support associated with the PMA submission and regulatory approval by the FDA, which was valued at $2,871,063 and was recorded as deferred revenue.

The second performance obligation was recognized over a period of time; from the commencement of the agreement to when management expects to submit the PMA. License revenue of $873,190 and $1,390,104 associated with this second performance obligation has been recognized for the year ended March 31, 2021 and 2020, respectively. As of March 31, 2021, and 2020, deferred revenue was $0 and $873,190, respectively.

NOTE 11 GRANT COLLABORATON AGREEMENT

On February 10, 2021, the Company received a grant for up to $2.17 million from the Cystic Fibrosis Foundation (“CFF”) to advance the clinical development of high concentration NO for the treatment of Nontuberculous Mycobacteria, or NTM pulmonary disease, which disproportionally affects CF patients. Under the terms of the agreement, the funding will be allocated to the ongoing LungFit® GO NTM pilot study. The grant provides milestones based upon achieving performance steps and requirements under a development program. The grant provides for royalty payments to CFF upon the commercialization of any product developed under the grant program at a rate of 10% of net sales. The royalties are capped at four times the grant actually paid to the Company.

NOTE 12 LONG-TERM LOAN

On March 17, 2020, the Company entered into the Facility Agreement for up to $25,000,000 in five tranches of $5,000,000 per tranche. Such tranches are at the option of the Company; provided, however that the Company may only utilize tranches three through five following FDA approval of the LungFit® PH product. The loan(s) are unsecured with interest at 10% per year which is to be paid quarterly. The loans may be prepaid with certain prepayment penalties. The effective interest rate for this loan is 13.3% per year. Each tranche shall be repaid in installments commencing June 15, 2023 with all amounts outstanding under any tranche due on March 17, 2025. The Company received proceeds from the first tranche in fiscal year 2020. A lender who is over a five percent stockholder loaned the Company $3,160,000 of the first tranche and, as such, related party interest expense for the years ended March 31, 2021 and March 31, 2020 was approximated $316,000 and $12,100 (not including amortization of debt discount and deferred offering costs), respectively.

In connection with the first tranche, the Company issued, in March 2020, warrants to the lenders for the purchase of 172,826 shares of the Company’s common stock at $7.26 per share. The warrants expire in five years. There are additional warrant issuances associated with each tranche. If the second tranche of $5 million is utilized by the Company, the warrants that will be issued is up to twenty five percent of its commitment value divided by the five-day volume-weighted average price (“VWAP”) prior to utilization date. For tranches three to five, if any of these tranches are utilized by the Company, the warrants that will be issued is up to ten percent of its commitment value divided by the five-day VWAP. The Company allocated the fair market value of the warrants at the date of grant to stockholders’ equity and reflected a debt discount of $594,979. Debt discount and debt issuance costs are amortized over the life of the loan.

NOTE 12 LONG-TERM LOAN (continued)

The Black-Scholes option pricing model used the following assumptions:

Expected term in years	5.0
Volatility	87.5%
Dividend yield	0.0%
Risk-free interest rate	0.7%

A summary of the long-term loan balance is as follows:

	March 31, 2021	March 31, 2020
Face value of loan	$ 5,000,000	$ 5,000,000
Debt discount	(594,979)	(594,979)
Accretion of debt discount	123,493	4,562
Amortization of debt offering costs	14,750	545
Debt offering costs	(71,063)	(71,063)
Total	$ 4,472,201	$ 4,339,065

Maturity of Long-Term Loan	March 31, 2021
2022	$ -
2023	-
2024	2,000,000
2025	3,000,000
Total	$ 5,000,000

NOTE 13 LOAN PAYABLE

As of March 31, 2021 and 2020 in connection with the Company's insurance policy, a loan was used to finance part of the premium. The following details concerning each loan is as follows:

	March 31, 2021	March 31, 2020
Amount outstanding	$ 556,514	$ 335,358
Monthly payments	$ 70,396	$ 42,366
Number of monthly payments	9	9
Interest rate	3.2%	4.3%
Due date	November 2021	November 2020

NOTE 14 INCOME TAXES

As of March 31, 2021, the Company has approximately $38,258,000 and $18,526,000 of unused NOL carryforwards for federal tax purposes and for Israeli tax purpose, respectively. Net operating loss carryforwards of approximately $1,375,000, which were generated prior to March 2018 expire through 2037. The net operating loss of approximately $36,883,000 can be carried forward indefinitely, but limited to offset 80% of taxable income. The entire net operating loss for Israel can be carried forward indefinitely. The Company also has state net operating losses in the amount of approximately $38,896,000 expiring during the years from 2035 to 2041. Under Section 382 of the Internal Revenue Code of 1986, as amended, changes in the Company's ownership may limit the amount of its net operating loss carryforwards that could be utilized annually to offset future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of the Company of more than 50% within a three-year period. The Company has not performed a study to assess whether an ownership change for purposes of Section 382 has occurred, or whether there have been multiple ownership changes since the Company's inception, due to the significant costs and complexities associated with such study.

Under Section 382 of the Internal Revenue Code of 1986, as amended, changes in the Company's ownership may limit the amount of its net operating loss carryforwards that could be utilized annually to offset future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of the Company of more than 50% within a three-year period. The Company has not performed a study to assess whether an ownership change for purposes of Section 382 has occurred, or whether there have been multiple ownership changes since the Company's inception, due to the significant costs and complexities associated with such study

NOTE 14 INCOME TAXES (continued)

The components of net loss before the provision for income taxes are as follows:

	For the Year Ended March 31, 2021	For the Year Ended March 31, 2020
Domestic	$ (21,417,016)	$ (16,685,568)
Foreign	(1,457,715)	(3,411,236)
Total	$ (22,874,731)	$ (20,096,804)

There is no provision for income taxes because the Company has historically incurred operating losses and maintains a full valuation allowance against its net deferred tax assets. The valuation allowance increased by approximately $6,678,000 during the year ended March 31, 2021.

The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets were as follows:

	March 31, 2021	March 31, 2020
Net operating loss carry forward	$ 15,121,000	$ 9,017,000
Research and development tax credits	939,000	524,000
Other	(48,000)	71,000
Reserves and allowances - foreign	-	6,000
Stock-based compensation	1,956,000	880,000
Capital loss carry forward	1,559,000	1,571,000
Research and development - foreign	-	550,000
Deferred revenue	-	241,000
Right-of-use asset	(516,000)	(56,000)
Lease liability	527,000	56,000
Net deferred tax	19,538,000	12,860,000
Valuation allowance	(19,538,000)	(12,860,000)
Net deferred tax asset	$ -	$ -

A reconciliation of income tax expense calculated at the federal enacted statutory rate of 21% is as follows:

	March 31, 2021	March 31, 2020
Federal income tax at statutory rate	(21.00)%	(21.00)%
State income tax, net of federal benefit	(6.25)	(7.08)
Permanent items	-	2.48
Change in valuation allowance	29.19	30.67
Research and development tax credits	(1.82)	(1.39)
Other	(0.12)	(3.68)
Effective income tax expense rate	0.00%	0.00%

NOTE 15 COMMITMENTS AND CONTINGENCIES

License Agreements

On October 22, 2013, the Company entered into a patent license agreement (the "CareFusion Agreement") with SensorMedics Corporation, a subsidiary of CareFusion Corp. ("CareFusion"), pursuant to which the Company agreed to pay to CareFusion a non-refundable upfront fee of $150,000 that is credited against future royalty payments, and is obligated to pay 5% royalties of any licensed product net sales, but at least $50,000 per annum during the term of the agreement. As of March 31, 2021, the Company has not paid any royalties to CareFusion since the Company has not received any revenues from the technology associated with the license under the CareFusion Agreement. The term of the CareFusion Agreement extends through the life of applicable patents and may be terminated by either party with 60 days' prior written notice in the event of a breach of the CareFusion Agreement, and may be terminated unilaterally by CareFusion with 30 days' prior written notice in the event that the Company does not meet certain milestones.

In August 2015, BA Ltd. entered into an Option Agreement (the "Option Agreement") with Pulmonox whereby BA Ltd. acquired the option to purchase certain intellectual property assets and rights. On January 13, 2017, the Company exercised the Option and paid $500,000 to Pulmonox. The Company becomes obligated to make certain one-time development and sales milestone payments to Pulmonox, commencing with the date on which the Company receive regulatory approval for the commercial sale of the first product candidate qualifying under the Option Agreement. These milestone payments are capped at a total of $87 million across three separate and distinct indications that fall under the agreement, with the majority of them, approximately $83 million, being sales-related based on cumulative sales milestones for each of the three products.

On January 31, 2018, the Company entered into the NitricGen Agreement to acquire a global, exclusive, transferable license and associated assets including intellectual property, know-how, trade secrets and confidential information from NitricGen related to the LungFit®. The Company acquired the licensing right to use the technology and agreed to pay NitricGen a total of $2,000,000 in future payments based upon achieving certain milestones, as defined in the NitricGen Agreement, and royalties on sales of the LungFit®. The Company paid NitricGen $100,000 upon the execution of the NitricGen Agreement, $100,000 upon achieving the next milestone and issued 100,000 warrants to purchase the Company's common stock valued at $295,000 upon executing the NitricGen Agreement. The remaining future milestone payments are $1,800,000 of which $1,500,000 is due six months after the first approval of the LungFit® by the FDA or the European Medicine Agency.

Employment Agreements

Certain agreements between the Company and its officers contain a change of control provision for payment of severance arrangements.

Supply Agreement and Purchase Order

In August 2020, the Company entered into a supply agreement expiring on December 31, 2024. The agreement will renew automatically for successive three-year periods unless and until the Company provides twelve months' notice of intent not to renew. In July 2020, the Company placed a non-cancellable purchase order and the outstanding amount remaining under the purchase order as of March 31, 2021 is approximately $1,054,000 with this supplier.

NOTE 15 COMMITMENTS AND CONTINGENCIES (continued)

Contingencies

On March 16, 2018, Empery Asset Master, Ltd., Empery Tax Efficient, LP and Empery Tax Efficient II, LP, (collectively, "Empery"), filed a complaint in the NY Supreme Court (the "NY Supreme Court"), relating to the notice of adjustment of both the exercise price of and the number of warrant shares issuable under warrants issued to Empery in January 2017 (the "Empery Suit"). The Empery Suit alleges that, as a result of certain circumstances in connection with the Company's February 2018 offering, the 166,672 warrants issued to Empery in January 2017 provide for adjustments to both the exercise price of the warrants and the number of warrant shares issuable upon such exercise. Empery seeks monetary damages and declaratory relief under theories of breach of contract or contract reformation.

While the Company believes that it has complied with the applicable protective features of the 2017 Warrants and properly adjusted the exercise price, if Empery were to prevail on all claims, the new adjusted total number of warrant shares could be as follows: 319,967 warrant shares for Empery Asset Master, Ltd., 159,869 warrant shares for Empery Tax Efficient, LP and 252,672 warrant shares for Empery Tax Efficient II, LP, and the exercise price could be reduced from $3.66 to $1.57 per share. On March 9, 2020, the Company filed a motion for summary judgment, which was denied by order of the NY Supreme Court entered on August 20, 2020, except for the second claim for relief for declaratory judgment which was dismissed as moot. On October 1, 2020, the Company filed a Notice of Appeal and appeal of the NY Supreme Court's denial of summary judgment remains pending. Trial of this matter was conducted from April 19, 2021 to April 21, 2021, and a decision was reserved pending post-trial briefing of various issues, to be fully submitted by June 30, 2021.

While the Company asserted at trial and continues to asset several meritorious defenses against the claims, the ultimate resolution of the matter, if unfavorable, could result in a material loss.

In addition to Empery, there are 1,139,220 2017 Warrants outstanding held by investors who did not participate in the February 2018 financing transaction. Any further adjustments to the 2017 Warrants pursuant to their antidilution provisions may result in additional dilution to the interests of the Company's stockholders and may adversely affect the market price of the Company's common stock. The antidilution provisions may also limit the Company's ability to obtain additional financing on terms favorable to it.

NOTE 16 SUBSEQENT EVENTS

On May 25, 2021, the Company and Circassia Limited entered into a Settlement Agreement resolving all claims by and between both parties and mutually terminating the Circassia agreement disclosed in Note 10. Pursuant to the terms of the Settlement Agreement, the Company agreed to pay Circassia $10.5 million in three installments, the first being a payment of $2.5 million to Circassia within fifteen (15) days following FDA approval of the LungFit® PH (the "Initial Payment Due Date"). Thereafter, the Company shall pay $3.5 million to Circassia on the first anniversary of the Initial Payment Due Date and $4.5 million on the second anniversary of the Initial Payment Due Date. Additionally, beginning in year three post-approval, Circassia will receive a quarterly royalty payment equal to 5% of LungFit® PH net sales in the US. This royalty will terminate once the aggregate payment reaches $6.0 million. This product candidate continues to be under FDA review.

Exhibit 21.1

Subsidiary	Jurisdiction of Incorporation
Beyond Air Ltd.	Israel
Beyond Air Ireland Limited	Ireland
Beyond Air Australia Pty. Ltd.	Australia

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-231416, 333-233283, and 333-237958) and Form S-8 (No. 333-227697 and 333-238239) of Beyond Air, Inc. (formerly AIT Therapeutics, Inc.) and Subsidiaries of our report dated June 10, 2021 relating to the consolidated financial statements of Beyond Air, Inc., which appear in this Form 10-K.

/s/ Friedman LLP

East Hanover, NJ
June 10, 2021

Exhibit 31.1

CERTIFICATIONS

I, Steven A. Lisi, certify that:

1. I have reviewed this Annual Report on Form 10-K of Beyond Air, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

June 10, 2021

/s/ Steven A. Lisi

Steven A. Lisi
Chairman and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Douglas Beck, certify that:

1. I have reviewed this Annual Report on Form 10-K of Beyond Air, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

June 10, 2021

/s/ Douglas Beck

Douglas Beck
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Steven A. Lisi, Chairman and Chief Executive Officer of Beyond Air, Inc. (the "Company"), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. The Annual Report on Form 10-K of the Company for the year ended March 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

June 10, 2021

/s/ Steven A. Lisi

Steven A. Lisi
Chairman and Chief Executive Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Douglas Beck, Chief Financial Officer of Beyond Air, Inc. (the "Company"), hereby certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

1. The Annual Report on Form 1010-K of the Company for the year ended March 31, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

June 10, 2021

/s/ Douglas Beck

Douglas Beck
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)