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, 2020

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 **(State or Other Jurisdiction of Incorporation or Organization)**	**47-3812456** **(I.R.S. Employer Identification No.)**
825 East Gate Boulevard, Suite 320 **Garden City, NY** **(Address of Principal Executive Offices)**	**11530** **(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, 2019, 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 $32,811,314 based on the last reported sale price of the registrant's common stock on the Nasdaq Capital Market.

There were 16,841,555 shares of common stock outstanding as of June 19, 2020.

DOCUMENTS INCORPORATED BY REFERENCE

None.

Beyond Air, Inc.

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FORWARD-LOOKING STATEMENTS AND MARKET DATA

This Annual Report on Form 10-K 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 and Section 21E of the Securities Exchange Act of 1934. 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 products, product approvals, 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 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 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 recent pandemic of COVID-19, 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.

PART I

ITEM 1. BUSINESS

Corporate History

Beyond Air, Inc., sometimes referred to as "we" or the "Company", was incorporated on April 24, 2015 as KokiCare, Inc. ("KokiCare") under the laws of the State of Delaware. On December 29, 2016, we entered into an Agreement and Plan of Merger, which, as amended, we refer to as the Merger Agreement, together with Red Maple Ltd., or Merger Sub, a wholly owned subsidiary of KokiCare, and Advanced Inhalation Therapies (AIT) Ltd., or AIT Ltd. The Merger Agreement provided for (i) the merger of Merger Sub with and into AIT Ltd. pursuant to the laws of the State of Israel, referred to as the Israeli Merger, and (ii) the conversion of the ordinary shares and other outstanding securities of AIT Ltd. into the right to receive shares and other applicable securities of KokiCare, with AIT Ltd. surviving as our wholly owned subsidiary, which we refer to as the Merger. The Israeli Merger became effective on December 29, 2016 and the Merger closed on January 13, 2017. On January 9, 2017, the Company changed its name to AIT Therapeutics, Inc. from KokiCare, Inc. On June 25, 2019, the Company changed its name to Beyond Air, Inc. from AIT Therapeutics, Inc., effective June 26, 2019.

AIT Ltd. was incorporated in Israel on May 1, 2011 and commenced its operations in May 2012. Effective July 4, 2019, AIT Ltd. changed its name to Beyond Air Ltd.

Business Overview

We are an emerging 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. LungFit™ can generate NO up to 400 parts per million ("ppm") for delivery to a patient's lungs. 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 LungFit™ can potentially address. Our current areas of focus with the LungFit™ are persistent pulmonary hypertension of the newborn ("PPHN"), severe acute respiratory syndrome coronavirus 2 (SARS CoV-2), bronchiolitis ("BRO") and nontuberculous mycobacteria ("NTM"). Our current product candidates will be subject to premarket reviews and approvals by the U.S. Food and Drug Administration, or 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 the Company is solid tumors. For this indication the LungFit™ system is not utilized due to the ultra-high concentrations of NO used. We have developed a delivery system that can safely deliver NO concentrations in excess of 10,000 ppm directly to a solid tumor. This program is in pre-clinical development and will require FDA, or similar agency in another country, approval to enter human studies.

With respect to PPHN, our novel LungFit™ 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). We believe LungFit™ has many competitive advantages over the current approved NO delivery systems in the U.S., European Union, Japan and other markets. For example, LungFit™ does not require the use of a high-pressure cylinder, utilizes less space than other similar devices, does not require cumbersome purging procedures and places less burden on hospital staff in carrying out safety procedures.

Our novel LungFit™ system can also deliver a high concentration of NO to the lungs, which we believe has the potential to eliminate microbial infections, including bacteria, fungi and viruses, among other benefits. We believe current FDA-approved NO vasodilation treatments would have limited success in treating microbial infections given the low concentrations of NO being delivered. 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 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 the delivery of a dosage of NO at 150 ppm or higher to the lungs.

To date, we have conducted the following studies:

Date	Study	Indication	Primary	Results
2011	Phase 1 Safety (n=10)	All comers	Safety	• No SAEs
2013 –2014	POC double blind randomized (n=43)	Bronchiolitis (due to any virus)	Safe & Eff	• No SAEs; 24 hour reduction in hospital length of stay
2013 - 2014	Pilot open label (n=9)	Cystic Fibrosis (CF)	Safe & Eff	• No SAEs; Lowered bacterial load
2016	Compassionate use ISR (n=2)	NTM abscessus (CF)	Safe & Eff	• No SAEs; clinical & surrogate endpoints improved
2017	Compassionate use National Institute of Health, US (n=1)	NTM abscessus (CF)	Safe & Eff	• No SAEs; Improvements in clinical endpoints
2017	Pilot open label (N=9)	NTM abscessus	Safe & Eff	• No SAEs; clinical & surrogate endpoints improved
2018	Pilot: double blind randomized (n=67)	Bronchiolitis (due to any virus)	Safe & Eff	• No SAEs; 27hr 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=89)	Bronchiolitis (due to any virus)	Safe & Eff	• No SAEs; 150 ppm treatment showed statistically significant improvements in primary and key secondary endpoints compared to both 85 ppm and control

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

Product	Indication	Development Status	Key Dates[1]	US Sales Potential[2]	Worldwide Sales Potential[2]
LungFit™ PH Ventilator compatible	In-Hospital use for PPHN and cardiac surgery	Final preparations for PMA	PMA filing 2H 2020 US launch 1H 2021	>$300 million	>$600 million
LungFit™	COVID-19	Pilot studies in progress	Pilot study data 2H 2020	N/A	N/A
	Bronchiolitis	3 Pilot studies complete Pivotal-ready	Pivotal starts 4Q21 US launch 2023	>$500 million Beyond Air to commercialize	>$1.2 billion
LungFit™ Home	Nontuberculous mycobacteria (NTM) lung infection	Pilot phase	4Q20 start for pilot Study with self-administration	>$1 billion	>$2.5 billion
	Severe exacerbations due to lung infections in COPD patients	Pre-clinical	Pilot study start 2H21	>$2.5 billion	>$6 billion
Solid Tumors	Multiple solid tumors	Pre-clinical	Initial data presented AACR June 2020	TBD	TBD

† *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) All figures are Company estimates for peak year sales: Global sales potential includes US sales potential

We plan to submit for premarket approval or ("PMA") to the FDA towards the end of the third quarter of 2020 for the use of the LungFit™ in PPHN. We also expect to make certain regulatory filings outside of the U.S. later in 2020. According to the 2019 year-end report from Mallinckrodt Pharmaceuticals, aggregate sales of low concentration NO in the U.S. were in excess of $500 million in 2019, while sales outside of the U.S., where there are multiple market participants, sales were considerably lower than in the U.S. We believe the U.S. sales potential of LungFit™ 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 both the U.S. and Israel in 2021 and will continue to launch globally throughout 2021 and beyond.

SARS CoV-2 is a global pandemic with a widespread impact across many countries. We have received approval from the FDA to run a study in COVID-19 (the disease caused by SARS CoV-2 infections) patients using our LungFit™ system. We have also received approval from Health Canada to run a similar study to the one approved by the FDA. We look forward to results from both of these studies in the summer/fall of 2020. The fact that our system does not need cylinders allows us to potentially provide a practical solution to this crisis. We have applied for grants related to COVID-19 in the United States and other countries. However, no external funding is required to perform the clinical studies recently approved by FDA and Health Canada.

With respect to bronchiolitis, we initiated in the fourth quarter of 2019 a double blind, controlled trial in infants hospitalized due to bronchiolitis with three arms and 89 subjects randomized 1:1:1 to standard supportive therapy (SST), SST plus 85 ppm NO and SST plus 150 ppm NO. The trial is complete and we recently released top line data. There were no SAE's related to NO therapy. With respect to efficacy, the 150 ppm arm was statistically significant when compared to both the control arm and the 85 ppm arm on the Primary endpoint of fit for discharge from the hospital and the key secondary endpoint of hospital length of stay. The 85 ppm was no different from control on both endpoints. We believe this is an exceptional result given the low number of patients and provides compelling evidence of the value of 150 ppm in achieving the desired efficacy. The pivotal study for bronchiolitis was originally set to be performed in the 2020/21 winter, but due to the SARS CoV-2 pandemic, hospitals will not be considering any new study proposals not related to SARS CoV-2 or COVID-19. We anticipate commencing a pivotal study in the United States in the fourth quarter of 2021 and completing it late in the second quarter of 2022. We expect that we will submit a PMA to the FDA about 6 months after trial completion. Regulatory filings outside of the U.S. would begin after our review process is completed in the U.S. as long as no additional trials are required. For this indication, we believe U.S. sales potential to be greater than $500 million and worldwide sales potential to be greater than $1.2 billion.

Over 3 million new cases of bronchiolitis are reported worldwide each year. In the U.S., there are approximately 130,000 annual bronchiolitis hospitalizations among children two years of age or younger and approximately 177,000 annual hospitalizations among the elderly population related to RSV infection only with the number rising higher due to other viruses similar to those that cause bronchiolitis in very young children.

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.

Our NTM program has produced data from four compassionate use subjects and nine patients from a multi-center pilot study completed in 2018. All patients suffered from NTM *abscessus* infection and had underlying cystic fibrosis. One compassion patient was treated with our nitric oxide generator at the National Heart, Lung and Blood Institute ("NHLBI"). All others were treated with our NO cylinder-based delivery system. All patients were treated with 160 ppm NO at intermittent 30-minute dosing over 21 days, except one patient who was treated over 26 days and another patient who was treated with 250 ppm NO over 28 days. We expected to begin a study by the end of 2020 (delayed about 6 months by the COVID-19 pandemic) where patients would self-administer high concentration NO at home over a period of 12 weeks with LungFit™. We now anticipate preliminary data for this study will be available during the first half of 2021 and that a full dataset will be available in the second half of 2021. If the trial is successful, we would commence a pivotal study in 2022. 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.

NTM lung infection is a rare and serious pulmonary disease associated with increased morbidity and mortality. There is an increasing rate of lung disease caused by NTM, which is an emerging public health concern worldwide. There are approximately 50,000 patients diagnosed with NTM in the U.S., and there are an estimated additional 100,000 patients in the U.S. that have not yet been diagnosed. In Asia, the number of patients suffering from NTM surpasses what is seen in the U.S. To date we have treated only the *abscessus* form of NTM which comprises approximately 20-25% of all NTM. We will be treating both the*abscessus and mycobacterium avium complex (MAC)* forms of NTM.

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 *abscessus* 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 NTM *abscessus* lung disease in North America, Europe or Japan. There is one inhaled antibiotic approved in the U.S. for the treatment of refractory NTM MAC. Current guideline-based approaches to treat NTM lung disease involve multi-drug regimens of anti-biotics 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 1997 and 2007, researchers found that the prevalence of NTM in the U.S. is increasing at approximately 8% per year and that NTM patients on Medicare over the age of 65 are 40% more likely to die over the period of the study than those who did not have the disease (Adjemian et al., 2012). NTM *abscessus* treatment costs are estimated to be more than double that of NTM MAC. In total, a 2015 publication from co-authors from several U.S. government departments stated that prior year statistics led to a projected 181,037 national annual cases in 2014 costing the U.S. healthcare system approximately $1.7 billion (Strollo et al., 2015).

For our solid tumor program, we released pre-clinical data at the virtual American Academy of Cancer Research (AACR) showing the promise of delivering NO at concentrations of 25,000 ppm – 200,000 ppm directly to tumors. Results showed local tumor ablation with complete eradication in 5 of 30 mice. Additionally, regardless of whether the tumor was completely or partially cleared, all colon tumor bearing mice were resistant to a second challenge of colon cancer. Breast tumor bearing mice showed a 7-10 day delay in the uptake of breast cancer post challenge. Pre-clinical work will continue throughout the rest of 2020 and most of 2021.

Our program in chronic obstructive pulmonary disease is in the pre-clinical stage and will remain there, subject to our obtaining additional financing

Background and 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 helminthes. 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 cystic fibrosis (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, or CVB, RSV, influenza, severe acute respiratory syndrome, or SARS, coronavirus, rhinovirus, herpes simplex virus, or HSV, 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. The 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 it user friendly, with operation and maintenance that we believe will be immediately familiar to medical staff. Our LungFit™ system for use with a mask 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 formulations of NO currently 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 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 chronic obstructive pulmonary disease (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. 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 U.S. Food and Drug Administration. 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 agree 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 options 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.

Strategies

Our objective is to build a leading medical device company that will develop and commercialize patented and proprietary products for the treatment of respiratory infections and diseases, with an initial focus on the treatment of PPHN, bronchiolitis, severe lung infections such as NTM and SARS Cov-2, severe infections in chronic obstructive pulmonary disease, or COPD, and CF patients. If our clinical trials for our product candidates are successful, we expect to seek marketing approval from the FDA and other worldwide regulatory bodies.

Our completed clinical trials and plans for future clinical trials are as follows:

- We licensed Phase 1 study results in healthy volunteers from University of British Columbia Hospital, or UBC. Results showed safe delivery of 160 ppm NO to the lung.

- *Bronchiolitis*. We have completed three separate double blind, randomized, placebo controlled studies conducted in Israel in infants with bronchiolitis. All three studies resulted in consistent data showing no serious adverse events (SAEs) related to NO therapy and a significant reduction in hospital length of stay. Our most recent study completed in May 2020 showed results in 89 subjects randomized 1:1:1 to SST, SST plus 85 ppm NO and SST plus 150 ppm NO where 150 ppm was statistically significant compared to both the 85 ppm NO arm and the control arm on the primary endpoint and key secondary endpoint with the 85 ppm arm no different from control. We intend to submit an Investigational Device Exemption ("IDE") to the FDA in 2020 and expect to commence a pivotal clinical trial in 2021 in the United States which will complete in 2022,

- *NTM*. Four patients with CF suffering from NTM infections (specifically, M. Abscessus) have been treated under compassionate use, including two patients at the Rambam healthcare campus in Israel, one at Soroka Medical Center in Israel and one patient in the United States, treated with an early version of our LungFit™ system, at the National Heart, Lung and Blood Institute (NHLBI). A pilot study of nine CF patients infected with NTM Abscessus in Israel treated with NO using cylinder gas was completed in the fourth quarter of 2017. In addition, we intend to perform an at-home self-administration study. The study will use the LungFit™ system and treat patients infected with NTM. Endpoints are expected to include physical function, bacterial load, forced expiratory volume in one second (FEV1), quality of life and safety. The study is anticipated to commence late in 2020.

- *CF-Related Lung Infections*. We completed a pilot open label, multi-center study in Israel of CF patients who are over 10 years old. Results showed a reduction in bacterial load in multiple infections.

Our Initial Disease Targets and Market Opportunity

Our initial targets are PPHN, infants suffering from bronchiolitis, Covid-19 patients and patients with NTM lung infection.

PPHN is a condition at birth that requires mechanical ventilation. NO is added as a vasodilator to improve oxygenation and reduce the need for ventilation in neonates with hypoxic respiratory failure. The use of NO in the hospital setting had associated net sales of greater than $500m in 2019 in the United States alone according to published reports.

According to the World Health Organization, bronchiolitis is the most common acute lower respiratory infection in infants, and is the leading cause of the hospitalization of infants during the first year of life. Bronchiolitis is an acute inflammatory injury of the bronchioles that is usually caused by viruses, most commonly by RSV. While bronchiolitis may affect persons of any age, severe symptoms are usually evident only in young infants. The initial symptoms of bronchiolitis are similar to that of a common cold, but the illness sometimes leads to fast and troubled breathing due to spread of the infection to the lower respiratory system. To date, the standard treatment has been supportive care consisting of assisted feeding and hydration, minimal handling, nasal suctioning and oxygen administration. In addition, better airway cleaning, which improves the respiratory function, has been achieved using nebulized hypertonic saline. We believe that many pharmacological therapies, ranging from bronchodilators to corticosteroids, have been found to offer either no or short-term benefits.

Each year, according to the World Health Organization, 150 million new cases of bronchiolitis are reported worldwide in infants, and 2-3% of infants affected require hospitalization. In the U.S., there are greater than 150,000 annual bronchiolitis hospitalizations among children younger than five years, of which greater than 100,000 hospitalizations are among children younger than two years old. These hospital visits resulted in total hospital charges of $1.7 billion in 2009 according to a study published in 2013. For infants, bronchiolitis accounts for 20% of annual hospitalizations and 18% of emergency department visits.

Clinical practice in the management of acute bronchiolitis varies widely even among medical centers in the same country, and there is much controversy, confusion and lack of evidence concerning the best treatment option. Disease management mainly consists of supportive care by means of oxygen supplementation, but also includes inhalations of hypertonic saline or steroids with or without beta agonist drugs, anti-viral therapy and chest physiotherapy.

We believe that none of the specified treatments has been proven to have a positive outcome on the course of the disease or a reduction in the length of hospitalization. In addition, some treatment strategies have been subject to debate regarding whether they work. For example, the anti-viral drug, Ribavirin, a broad-spectrum antiviral agent approved for treatment of RSV infections, is controversial due to questions regarding its high cost and uncertain treatment effect.

NTM infection of the lungs is a chronic, as well as a progressive lung condition. NTM exhibits across a variety of lung diseases such as bronchiectasis, COPD, Asthma, CF and Cancer. In certain severe NTM cases, life expectancy is under five years, for which we believe there are no successful treatments available.

There are an estimated 50,000-86,000 cases of NTM lung infections in the U.S. with an annual 8% increase. More than 70% of NTM cases are underreported, and therefore the projected number of NTM cases could be as high as 181,000 in the U.S. alone. With the rise of NTM infections, NTM is currently more prevalent than tuberculosis in the U.S. NTM mostly affects adults middle-aged to elderly, with increasing infection in patients aged 65 and over, a population that is expected to double by the year 2030.

NTM lung infections also pose a substantial financial burden on the U.S. healthcare system. In 2010, the annual cost was over $800 million, and the same study estimated the cost for 2014 to be $1.7 billion in the U.S.

Our initial indication is for the treatment of both NTM*abscessus* and MAC, which is the vast majority of the market discussed above.

There are no approved products in the U.S. and Europe to treat NTM*abscessus* infections.

For NTM patients, prolonged treatment is necessary and varies among different types of NTM species, severity of the disease and drug-susceptibility. As NTM are typically antibiotic-resistant, treatment requires a combination of two, three or more different drugs. Therefore, current treatment includes a mixture of IV antibiotics as well as steroids.

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:

A prospective, open label, controlled, single-center Phase 1 study was conducted on ten healthy adults between 20 and 62 years of age. Subjects received our proprietary 160 ppm NO formulation for 30 minutes, five times a day, for five consecutive days by direct inhalation to the lungs via a prototype delivery system

The primary objective of the study was to determine the effect of the inhaled NO formulation treatment, to determine the effect of the treatment based on pulmonary function test results, to determine the met hemoglobin (MetHb - a form of hemoglobin that cannot bind oxygen, a bi-product of NO and hemoglobin) level associated with the inhaled NO formulation treatment and to assess adverse events associated with the treatment. Secondary objectives of the study were to assess the changes in cytokine levels. NO and NO_2 concentrations (a gaseous substance that is a bi-product of NO and O_2, that can be toxic at high concentrations), inhaled fraction of inspired oxygen (FiO_2), as well as. MetHb and oxygen saturation (SaO2) were continuously monitored, as elevation of MetHb or reduction in SaO_2 levels may be harmful. 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 maximal 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 to a level 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.

Rambam healthcare campus in Israel conducted a compassionate use treatment for two patients with CF who suffer from NTM*Abscessus* 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 AIT Ltd. 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 NTM 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 test and the sputum culture became negative, which is consistent with eradication of the NTM Abscessus.

Further information is needed, but we believe these results suggest that the treatment of NTM Abcsessus with high dose inhaled NO is effective.

Further, one patient with CF who suffers from NTM infections (specifically, *M. abscessus*) has been treated 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 6-minute walk, 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.

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 6-minute walk, 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.

We have completed a Phase 2 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, or AEs, and/or SAEs, or for any other reason.

AEs were reported by five (55.5%) subjects. There were no SAEs related to NO therapy, no treatment 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 haemoptysis were reported in two subjects and all events were mild in severity.

There were no subjects with MetHb >5% at any point during the study and 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 Asperigillus 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.

We completed a double blind, randomized Pilot study for infants with bronchiolitis 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 deaths during the study. 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. It should be noted that 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).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.

Furthermore, the FDA or other regulatory agencies may not concur with our assessment of safety and efficacy. Product candidates that have shown promising results in early-stage clinical studies may still suffer significant setbacks in subsequent advanced clinical studies. We do not know whether any Phase 2, Phase 3 or other clinical studies we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain regulatory approval to market our product candidates. While we believe the results of our Phase 2 trials in bronchiolitis and CF demonstrated improvements in various endpoints and clinical outcomes, the trials were small, and it is likely that the FDA will view them as not statistically or clinically significant because of their size and scope. We must conduct larger clinical trials with statistically significant favorable results or we will not be able to obtain regulatory approval to market our product candidates.

We have completed a single-arm, open-label Pilot trial in nine patients with MABSC, 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 6-minute walk test, FEV1, Quality of Life and Mycobacterium 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.

We have completed a second pilot study in bronchiolitis in 6 centers in Israel. The prospective, randomized, double-blind, controlled pilot study enroll 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 length-of-stay (LOS) was met with a 23 hour reduction in hospital length of stay demonstrated (p=0.085). 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 (SaO2) of 92% or greater showed improvement versus the standard-of-care. There were no issues with NO2 or metHb and no SAEs were recorded.

We have completed a third pilot study in bronchiolitis in 8 centers in Israel. The prospective, randomized, double-blind, controlled pilot study enrolled 89 patients, 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	150 ppm vs. SST	85 ppm vs. SST
Primary endpoint: Time to fit-for-discharge			
Hazard ratio (95% CI)	2.11 (1.03, 4.31)	2.32 (1.01, 5.33)	0.90 (0.44, 1.81)
P-value	0.041	0.049	Not significant
Key secondary endpoint: Hospital length of stay			
Hazard ratio (95% CI)	2.01 (1.01, 3.99)	2.28 (1.03, 5.06)	0.77 (0.40, 1.48)
P-value	0.046	0.043	Not significant

We plan to seek 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 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 rats and treated rats on observation during the treatment period prior to sacrifice and no observations on histopathology
- **Rats:** Geno toxicology study of intermittent 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, Mallinkrodt 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 Mallinkrodt 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. Bellepheron Therapeutics is developing NO-based products for pulmonary arterial hypertension and pulmonary hypertension associated with chronic obstructive pulmonary disease. Geno LLC is developing NO-based products for the treatment of a variety of pulmonary and cardiac diseases such as acute vasoreactivity testing, pulmonary arterial hypertension and pulmonary hypertension associated with idiopathic pulmonary fibrosis. 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. If the FDA approves Novoteris' product candidate for the indication for which it received orphan drug designation, then Novoteris will be eligible for orphan drug exclusivity if its product receives approval first, which would have no effect on our product given we are a medical device. In January 2015, Ikaria entered into an agreement with Novoteris to collaborate on the development of an outpatient program for treating bacterial infections associated with CF. Recently, we have become aware that each of Ikaria and Novoteris is conducting a Phase 2 clinical trial using a 160 ppm NO formulation to treat patients with CF. Moreover, Novoteris is also conducting a Phase 2 study in NTM *Abscessus* in Canada.

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 a third-party contract manufacturer, Sparton Corporation, who has completed a substantial portion of the commercial manufacturing process for our generator based NO delivery system. We will be reliant on our partner 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, NO2 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 is 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 whereby we acquired the option, referred to as 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, acquired 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 common stock of the Company at an exercise price of $4.80 per share for each share of common stock. On May 10, 2018, the Company issued to the same third-party additional fully vested warrants to purchase up to 29,763 common stock of the Company at an exercise price of $4.80 per share.

Patent Applications. We have filed over 20 US and foreign patents and patent applications, 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 Regulations

U.S. Regulation. In the U.S., the FDA regulates drug and medical device products under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 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 in the Unites States as drug-device combinations, we expect our device to not only be reviewed by CDRH, but also have input from the Center for Drug Evaluation and research (CDER).

Among other things, we will have to demonstrate compliance with applicable QSRs, to ensure that the device is in compliance with applicable performance standards.

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 patients 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 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 entitled to orphan product exclusivity, which (with certain limited exceptions) blocks for seven years FDA approval of another product with the same active ingredient for the same indication.

Approval or Clearance of Medical Devices. To varying degrees, each of the regulatory agencies having oversight over medical devices, including the FDA and comparable foreign regulators, has laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of medical devices. In the U.S., medical device products are subject to regulation that is intended to ensure that the device is either safe and effective or is substantially equivalent to a previously marketed device. Medical devices are classified into one of three classes based on the level of control necessary to assure the safety and effectiveness of the device. The three classes and the requirements that apply to them are: (i) Class I General Controls, with exemptions and without exemptions, (ii) Class II General Controls and Special Controls, with exemptions and without exemptions and (iii) Class III General Controls and Premarket Marketing authorization. The class to which a device is assigned determines the process that applies for gaining marketing authorization. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification clearance under section 510(k) of the Food, Drug, and Cosmetic Act; and most Class III devices require Premarket Approval.

A brief summary overview of the three classifications is set forth below.

Exempt Class I Medical Device: Prior to marketing an exempt Class I medical device, the manufacturer must register its establishment, list the generic category or classification name of the medical device being marketed and pay a registration fee.

510(k) Clearance Process: A Class II medical device normally requires FDA clearance in the U.S. pursuant to the 510(k) clearance process. The 510(k) clearance process is available to medical device developers that can demonstrate that their device is substantially equivalent to a legally marketed medical device. In this process, the developer would be required to submit data that supports the equivalence claim and wait for an order from the FDA finding substantial equivalence to another legally marketed medical device before distributing the device for commercial sale. Modifications to cleared medical devices can be made without using the 510(k) process if the changes do not significantly affect safety or effectiveness.

Premarket Approval: A more rigorous and time-consuming process applicable to Class III medical devices, known as pre-market approval ("PMA") which would require the developer to independently demonstrate that a medical device is safe and effective. This is done by submitting data regarding design, materials, bench and animal testing and human clinical data for the medical device. The FDA will authorize commercial release of a Class III medical device if it determines there is reasonable assurance that the medical device is safe and effective. This determination is based on benefit outweighing risk for the population intended to be treated with the device. This process is much more detailed, time-consuming and expensive than the 510(k) clearance process.

The basic design of our delivery system will be similar to those functions used in current predicate devices. However, our therapy requires the administration of a higher concentration of NO than is currently approved by the FDA. Therefore, the FDA could reject a Class II-510(k) and declare it not substantially equivalent to a legally marketed device, and set it on the regulatory path of Class III-PMA.

Continuing Regulation of Approved or Cleared Drugs and Medical Devices. Products manufactured or distributed pursuant to FDA approval or clearance are subject to continuing regulation by the FDA, including requirements for ongoing recordkeeping, annual product quality review, annual reporting, post-market surveillance requirements, post-market study commitments, drug adverse experience reporting in a timely fashion, maintenance of pharmacovigilance program to proactively monitor for adverse events and medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur.

Quality System Regulation. Companies engaged in the manufacture of medical devices or their components are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements. Medical devices must comply with QSR requirements. 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. 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, such as suspension of manufacturing, operating restrictions, seizure or recall of product, injunctive action, withdrawal of approval or clearance, import detention, refusal or delay in approving or clearing new products or supplemental applications, fines, civil penalties and 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.

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.

Anti-Kickback, False Claims Act and Other Laws. In addition to the FDA's ongoing post-approval regulation of devices discussed above, several other types of laws and regulations, subject to differing enforcement regimes, govern advertising and promotion. In recent years, 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.

A development affecting the healthcare industry is the increased use of the federal civil False Claims Act to impose liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. In addition, many states have enacted false claim laws similar to the federal False Claims Act. If certain conditions are met, the False Claims Act allows a private individual (typically a "whistleblower") to bring a civil action on behalf of the federal government and to share in any monetary recovery. Engaging in impermissible promotion of our products for off-label uses can subject us to false claims litigation under federal and state statutes, which can lead to civil money penalties, restitution, criminal fines and imprisonment and exclusion from participation in Medicare, Medicaid and other federal and state health care programs In recent years, the number of suits brought by private individuals against pharmaceutical and device companies for off-label promotion has increased dramatically.

The federal Anti-Kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical or device manufacturers, on the one hand, and prescribers, purchasers and formulary managers on the other. Violations are punishable by imprisonment, criminal fines, 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 Anti-Kickback statute. Many states have likewise adopted state anti-kickback statutes and enforcement has been significant.

A host of other laws and regulations govern the advertising and promotion of devices. The federal Sunshine Law, which is part of the Health Care Reform Law, each enacted in March 2010, imposes federal "sunshine" provisions, requiring annual reporting of various types of payments to physicians and teaching hospitals. CMS published the first set of data about these financial relationships on its website on September 30, 2014. Inaccurate or incomplete reports may be subject to enforcement. Like the federal Sunshine Law, several states have existing laws that require manufacturers to report transfers of value to select healthcare providers licensed within the state. 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.

Canadian Regulation. In Canada, the Therapeutic Products Directorate of Health Canada ("TPD") is the Canadian federal authority that regulates pharmaceutical drugs and medical devices for human use. Prior to being given market authorization, a sponsor must present substantive scientific evidence of a product's safety, efficacy and quality as required by the Food and Drugs Act and other legislation and regulations. The requirements for the development and sale of pharmaceutical drugs in Canada are substantially similar to those in the U.S., which are described above.

In general, prior to being given market authorization to sell a Class II, III or IV medical device in Canada, a manufacturer must present and/or attest to substantive scientific evidence of a product's safety, efficacy and quality as required by the Food and Drugs Act and the Medical Devices Regulations ("Canada MDR").

The Medical Devices Bureau ("MDB") of the TPD applies the Canada MDR through a combination of pre-market review, post-approval surveillance and quality systems in the manufacturing process. Medical devices are classified into one of four classes, where Class I represents the lowest risk and Class IV represents the highest risk. In order to perform investigational testing in Canada for a Class II, III or IV medical device, authorization for the testing must be granted by the MDB. A Medical Device License is a pre-market requirement for a Class II, III and IV medical device, including for Class II, III or IV medical devices previously authorized for sale for investigational testing now to be offered for general/commercial sale. A Medical Device License is issued to the device manufacturer, provided the requirements of the Canada MDR are met.

The Canada MDR requires that medical devices be manufactured under a certified quality management system that meets the criteria of the international standard, ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes. The MDB currently recognizes the Medical Device Single Audit Program, a program designed to include compliance with the quality management requirements of the Canada MDR.

European Regulation. In order for our products to be marketed and sold in the EEA, we must obtain the required regulatory approvals and comply with the extensive regulations regarding safety, manufacturing processes and quality requirements of the respective countries. These regulations, including the requirements for approvals to market, and the various regulatory frameworks may differ. In addition, there may be foreign regulatory barriers other than approval or clearance.

Medicinal Product Approval. In the EEA, we expect our products to be regulated as a combination drug-delivery device product falling within the scope of Directive 2001/83/EC, commonly known as the Community Code on medicinal products. Under this Directive, we are required to obtain a marketing authorization for our products before they are placed on the market. Medicinal products must be authorized in one of two ways, either through the decentralized procedure or mutual recognition procedure by the competent authorities of the EEA Member States, or through the centralized procedure by the European Commission following a positive opinion by the EMA. The authorization process is essentially the same irrespective of which route is used, and requires us to demonstrate the quality, safety and efficacy of the NO delivered to the patient by our product. We are also required to demonstrate that the drug delivery component of our products complies with the relevant Essential Requirements contained in Annex I to the Medical Devices Directive.

Innovative medicinal products are authorized in the EEA on the basis of a full marketing authorization application that must contain the results of pharmaceutical tests, pre-clinical tests and clinical trials conducted with the medicinal product for which marketing authorization is sought, and demonstrating the product's quality, safety and efficacy. Once approved, an innovative medicinal product is entitled to eight years of data exclusivity. During this period, no application for approval of a generic version of the innovative product relying on data contained in the marketing authorization dossier for the innovative product may be submitted. Innovative medicinal products are also entitled to ten years of market exclusivity. During this 10-year period, no generic medicinal product can be placed on the EU market. The 10-year period of market exclusivity can be extended to a maximum of 11 years if, during the first eight years of those ten years, the holder of the marketing authorization for the innovative product obtains an authorization for one or more new therapeutic indications that are held to bring a significant clinical benefit in comparison with existing therapies.

After expiration of the data exclusivity period, an application for marketing authorization for a generic version of an approved innovative medicinal product may be submitted. Such an application does not contain data demonstrating the proposed product's quality, safety and efficacy, but instead relies on the data in the dossier for the related innovative product, and a demonstration that the two products are the same and bioequivalent. If approved, the generic product may not be placed on the market until expiration of the 10-year marketing exclusivity period for the innovative medicinal product.

A marketing application for a product that, although similar to an approved medicinal product does not qualify as a generic, may also seek to rely to some degree on the data in the dossier for the approved product. As with a generic product, the application may not be submitted until expiration of the data exclusivity period, and the product, if approved, may not be placed on the market until expiration of the market exclusivity period. Such an application must also contain data specific to the proposed product, however. The extent to which such a "hybrid" application requires new data is determined on a case-by-case basis by the competent authorities, based on the differences between the innovative medicinal product and the medicinal product subject to the hybrid application for marketing authorization. The purpose of the pre-clinical tests and clinical trials is to generate additional data that complement the data relating to the innovative medicinal product and to demonstrate the quality, safety and efficacy of the medicinal product for which authorization is sought.

Because a NO formulation is already authorized in the EEA for treating pulmonary hypertension, we expect to be able to seek marketing authorization for our products under the "hybrid" approach described in the previous paragraph. We anticipate that the hybrid application for marketing authorization will require the successful completion of limited studies confirming the quality, safety and efficacy of the NO formulation delivered using our proprietary delivery technology.

Continuing Regulation. As in the U.S., marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and/or the competent authorities of the EEA Member States. This oversight applies both before and after grant of manufacturing and marketing authorizations. It includes control of compliance with EU GMP rules and pharmacovigilance rules.

In the EEA, the advertising and promotion of our products will also be subject to EEA Member States' laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices, as well as other EEA Member State legislation that may apply to the advertising and promotion of medicinal products. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC"), as approved by the competent authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion, which is prohibited. The applicable laws at the EU level and in the individual EEA Member States also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the EEA could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

Interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct in the individual EEA Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EEA Members states, including the UK Bribery Act 2010. Payments made to physicians in certain EEA Member States must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent professional organization and/or the competent authorities of the individual EEA Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EEA Member States.

Pricing and Reimbursement. Each EEA Member State is free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement levels of medicinal products for human use. An EEA Member State may approve a specific price or level of reimbursement for the medicinal product, or alternatively adopt a system of direct or indirect controls on the profitability of the company responsible for placing the medicinal product on the market, including volume-based arrangements and reference pricing mechanisms.

Health technology assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EEA Member States, particularly the United Kingdom, France, Germany and Sweden. The HTA process in each EEA Member State is governed by the national laws of the country. HTA is the procedure according to which an assessment is conducted of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost and cost-effectiveness of individual medicinal products, as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment options available on the market. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EEA Member States. The extents to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product vary between EEA Member States.

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.

Certain Recent Developments

On December 18, 2019, we terminated our license agreement with Circassia Limited and its affiliates (collectively, "Circassia") pursuant to which we had granted Circassia an exclusive royalty-bearing license to distribute, market and sell our nitric oxide generator and delivery system in the United States and China.

On March 16, 2020, we announced that we had submitted an Investigational Device Exemption (IDE) to the US Food and Drug Administration (FDA for approval to study the use of our LungFit™ -BRO system in patients infected with COVID-19. An IDE approval from the FDA is a necessary step before performing any clinical study with a medical device. The FDA typically responds within 30 days of an IDE submission. On April 16, 2020, the FDA agreed with the initiation of a clinical study in the U.S. using our LungFit™ system to treat COVID-19 patients. The LungFit™ will be used in an open-label study, to treat 20 patients between the ages of 22 and 65 years hospitalized with COVID-19. Subjects will be randomized 1:1 and treated with 80 ppm NO administered over 40 minutes, 4 times per day, in addition to standard of care (SOC) or treated with SOC alone. The primary endpoint is time to clinical deterioration as measured by the need for: 1) non-invasive ventilation: or 2) high flow nasal cannula; or 3) intubation. Other endpoints include reduction in viral load, need for supplemental oxygen, hospital length of stay, mortality, safety and various biomarkers.

On March 17, 2020, our wholly owned subsidiary Beyond Air Ireland Limited ("BAL") entered into a facility agreement (the "Facility Agreement") with certain lenders pursuant to which the lenders shall loan to BAL up to $25,000,000 in five tranches of $5,000,000 per tranche at the option of BAL ("Tranches"), provided however that BAL may only utilize tranches three through five following FDA approval of our LungFit™ PH product. The loans bear interest at 10% per year and may be prepaid with certain prepayment penalties. Each tranche shall be repaid in installments commencing June 15, 2023 with all amounts outstanding under any tranche due on March 17, 2025. BAL borrowed the first tranche on March 17, 2020.

In connection with BAL's utilization of the first tranche, on March 17, 2020 we issued to the lenders five-year warrants to purchase up to 172,187 shares of common stock at an exercise price of $7.26 per share. The Company filed a Registration Statement on Form S-3 (File No. 333-237958) to register for resale the shares issuable upon the exercise of the Warrants. The Registration Statement was declared effective by the SEC on May 11, 2020.

On April 2, 2020 we entered into an At-The-Market Equity Offering Sales Agreement (the "Sales Agreement") with SunTrust Robinson Humphrey, Inc. and Oppenheimer & Co. (collectively, the "Agents") under which we may offer and sell, from time to time at its sole discretion, shares of our common stock having an aggregate offering price of up to $50,000,000 through the Agents as our sales agent. The issuance and sale, if any, of common stock under the Sales Agreement was pursuant to our shelf registration statement on Form S-3 (File No. 333-231416) declared effective by the SEC on July 2, 2019, the prospectus supplement relating to the offering filed with the SEC on April 2, 2020, and any applicable additional prospectus supplements related to the offering that form a part of the that registration statement. Subject to the terms and conditions of the Sales Agreement, the Agents may sell the common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act. The Agents will use commercially reasonable efforts to sell the common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay the Agents a commission equal to up to three percent (3%) of the gross sales proceeds of any common stock sold through the Agents under the Sales Agreement, and also have provided the Agents with certain indemnification rights.

We are not obligated to make any sales of common stock under the Sales Agreement. The offering of shares of common stock pursuant to the Sales Agreement will terminate upon the earlier of (i) the sale of all common stock subject to the Sales Agreement or (ii) termination of the Sales Agreement in accordance with its terms.

On May 14, 2020, we entered into a Purchase Agreement ("Purchase Agreement") with Lincoln Park Capital Fund LLC ("Lincoln Park"), which provides that, upon the terms and subject to the conditions and limitations set forth therein, we have the right to sell to Lincoln Park up to $40,000,000 of shares of our common stock at our discretion subject to the terms and conditions of the Purchase Agreement. The issuance and sale of common stock under the Purchase Agreement was pursuant to our shelf registration statement on Form S-3 (File No. 333-231416) declared effective by the SEC on July 2, 2019, the prospectus supplement relating to the offering filed with the SEC on May 14, 2020, and any applicable additional prospectus supplements related to the offering that form a part of the that registration statement. The offer and sale of up to $40,000,000 of shares of our common stock consists of up to (i) 325,000 shares of our common stock that we may sell to Lincoln Park at any time within 30 days of the Commencement Date (as defined in the Purchase Agreement) as the initial purchase under the Purchase Agreement and (ii) additional shares of our common stock with an aggregate offering price of up to $37,211,500, which we may sell from time to time in our sole discretion to Lincoln Park over the next 36 months, subject to the conditions and limitations in the Purchase Agreement.

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:

- December 31, 2021;
- 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, or SEC, our annual report 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 Securities Exchange Act of 1934, as amended. 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. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is 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

Employees

As of June 19, 2020, we had 23 full-time employees. None of our employees are represented by a labor union and we consider our employee relations to be good.

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 on Form 10-K. 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, including a net loss attributed to common shareholders of $20.4 million for the year ended March 31, 2020, and an accumulated deficit of approximately $57.6 million as of March 31, 2020, and anticipate that we will 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 approved for sale by the FDA or any other regulatory agencies, 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.

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 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 studies and providing general and administrative support for these operations. Our future success is dependent on our ability to successfully develop, obtain regulatory 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 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 a pilot clinical trial involving 43 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 studies were conducted outside the U.S. and were not conducted pursuant to an FDA IND. The results of these three studies showed 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. 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 approval to market our product candidates. It may be years before a pivotal study is initiated, if at all. 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 regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

We as a company have never submitted marketing applications for approval of our product candidates to the FDA or comparable foreign regulatory authorities; although in 2014 the FDA granted the Company orphan drug designation for the use of NO in the treatment of CF and in 2015, the EU also granted the Company 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 studies or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical studies. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we do receive FDA approval for our drug, 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 regulatory approval to commercialize our product candidates in the U.S., the EU and in additional foreign countries. To obtain regulatory approvals we must comply with the numerous and varying regulatory requirements of such countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical studies, commercial sales, pricing and distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations would be negatively affected.

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

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, typically takes many years following the commencement of clinical studies and depends upon numerous factors. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. We have not obtained 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 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 ("cGCPs") 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 ten months of filing. However, the review process is often significantly extended by FDA requests for additional information or clarification. 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 or comparable foreign regulatory authorities 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 may significantly change in a manner rendering our clinical data insufficient for approval; and

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

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 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.

We are working on NTM Abscessus which is very rare.

NTM *Abscessus* 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 *Abscessus* or, even if approved, the device for that indication may never be profitable. In addition, there are many strains of NTM but our study is only on one of them, *Abscessus*. Therefore, we may face a situation that this strain will disappear or there will be no candidates with this strain, so the FDA may not grant us approval to treat other NTM strains without further validation and trials, or possibly ever, and/or the FDA may not allow us to work on NTM in patients who do not have CF.

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 regulatory approval may not be easily obtained.

Our NO Delivery System has not yet been manufactured for use with a ventilator and this process has significant risks. Additionally, 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.

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 5,000 patients suffer from NTM *abscessus* 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 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 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;
- patients dropping out of a study;
- 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 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 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 methemoglobin, nitrogen dioxide ("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 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;
- as a condition of approval, we may be required to create a Risk Evaluation and Mitigation Strategy ("REMS") plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- 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 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.

Even if we obtain regulatory approval for one or more of our product candidates in the U.S., the FDA may still impose significant restrictions on the indicated uses or marketing or to the conditions for approval, or impose ongoing requirements for potentially costly post-approval studies, including post-market surveillance. As a condition to granting marketing approval of a product, the FDA may require a company to conduct additional clinical trials. The results generated in these post-approval clinical trials could result in loss of marketing approval, changes in product labeling, or new or increased concerns about side effects or efficacy of a product. For example, the labeling for our product candidates, if approved, may include restrictions on use or warnings. The Food and Drug Administration Amendments Act of 2007 ("FDAAA") gives the FDA enhanced post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information, and compliance with FDA-approved REMS programs. If approved, our product candidates will also be subject to ongoing FDA requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record keeping, and reporting of safety and other post-market information. The FDA's exercise of its authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements, and potential restrictions on sales of approved products. Foreign regulatory agencies often have similar authority and may impose comparable costs. Post-marketing studies, whether conducted by us or by others and whether mandated by regulatory agencies or voluntary, and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of our product candidates once approved, and potentially our other marketed products. Further, the discovery of significant problems with a product similar to one of our products that implicate (or are perceived to implicate) an entire class of products could have an adverse effect on sales of our approved products. Accordingly, new data about our products could negatively affect demand because of real or perceived side effects or uncertainty regarding efficacy and, in some cases, could result in product withdrawal or recall. Furthermore, new data and information, including information about product misuse, may lead government agencies, professional societies, and practice management groups or organizations involved with various diseases to publish guidelines or recommendations related to the use of our products or the use of related therapies or place restrictions on sales. Such guidelines or recommendations may lead to lower sales of our products.

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. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials. 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 cGMPs regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility, or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing, requiring new warnings or other labeling changes to limit use of the product, requiring that we conduct additional clinical trials, imposing new monitoring requirements, or requiring that we establish a REMS program for our approved products. Advertising and promotional materials must comply with FDA rules in addition to other potentially applicable federal and state laws. The distribution of product samples to physicians must comply with the requirements of the Prescription Drug Marketing Act. Sales, marketing, and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, and similar state laws. We would also be required under the Sunshine provision of the Affordable Care Act ("ACA") to report annually to the Centers for Medicare & Medicaid Services on payments that we make to physicians and teaching hospitals and ownerships interests in the company held by physicians. 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 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 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 Good Clinical Practice ("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 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 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 an PMA or Marketing Authorization Application amendment, or equivalent foreign regulatory filing, which could result in further delay. 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.

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 intend to rely on third-party manufacturers to produce our product candidates, but we have not entered into binding agreements with any such manufacturers to support commercialization.

We have not yet secured manufacturing capabilities for commercial quantities of our product candidates. We intend to rely on third-party manufacturers for commercialization. We may be unable to negotiate binding agreements with the manufacturers to support our commercialization activities on commercially reasonable terms, or at all. See *"Risk Related to our Reliance on Third Parties—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."*

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 medical device, biotechnology and pharmaceutical industries are highly competitive. There are many medical device companies, pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of products that may be similar to our products. We are aware of several companies currently developing and/or selling NO therapies for various indications such as PPHN. 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. 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. Bellepheron Therapeutics is developing NO-based products for persistent arterial hypertension and pulmonary hypertension associated with chronic obstructive pulmonary disease. Vero Biotech has received US approval of a generic version to INOMAX using their GENOSYL delivery system. 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 EMA for the use of inhaled NO-based treatments in treating CF. In January 2015, Mallinckrodt entered into an agreement with Novoteris to collaborate on the development of an outpatient program for treating bacterial infections associated with CF. Recently, we have become aware that Mallinckrodt and Novoteris are running a Phase 2 clinical trial using a 160 ppm NO formulation to treat patients with 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 inhaled short-acting beta-2 agonist and oral corticosteroids for the treatment of asthma 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 biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain 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, 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 no marketing and sales organization. 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.

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 no marketing or sales organization. To successfully commercialize any products that may result from our development programs, we will need to develop these capabilities, either on our own or with others. If our product candidates receive regulatory approval, we intend to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates in major markets, 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.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the U.S., there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and American Care Act ("ACA") as amended by the ACA was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. medical device industry. We can't predict how our product candidates may be impacted.

Future legislation or regulations may adversely affect reimbursement from government programs.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve targeted deficit reductions, triggering the legislation's automatic reduction of several government programs. This includes aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several categories of healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. On December 13, 2016, the President signed into law the 21st Century Cures Act, which, among other things, may increase the types of clinical trial designs that would be acceptable to support a PMA. It is unclear, at this time, how these provisions will be implemented or whether they would have any effect on our company.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for medical device products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates may be. In that regard, Congress has taken the first step in repealing the funding mechanism for certain aspects of the ACA. If the ACA or parts of it are repealed, it is unclear what impact that would have on reimbursements or coverage and it is equally unclear what programs, if any, Congress and the Trump Administration might enact and sign into law to replace the repealed portions of the ACA.

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, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order, or recommendation of, any good or service for which payment may be made under government health care programs such as the Medicare and Medicaid programs;

- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government health care programs that are false or fraudulent;

- federal criminal laws that prohibit executing a scheme to defraud any health care benefit program or making false statements relating to health care matters; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, the ACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity can now be found guilty of fraud or false claims under the ACA without actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare, Medicaid and other government programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations, and financial condition.

The ACA also imposes new reporting requirements on device and pharmaceutical manufacturers to make annual public disclosures of payments to certain health care providers and physician ownership of their stock by health care providers. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value, or ownership or investment interests that are not reported. Manufacturers were required to begin data collection on August 1, 2013 and were required to report such data to CMS by March 31, 2014.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation, and other remuneration to physicians.

The scope and enforcement of these laws is uncertain and subject to change in the current environment of health care reform, especially in light of the lack of applicable precedent and regulations. 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 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.

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 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 candidate. 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. For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. 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 expect to 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 partes 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 ordinary shares.

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 5we 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.

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.

Risks Relating to Our Business Operations

We manage our business through a small number of employees and key consultants. We depend on them even more than similarly-situated companies.

We have a total of 23 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 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.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval and commercialization of our existing product candidates, the success of our business also depends 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 products 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.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the U.S., our operations may directly, or indirectly through our customers, subject us to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and physician sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology and Clinical Health Act ("HITECH"), and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the federal physician sunshine requirements under the Health Care Reform Laws requires manufacturers of drugs, devices and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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. In addition, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

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.

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. or Israel.

Other than our operations that are located in 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 sales representatives and conduct physician and patient association outreach activities, as well as clinical trials, outside of the U.S. 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 approvals, permits and licenses;

- failure by us to obtain 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.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts, business operations and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

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 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.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce the data. If any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and/or the further development of our product candidates could be delayed.

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

The development of our product candidates could be disrupted and materially adversely affected by the recent outbreak of COVID-19. As a result of measures imposed by the governments in affected regions, businesses and schools have been suspended due to quarantines intended to contain this outbreak. The spread of SARS CoV-2 from China to other countries has resulted in the Director General of the World Health Organization declaring COVID-19 a pandemic on March 11, 2020. International stock markets have begun to reflect the uncertainty associated with the slow-down in the Chinese economy and the reduced levels of international travel experienced since the beginning of January and the significant declines in the Dow Industrial Average at the end of February and in March 2020 was largely attributed to the effects of COVID-19. We are still assessing our business plans and the impact COVID-19 may have on our ability to conduct our preclinical studies and clinical trials or rely on our third-party manufacturing and supply chain, but there can be no assurance that this analysis will enable us to avoid part or all of any impact from the spread of COVID-19 or its consequences, including downturns in business sentiment generally or in our sector in particular. Site initiation and patient enrollment for non-COVID-19 studies may be delayed or disrupted due to prioritization of hospital and medical resources toward the COVID-19 pandemic or inability to access hospital and other clinical sites. The extent to which the COVID-19 pandemic and global efforts to contain its spread will impact our operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, and include the duration, severity and scope of the pandemic and the actions taken to contain or treat the COVID-19 pandemic.

Our planned LungFit™ COVID-19 program may never be approved.

In response to the global outbreak of COVID-19, we have applied and received approval to study our LungFit™ system as a treatment option for patients with COVID-19 from both the FDA and Health Canada. If the outbreak is effectively contained or the risk of COVID-19 infection is diminished or eliminated, including if other parties are successful in producing an effective vaccine or other treatment for COVID-19, before we can successfully test our LungFit™ system on patients with COVID-19, the commercial viability of such product candidate for this indication may be significantly diminished. We are also committing financial resources and personnel to this study which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties surrounding the longevity and extent of COVID-19 as a global health concern. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our LungFit™ system may not be effective. Even if clinical testing shows that our LungFit™ system is an effective treatment option for patients with COVID-19 and we receive clearance from FDA, other parties may produce a more effective or more cost-effective treatment for COVID-19, which may lead to our LungFit™ system not being adopted in the marketplace or not receiving insurance or government reimbursement. It may also lead to the diversion of governmental and quasi-governmental funding away from us and toward other companies.

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.

Our common stock has recently experienced extreme volatility. During the last six months, our common stock has closed as low as $3.94 per share and as high as $10.93 per share, with heavy daily trading volume. Our common stock may continue to be volatile and could materially fall for a number of reasons including:

- Announcements by competitors that they have successfully produced an effective vaccine or other treatment option for COVID-19;
- Public announcement that the rapid spread of COVID-19 has receded;
- Announcements by us of results from future clinical trials, if any, showing that the use of our LungFit™ system is not an effective treatment option for patients with COVID-19;
- The termination of any other factors which may have created volatility and spike in volume; or
- Other possible reasons for volatility which we have disclosed in this "Risk Factors" section and elsewhere in this Annual Report;

- the product candidates we seek to pursue, and our ability to obtain rights to develop, commercialize and market those product candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- actual or anticipated adverse results or delays in our clinical trials;
- our failure to commercialize our product candidates, if approved;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- adverse regulatory decisions;
- additions or departures of key scientific or management personnel;
- changes in laws or regulations applicable to our product candidates, including without limitation clinical trial requirements for approvals;

- disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our product candidates;
- our dependence on third parties, including CROs as well as our potential partners that provide us with companion diagnostic products; failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- introduction of new products offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to maintain an adequate rate of growth and manage such growth;
- issuances of debt or equity securities;
- sales of our common stock by us or our stockholders in the future, or the perception that such sales could occur;
- trading volume of our common stock; ineffectiveness of our internal control over financial reporting or disclosure controls and procedures;
- general political and economic conditions;
- effects of natural or man- made catastrophic events; and
- other events or factors, many of which are beyond our control.

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.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

Any trading market for our common stock that may develop will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on us or our business. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively affected. If securities or industry analysts initiate coverage, and one or more of those analysts downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

We incur increased costs associated with, and our management currently do and, in the future, will need to devote substantial time and effort to, compliance with public company reporting and other requirements.

As a public company, and particularly if and after we cease to be an "emerging growth company" or a "smaller reporting company," we incur significant legal, accounting and other expenses. In addition, the rules and regulations of the SEC and national securities exchanges impose numerous requirements on public companies, including requirements relating to our corporate governance practices, with which we now need to comply. Since becoming subject to the Exchange Act, we have been required to, among other things, file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel currently do and, in the future, will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations, and our efforts and initiatives to comply with those requirements could be expensive.

We are an emerging growth company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may choose to take advantage of certain exemptions from various reporting requirements applicable to other public companies, including, among other things:

- exemption from the auditor attestation requirements under Section 404 of the Sarbanes-Oxley Act of 2002;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements;
- exemption from the requirements of holding non-binding stockholder votes on executive compensation arrangements; and
- exemption from any rules requiring mandatory audit firm rotation and auditor discussion and analysis and, unless the SEC otherwise determines, any future audit rules that may be adopted by the Public Company Accounting Oversight Board.

We will be an emerging growth company until the earliest of (i) December 31, 2021, (ii) the last day of the fiscal year during which we have total annual gross revenues of $1.07 billion or more, (iii) the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt and (iv) the date on which we are deemed to be a large accelerated filer under the federal securities laws. We will 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, (ii) have been public for at least 12 months and (iii) have filed at least one annual report pursuant to the Exchange Act.

We cannot predict if investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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, adjusted the exercise price down to $3.66 per share pursuant to the terms of the 2017 Warrants. As of the June 19, 2020 there are 3,136,436 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, 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 predicated on mutual mistake. 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 Master, 159,869 warrant shares for Empery I and 252,672 warrant shares for Empery II and the exercise price could be reduced from $3.66 to $1.57 per share. While the Company has several meritorious defenses against the claims, the ultimate resolution of the matter, if unfavorable, could result in a material loss. On March 9, 2020, we filed a motion for summary judgment, which remains pending.

In addition to Empery, there are 1,139,220 warrants outstanding held by investors in the 2017 Warrants who did not participate in the February 2018 financing transaction. Any further adjustments to these 2017 Warrants pursuant to the 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.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans or otherwise, could result in dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors in a prior transaction may be materially diluted by subsequent sales. Additionally, any such sales may result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

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.

The elimination of personal liability against our directors and officers under Delaware law and the existence of indemnification rights held by our directors, officers and employees may result in substantial expenses.

Our Amended and Restated Certificate of Incorporation and our Bylaws eliminate the personal liability of our directors and officers to us and our stockholders for damages for breach of fiduciary duty as a director or officer to the extent permissible under Delaware law. Further, our Amended and Restated Certificate of Incorporation and our Bylaws and individual indemnification agreements we have entered with each of our directors and executive officers provide that we are obligated to indemnify each of our directors or officers to the fullest extent authorized by the Delaware law and, subject to certain conditions, advance the expenses incurred by any director or officer in defending any action, suit or proceeding prior to its final disposition. Those indemnification obligations could expose us to substantial expenditures to cover the cost of settlement or damage awards against our directors or officers, which we may be unable to afford. Further, those provisions and resulting costs may discourage us or our stockholders from bringing a lawsuit against any of our current or former directors or officers for breaches of their fiduciary duties, even if such actions might otherwise benefit our stockholders.

We do not intend to pay cash dividends on our capital stock in the foreseeable future.

Other than the cash dividend paid in connection with the Merger, we have never declared or paid any dividends on our common stock and do not anticipate paying any dividends in the foreseeable future. Any future payment of cash dividends in the future would depend on our financial condition, contractual restrictions, solvency tests imposed by applicable corporate laws, results of operations, anticipated cash requirements and other factors and will be at the discretion of our Board of Directors. Our stockholders should not expect that we will ever pay cash or other dividends on our outstanding capital stock.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We may be subject to certain claims by Circassia.

In connection with the termination of our license agreement with Circassia, we may be subject to certain claims by Circassia. Adverse outcomes in some or all of these claims may negatively affect our ability to conduct our business. However, as of the date of this Annual Report, we cannot estimate the likelihood that we will be subject to any claims or the effects thereof on our business and operations

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 expires on March 2021. The Company has a research and development facility in Madison, Wisconsin under a lease that expires on May 2026.

ITEM 3. LEGAL PROCEEDINGS

On March 16, 2018, Empery Asset Master, Ltd., Empery Tax Efficient, LP and Empery Tax Efficient II, LP, (filed a complaint in the Supreme Court of the State of New York, 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 predicated on mutual mistake. 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 Master, 159,869 warrant shares for Empery I and 252,672 warrant shares for Empery II and the exercise price could be reduced from $3.66 to $1.57 per share. While the Company has several meritorious defenses against the claims, the ultimate resolution of the matter, if unfavorable, could result in a material loss. On March 9, 2020, we filed a motion for summary judgment, which remains pending.

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 19, 2020, there were approximately 108 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 11 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

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 "Item 6. Selected Consolidated Financial Data" and 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 on Form 10-K 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 an emerging 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. LungFit™ can generate NO up to 400 parts per million ("ppm") for delivery to a patient's lungs. 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 lung disease 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 LungFit™ can potentially address. Our current areas of focus with the LungFit™ are persistent pulmonary hypertension of the newborn ("PPHN"), severe acute respiratory syndrome coronavirus 2 (SARS CoV-2), bronchiolitis ("BRO") and nontuberculous mycobacteria ("NTM"). Our current product candidates will be subject to premarket reviews and approvals by the U.S. Food and Drug Administration, or 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 U.S.

An additional focus of the Company is solid tumors. For this indication the LungFit™ system is not utilized due to the ultra-high concentrations of NO used. We have developed a delivery system that can safely delivery NO concentrations in excess of 10,000 ppm directly to a solid tumor. This program is in pre-clinical development and will require FDA, or similar agency in another country, approval to enter human studies.

With respect to PPHN, our novel LungFit™ 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). We believe LungFit™ has many competitive advantages over the current approved NO delivery systems in the U.S., European Union, Japan and other markets. For example, LungFit™ does not require the use of a high-pressure cylinder, utilizes less space than other similar devices, does not require cumbersome purging procedures and places less burden on hospital staff in carrying out safety procedures.

Our novel LungFit™ can also deliver a high concentration of NO to the lungs, which we believe has the potential to eliminate microbial infections, including bacteria, fungi and viruses, among other benefits. We believe current FDA-approved NO vasodilation treatments would have limited success in treating microbial infections given the low concentrations of NO being delivered. 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 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 the delivery of a dosage of NO at 150 ppm or higher to the lungs.

To date, we have conducted the following studies:

Date	Study	Indication	Primary	Results
2011	Phase 1 Safety (n=10)	All comers	Safety	• No SAEs
2013 –2014	POC double blind randomized (n=43)	Bronchiolitis (due to any virus)	Safe & Eff	• No SAEs; 24 hour reduction in hospital length of stay
2013 - 2014	Pilot open label (n=9)	Cystic Fibrosis (CF)	Safe & Eff	• No SAEs; Lowered bacterial load
2016	Compassionate use ISR (n=2)	NTM abscessus (CF)	Safe & Eff	• No SAEs; clinical & surrogate endpoints improved
2017	Compassionate use National Institute of Health, US (n=1)	NTM abscessus (CF)	Safe & Eff	• No SAEs; Improvements in clinical endpoints
2017	Pilot open label (N=9)	NTM abscessus	Safe & Eff	• No SAEs; clinical & surrogate endpoints improved
2018	Pilot: double blind randomized (n=67)	Bronchiolitis (due to any virus)	Safe & Eff	• No SAEs; 27hr 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=89)	Bronchiolitis (due to any virus)	Safe & Eff	• No SAEs; 150 ppm treatment showed statistically significant improvements in primary and key secondary endpoints compared to both 85 ppm and control

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

Product	Indication	Development Status	Key Dates[1]	US Sales Potential[2]	Worldwide Sales Potential[2]
LungFit™ PH Ventilator compatible	In-Hospital use for PPHN and cardiac surgery	Final preparations for PMA	PMA filing 2H 2020 US launch 1H 2021	>$300 million	>$600 million
LungFit™	COVID-19	Pilot studies in progress	Pilot study data 2H 2020	N/A	N/A
	Bronchiolitis	3 Pilot studies complete Pivotal-ready	Pivotal starts 4Q21 US launch 2023	>$500 million Beyond Air to commercialize	>$1.2 billion
LungFit™ Home	Nontuberculous mycobacteria (NTM) lung infection	Pilot phase	4Q20 start for pilot Study with self-administration	>$1 billion	>$2.5 billion
	Severe exacerbations due to lung infections in COPD patients	Pre-clinical	Pilot study start 2H21	>$2.5 billion	>$6 billion
Solid Tumors	Multiple solid tumors	Pre-clinical	Initial data presented AACR June 2020	TBD	TBD

† *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) All figures are Company estimates for peak year sales: Global sales potential includes US sales potential

We plan to submit for premarket approval or ("PMA") to the FDA towards the end of the third quarter of 2020 for the use of the LungFit™ in PPHN. We also expect to make certain regulatory filings outside of the U.S. later in 2020. According to the 2019 year-end report from Mallinckrodt Pharmaceuticals, aggregate sales of low concentration NO in the U.S. were in excess of $540 million in 2019, while sales outside of the U.S., where there are multiple market participants, sales were considerably lower than in the U.S. We believe the U.S. sales potential of LungFit™ 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 both the U.S. and Israel in 2021 and will continue to launch globally throughout 2021 and beyond.

SARS CoV-2 is a global pandemic with a widespread impact across many countries. We have received approval from the FDA to run a study in COVID-19 (the disease caused by SARS CoV-2 infections) patients using our LungFit™ system. We have also received approval from Health Canada to run a similar study to the one approved by the FDA. We look forward to results from both of these studies in the summer/fall of 2020. The fact that our system does not need cylinders allows for us to potentially provide a practical solution to this crisis. We have applied for grants related to COVID-19 in the United States and other countries. However, no funding is required to perform the clinical studies recently approved by FDA and Health Canada.

With respect to bronchiolitis, we initiated a randomized, double blind, controlled trial with three arms randomized 89 subjects 1:1:1 to standard supportive therapy (SST), SST plus 85 ppm NO and SST plus 150 ppm NO for infants hospitalized due to bronchiolitis in the fourth quarter of 2019. The trial is complete and we recently released top line data. These data were consistent on safety with no SAE's related to NO therapy. With respect to efficacy, the 150 ppm arm was statistically significant when compared to both the control arm and the 85 ppm arm on the Primary endpoint of fit for discharge from the hospital and the key secondary endpoint of hospital length of stay. The 85 ppm was no different from control on both endpoints. This is an exceptional result given the low number of patients and provides clear evidence of the need for 150 ppm to achieve the desired efficacy. The pivotal study for bronchiolitis was originally set to be performed in the 2020/21 winter, but due to the SARS CoV-2 pandemic, hospitals will not be considering any new study proposals not related to SARS CoV-2 or COVID-19. At this time, we anticipate commencing a pivotal study in the United States in the fourth quarter of 2021 and complete it late in the second quarter of 2022. We would submit a PMA to the FDA about 6 months after trial completion. Regulatory filings outside of the U.S., as long as no additional trials are required, would begin after our review process is completed in the U.S. For this indication, we believe U.S. sales potential to be greater than $500 million and worldwide sales potential to be greater than $1.2 billion.

Over 3 million new cases of bronchiolitis are reported worldwide each year. In the U.S., there are approximately 130,000 annual bronchiolitis hospitalizations among children two years of age or younger and approximately 177,000 annual hospitalizations among the elderly population related to RSV infection only with the number rising higher due to other viruses similar to those that cause bronchiolitis in very young children.

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.

Our nontuberculous mycobacteria (NTM) program has produced data from four compassionate use subjects and nine patients from a multi-center pilot study completed in 2018. All patients suffered from NTM *abscessus* infection and had underlying cystic fibrosis. One compassion patient was treated with our nitric oxide generator at the National Heart, Lung and Blood Institute ("NHLBI"). The rest were treated with our NO cylinder-based delivery system. All patients were treated with 160 ppm NO at intermittent 30-minute dosing over 21 days, except one patient who was treated over 26 days and another patient who was treated with 250 ppm NO over 28 days. We expected to begin a study by the end of 2020 (delayed about 6 months by the COVID-19 pandemic) where patients would self-administer high concentration NO at home over a period of 12 weeks with LungFit™. We now anticipate preliminary data for this study will be available during the first half of 2021 and that a full dataset will be available in the second half of 2021. If the trial is successful, we would commence a pivotal study in 2022. 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.

NTM lung infection is a rare and serious pulmonary disease associated with increased morbidity and mortality. There is an increasing rate of lung disease caused by NTM, which is an emerging public health concern worldwide. There are approximately 50,000 patients diagnosed with NTM in the U.S., and there are an estimated additional 100,000 patients in the U.S. that have not yet been diagnosed. In Asia, the number of patients suffering from NTM surpasses what is seen in the U.S. To date we have treated only the *abscessus* form of NTM which comprises approximately 20-25% of all NTM. We will be treating both the*abscessus and mycobacterium avium complex (MAC)* forms of NTM.

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 *abscessus* 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 NTM *abscessus* lung disease in North America, Europe or Japan. There is one inhaled antibiotic approved in the U.S. for the treatment of refractory NTM MAC. Current guideline-based approaches to treat NTM lung disease involve multi-drug regimens of anti-biotics 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 1997 and 2007, researchers found that the prevalence of NTM in the U.S. is increasing at approximately 8% per year and that NTM patients on Medicare over the age of 65 are 40% more likely to die over the period of the study than those who did not have the disease (Adjemian et al., 2012). NTM *abscessus* treatment costs are estimated to be more than double that of NTM MAC. In total, a 2015 publication from co-authors from several U.S. government departments stated that prior year statistics led to a projected 181,037 national annual cases in 2014 costing the U.S. healthcare system approximately $1.7 billion (Strollo et al., 2015).

For the solid tumor program, we have just released pre-clinical data at the virtual American Academy of Cancer Research (AACR) which showed the promise of delivering NO at concentrations of 25,000 ppm – 200,000 ppm directly to tumors. Results showed local tumor ablation with complete eradication in 5 of 30 mice. Additionally, regardless of whether the tumor was completely or partially cleared, all colon tumor bearing mice were resistant to a second challenge of colon cancer. Breast tumor bearing mice a 7-10 day delay in the uptake of breast cancer post challenge. Pre-clinical work will continue throughout the rest of 2020 and most of 2021.

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

Over 3 million new cases of bronchiolitis are reported worldwide each year. In the U.S., there are approximately 130,000 annual bronchiolitis hospitalizations among children two years of age or younger and approximately 177,000 annual hospitalizations among the elderly population related to RSV infection only with the number rising higher due to other viruses similar to those that cause bronchiolitis in very young children.

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 have not generated revenues from royalties or sales of any product and will not until we obtain marketing approval of, and commercialize, our product candidates. As of March 31, 2020, we had an accumulated deficit of $57.6 million. Our financing activities are described below under “Liquidity and Capital Resources.”

The impact of COVID-19 on the Company is unknown at this time. The financial consequences of this situation cause uncertainty as to the future and its effects on the economy and the Company.

Financial Operations Overview

Critical Accounting Estimates and Policies

We describe our significant accounting policies more fully in Note 2 to our consolidated financial statements for the years ended March 31, 2020 and March 31, 2019.

Use of Estimates

The preparation of financial statements in conformity with 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's evaluates its significant estimates including accruals for expenses under consulting, licensing agreements, and clinical trials, stock-based compensation, warrant fair value determination and associated debt discount and classification within stockholders' equity, assumptions associated with revenue recognition, and the determination of deferred tax attributes and the valuation allowance thereon.

Revenue

The Company recognizes revenue when we transfer promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers we perform 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, we assess the goods or services promised within each contract, assess whether each promised good or service is distinct and identify those that are performance obligations.

The Company must use 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 the contract are satisfied.

Research and Development

Research and development expenses are charged to the statement of operations and comprehensive loss as incurred. Research and development expenses include salaries, costs incurred by outside laboratories, manufacturer's, consultants, accredited facilities in connection with clinical trials and preclinical studies and stock based-compensation.

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 stock on the date of grant. That cost is recognized over the period during which an 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 the Company has not paid any dividends since its inception and does not anticipate paying dividends in the foreseeable future. The Company started to blend its trading activity with it traded peer group to obtain expected volatility. Due to the Company's limited trading history, the Company utilizes an implied volatility based on an aggregate of guideline companies. In 2020, the Company began to blend its historical volatility with the peer group in order to obtain expected volatility. The peer companies were based similar publicly traded peer companies. The Company routinely reviews its calculation of volatility based on, the Company's life cycle, its peer group, and other factors. The Company uses the simplified method for share-based compensation to estimate the expected term.

Compensation expense for options and warrants granted to non-employees is determined by the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured, and is recognized over the service period. The expense was previously adjusted to fair value at the end of each reporting period until such awards vested, and the fair value of such instruments, as adjusted, was expensed over the related vesting period. Adjustments to fair value at each reporting date resulted in income or expense, depending upon the estimate of fair value and the amount of expense recorded prior to the adjustment. In June 2018, the FASB issued ASU No. 2018-07, Stock-based Compensation: Improvements to Nonemployee Share-based Payment Accounting, which amends the existing accounting standards for share-based payments to nonemployees. This ASU aligns much of the guidance on measuring and classifying nonemployee awards with that of awards to employees. Under the new guidance, the measurement of nonemployee equity awards is fixed on the grant date. We adopted this ASU the fourth quarter of fiscal 2019, and as a result, the fair value of all non-employee awards became fixed at the start of the fourth quarter.

Investment in Marketable Securities

Investments in equity marketable securities classified available-for-sale are carried at fair value with the changes in unrealized gains and losses recognized in the Company's results in operations. Realized gains and (losses) from the sale of marketable securities are recognized in the statement of operations using the specific identification method on a trade date basis.

Licensed Right to Use Technology

Licensed right to use technology that is considered platform technology is recorded as an intangible asset which resulted from the NitricGen transaction, see Note 11. The intangible asset was valued based upon the fair value of the options issued to NitricGen and the cash paid for this transaction. The license also contains two future milestone additional payments aggregating $1,800,000. The intangible asset is being amortized on a straight-line method over its estimated useful life of thirteen years.

Impairment of 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 we consider 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 our use of the acquired assets or the strategy for our overall business,
- significant negative regulatory or economic trends, and
- significant technological changes, which would render equipment and manufacturing processes obsolete.

Recoverability of assets that will continue to be used in our 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, 2020, and March 31, 2019, the Company 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.

The Company files a 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. The Company has recorded a liability in accrued expenses $154,300 for uncertain tax positions as of March 31, 2019 and reversed this accrual for the year ended March 31, 2020 which resulted in income. Tax years 2016 through 2020 remain open to examination by federal and state tax jurisdictions. The Company files tax returns in Israel for which tax years 2014 through 2020 remain open.

Commitments

License Agreements

On October 22, 2013, the Company entered into a patent license agreement with CareFusion, pursuant to which it agreed to pay to the third party a non-refundable upfront fee of $150,000 and is obligated to pay 5% royalties of any licensed product net sales, but at least $50,000 per annum through the term of the agreement and the advance is credited against future royalties payments. As of December 31, 2019, the Company did not pay any royalties since the Company did not have any revenues from this license. The term of the 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 agreement, and may be terminated unilaterally by CareFusion with 30 days' prior written notice in the event that we do 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 (the "Option") on September 7, 2016 for $25,000. On January 13, 2017, the Company exercised the Option and paid $500,000. The Company becomes 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 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 an agreement ("Agreement") with NitricGen, Inc. ("NitricGen") acquire a global, exclusive, transferable license and associated assets including intellectual property, know-how, trade secrets and confidential information from NitricGen related to 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 Agreement, and royalties on sales LungFit™. The Company paid NitricGen $100,000 upon the execution agreement, $100,000 upon achieving the next milestone and issued 100,000 options to purchase the Company's stock valued at $295,000 upon executing the agreement. The remaining future milestone payments are $1,800,000 of which $1,500,000 in due after six months after the first approval of LungFit™ by the Food and Drug Administration or the European Medicine Evaluation Agency.

On September 18, 2019, the Company entered into an agreement with a contract research organization to perform a pilot study for bronchiolitis. As of March 31, 2020, the remaining cash commitment under this agreement is approximately $303,000. The Company recorded $754,000 expense for the year ended March 31, 2020.

Employment Agreements

Certain officer agreements contain a change of control provision for payment of severance arrangements.

Contingencies

On March 16, 2018, Empery Asset Master, Ltd., Empery Tax Efficient, LP and Empery Tax Efficient II, LP, filed a complaint in the Supreme Court of the State of New York, 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 predicated on mutual mistake. 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 Master, 159,869 warrant shares for Empery I and 252,672 warrant shares for Empery II and the exercise price could be reduced from $3.66 to $1.57 per share. While the Company has several meritorious defenses against the claims, the ultimate resolution of the matter, if unfavorable, could result in a material loss. On March 9, 2020, we filed a motion for summary judgment, which remains pending.

Results of Operations

Comparison for the year ended March 31, 2020 to the year ended March 31, 2019.

	Year Ended March 31, 2020	Year Ended March 31, 2019
License revenue	$ 1,390,104	$ 7,724,001
Operating expenses		
Research and development	(10,648,920)	(3,929,558)
General and administrative	(8,883,119)	(6,852,988)
Operating loss	(18,141,935)	(3,058,545)
Other income (loss)		
Realized and unrealized loss on available for sale marketable securities	(2,075,602)	(3,581,193)
Dividend income	115,716	86,748
Interest expense	(30,543)	(1,506)
Foreign exchange gain (loss)	35,560	(920)
Other expenses	-	(3,034)
Total other loss	(1,954,869)	(3,499,905)
Net loss before income taxes	(20,096,804)	(6,588,450)
Benefit for income taxes	154,300	-
Net loss	$ (19,942,504)	$ (6,558,450)
Deemed dividend from warrant modification	(522,478)	-
Net loss attributed to common shareholders	$ 20,464,982	$ (6,558,450)
Net loss per share – basic and diluted	$ (1.78)	$ (0.77)
Weighted average number of common shares outstanding – basic and diluted	11,506,212	8,498,525

License Revenue

License revenue for the year ended March 31, 2020 was $1,390,104 and for the year ended March 31, 2019 was $7,724,000, respectively. On January 23, 2019, the Company entered into an agreement for commercial rights (the "License Agreement") with Circassia Limited and its affiliates (collectively, "Circassia") for persistent pulmonary hypertension of the newborn ("PPHN") and future related indications at concentrations of ≤ 80 ppm in the hospital setting in the United States and China. On December 18, 2019, the Company terminated the License Agreement, see Note 13. The Company would have received payments up to $32.55 million in up front and regulatory milestones, of which $31.5 million was associated with the U.S. market. All such payments were payable in cash or ordinary shares of Circassia, at the discretion of Circassia, with payments in cash discounted by approximately 5%. Royalties are payable only in cash. In consideration of the rights and licenses granted to Circassia by the Company, there were five milestone that were associated with Agreement. Due to the consideration constraints associated with milestones 3, 4, and 5, only the amounts associated with milestone 1 and 2 have been allocated. During the year ended March 31, 2019, the Company met the first two milestones under the license agreement and received 17,572,815 ordinary shares 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 recorded as deferred revenue to be recognized over a period of time from the commencement of the agreement to when management expects to submit the PMA. For the year ended March 31, 2020 and March 31,2019, $1,390,1049 and $607,769, respectively of such revenue associated with this second performance obligation has been recognized. As of March 31, 2020, and March 31, 2019, deferred revenue was $873,190 and $2,263,294, respectively. On December 18, 2019, the Company terminated the License Agreement with Circassia pursuant to which the Company had granted Circassia an exclusive royalty-bearing license to distribute, market and sell the Company's nitric oxide generator and delivery system in the United States and China.

Research and Development

Research and development for the year ended March 31, 2020 was $10,648,920, as compared to $3,929,558 for the year ended March 31, 2019. The increase of $6,719,362 was primarily attributed an increase in the development of the LungFit System for PPHN and an increase in pre-clinical studies for bronchiolitis, an increase in salaries and employee benefits and an increase in stock-based compensation.

General and Administrative Expenses

General and administrative expense for the year ended March 31, 2020 and March 31, 2019 was $8,883,119, as compared to $6,852,988, respectively. The increase of $2,030,131 was primarily attributed to an increase in non-cash stock-based compensation expense, an increase in professional fees and an increase of insurance expense.

Other Income (Loss)

Other loss for the year ended March 31, 2019 was $1,954,869 as compared to $3,499,905 for the year ended March 31, 2020. For the year ended March 31, 2019, $3,581,193 was primarily from for the unrealized loss and realized loss on available for sale securities and realized loss primarily related to Circassia Pharmaceuticals plc stock.

Net Loss Attributed to Common Shareholders

For the year ended March 31, 2020, the Company recorded a non-cash deemed dividend of $522,478 that represented a warrant modification. This increased the loss to the common shareholders. As a result of the foregoing, our net loss attributed to common shareholders for the year ended March 31, 2020, was $20,464.982 or $1.78 per share, basic and diluted, as compared to a net loss for the year ended March 31, 2019 of $6,558,450 or $0.77 per share, basic and diluted.

Liquidity and Capital Resources

Overview Update

We have incurred losses and generated negative cash flows from operations since inception. To date, 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 regulatory approval is received for our product candidates. Since the time the Company became public through March 31, 2020, we have funded our operations principally through the issuance of equity securities. As shown in the accompanying financial statements, the Company has an operating cash flow decrease of $15.3 million for the year March 31, 2020 and has accumulated losses of $57.6 million since inception through March 31, 2020. The Company has cash, cash equivalent and restricted cash of $25.5 million as of March 31, 2020. The Company estimates that it has enough cash and liquidity to execute its current business plan for at least one year from the date of the filing of this annual report on Form 10-K.

On March 17, 2020, the Company entered into a facility agreement (the "Facility Agreement") with certain lenders pursuant to which the lenders shall loan to up to $25,000,000 in five tranches of $5,000,000 per tranche at the option of the Company ("Tranches"), provided however that the Company may only utilize tranches three through five following FDA approval of our LungFit™ PH product. 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. Beyond Air has the ability to draw down on a $5 million tranche prior to FDA approval of the LungFit™ PH product.

On April 2, 2020, Beyond Air, Inc. entered into an At-The-Market Equity Offering for $50 million and utilized the Company's shelf registration statement. The Company may sell shares of our common stock having aggregate sales proceeds of up to $50,000,000 from time to time in this offering. If shares are sold, there is a three 3 percent fee paid to the sales agent.

On May 14, 2020, the Company entered into a $40 million New Purchase Agreement with LPC, that replaced the existing $20 million purchase agreement. The New Purchase Agreement provides for the issuance of up to $40 million of the Company's common stock which we may sell from time to time in our sole discretion to Lincoln Park over the next 36 months, subject to the conditions and limitations in the New Purchase Agreement.

Our ability to continue to operate is dependent upon the filing of our PMA, expected timing of the Company's launch of our product, obtaining Partners in other parts of the world, timing of future milestones and royalties, raising additional funds to finance our activities. There are no assurances that we will be successful in obtaining an adequate level of financing for the development and commercialization of our product candidates. The Company's ability to continue to operate is dependent upon raising additional funds to finance its activities.

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

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

- the progress and costs of our preclinical studies, clinical trials and other research and development activities;
- the scope, prioritization and number of our clinical trials and other research and development programs;
- the costs and timing of obtaining 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, 2020 and March 31, 2019.

	For The Year Ended March 31, 2020	For The Year Ended March 31, 2019
Net cash provided by (used in):		
Operating activities	$ (15,250,049)	$ 1,341,052)
Investing activities	$ 4,423,433	$ (1,793,639)
Financing activities	$ 34,934,590	$ 1,071,490
Net increase in cash, cash equivalents and restricted stock	$ 24,107,974	$ 618,903

Comparison between March 31, 2020 and March 31, 2019

Operating Activities

For the year ended March 31, 2020, net cash used by operating activities was $15,250,049 which was primarily due to our net loss of $19,942,504, a decrease in current assets prepaid expenses, accrued expenses and deferred revenue and operating lease payments of $2,180,374 and was offset by an increase in unrealized and realized loss in available for sale securities of $2,075,602 an increase in operating lease expense, accounts payable of $1,154,433 and non-cash expense of $3,741,704. For the year ended March 31, 2019, net cash provided by in operating activities was $1,341,052 which was primarily due to the net loss of $6,558,450, a use of cash $729,159 for other current assets and prepaid expenses which was offset by unrealized and realized loss marketable securities of $3,498,883, a source of cash for accounts payable, accrued expenses and deferred revenue of $2,862,684 and non-cash expense of $2,464,108.

Investing Activities

For the year ended March 31, 2020, cash provided by investing activities was $4,423,433 which was from the net purchases of available for sale marketable securities of $4,467,064 and $43,631 purchase of property and equipment. For the year ended March 31, 2019, the Company used in activities $1,793,639 which was from the net purchases of available for sale marketable securities of $1,737,164 and $56,475 purchase of property and equipment.

Financing Activities

For the year ended March 31, 2020, net cash provided by financing activities was $34,934,590 was primarily from the net proceeds an underwritten offering and private placement of $10,169,300, net proceeds from a private placement of $7,839,500, and the issuance and sales of $7,740,000 of common stock to Lincoln Park Financial Corporation (“LPC”), proceeds from the issuance of common stock from warrant exercises of $3,968,900 and proceeds from the issuance of common stock from the exercise of options for $210,700. For the year ended March 31, 2019, net cash provided by financing activities was $1,071,490 which was primarily from the net proceeds of $799,156 from the sale of stock to LPC and a bank loan of $292,250.

Contractual Obligations

The following tables sets forth our contractual obligations for the next five years and thereafter for the year ended March 31, 2020:

	2021	2022	2023	2024	2025	Total
Rent	$ 90,100	$ 65,400	$ 64,700	$ 16,300	$ -	$ 236,500
Facility loan agreement	-		1,500,000	2,750,000	750,000	5,000,000
Loan	335,400	-	-	-	-	335,400
CRO	302,500	-	-	-	-	302,500
Total	**$ 728,000**	**$ 65,400**	**$ 1,564,700**	**$ 2,766,300**	**$ 750,000**	**$ 5,874,400**

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 ("NIS"). 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 on Form 10-K. An index of those consolidated financial statements is found in Item 15 of this Annual Report on Form 10-K.

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 principal executive officer and 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) as of the end of the period covered by this Annual Report are effective at such reasonable assurance level.

(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 Securities Exchange Act of 1934, as amended. 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 conducted an evaluation of the effectiveness of our internal control over financial reporting as of March 31, 2020, 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, 2020.

(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, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

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	49	Chief Executive Officer and Chairman of the Board of Directors
Amir Avniel	46	President, Chief Operating Officer and Director
Douglas Beck, CPA	59	Chief Financial Officer
Ron Bentsur	52	Director
Erick J. Lucera	53	Director
Yoori Lee	47	Director
Dr. William Forbes	58	Director
Robert F. Carey	61	Director

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

Steven Lisi has served on our Board since January 13, 2017, and has served on the Board of AIT 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 $100,000,000 in enterprise value to $1 billion in three years. Mr. Lisi raised $121 million in equity, led the sale of Flamel's contract manufacturing facility, rationalized the product pipeline, refocused the business development effort, transformed the investor base and established Flamel's presence in Ireland. Prior to his position with Flamel, 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 Masters in International Business from Pepperdine University.

Amir Avniel, President, Chief Operating Officer and Director

Amir Avniel has served on AIT Ltd.'s Board since 2011 and became AIT 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.

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 16 until October 31, 2018, the Chief Financial Officer of Relmada Therapeutics, Inc. from December 2013 and was the Chief Financial Officer for iBio, Inc. from January 2011 to March 2013. 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 AIT 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 ^{TM} (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. Ron's vast industry experience is invaluable to our Board.

Yoori Lee, Director

Ms. 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. Yoori's perspective on the industry is unique and provides Beyond Air with a distinct advantage over other companies of our size and stage of development.

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 founder, President and Chief Executive Officer of Vivelix Pharmaceuticals, Ltd., a clinical-stage pharmaceutical company focused on gastrointestinal diseases since 2016. Prior to founding Vivelix, 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.

Robert F. Carey

Mr. Carey joined Beyond Air's Board of Directors in February 2019. He has an extensive track record of accomplishment within the 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. Mr. Carey 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 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 a managing director in the healthcare groups at Dresdner Kleinwort Wasserstein and Vector Securities for a total of 14 years. 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.

Erick J. Lucera, Director

Erick J. Lucera joined Beyond Air's Board of Directors in August 2017 and serves on our Audit Committee. He was appointed Chief Financial Officer for AVEO Oncology, a NASDAQ traded biopharmaceutical company focused on targeted medicines for oncology and other unmet medical needs in 2020. Erick was the Chief Financial Officer of Valeritas, 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 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. Erick's financial and industry background serve us well on many fronts, including our audit committee.

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

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 period ended March 31, 2019. 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 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 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. 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

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.

Delinquent Section 16(a) Reports

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

ITEM 11. EXECUTIVE COMPENSATION

Executive Compensation

The following table provides information regarding the compensation earned by our named executive officers for the years ended March 31, 2020 and March 31, 2019.

Name and Principal Position	Year	Salary Cost	Restricted Stock Awards (A)	Option Awards (A)	Bonus	Total
Steven A. Lisi.	2020	$ 450,000	$ 546,535	$ 272,300	$ -	$ 1,268,835
Chief Executive Officer and Chairman of the Board	2019	$ 450,000	$ 462,007	$ 1,927,657	$ -	$ 2,839,664
Amir Avniel	2020	$ 400,000	$ 264,115	$ 155,600	$ -	$ 819,715
President, Chief Operating Officer and Director	2019	$ 400,000	$ 220,200	$ 727,790	$ -	$ 1,347,990
Douglas Beck, CPA (1)	2020	$ 250,000	$ 78,450	77,800	$ -	$ 406,250
Chief Financial Officer	2019	$ 104,167	$ -	$ 300,012	$ -	$ 404,179
Adam Newman	2020	$ 250,000	$ 237,965	$ 155,600	$ -	$ 643,565
Inhouse Counsel	2019	$ 250,000	$ 229,500	$ 492,493	$ -	$ 971,993
Duncan Fatkin (2)	2020	$ 250,000	$ 130,750	$ 136,150	$ -	$ 516,900
Chief Commercial Officer	2019	$ 104,167	$ -	$ 312,934	$ -	$ 417,101

(A) This column represents the grant date fair value of the award in accordance with stock-based compensation rules under Accounting Standards Codification Topic 718

(1) Mr. Beck was appointed as the Company's Chief Financial Officer on November 1, 2018.

(2) Mr. Fatkin was appointed as the Company's Chief Commercial Officer on January 14, 2019.

Employment and Service Agreements with Executive Officers; Consulting and Directorship Services with Directors

Our employment and service agreements with our Executive Officers and Directors contain provisions standard for a company in our industry regarding non-competition, confidentiality of information and assignment of inventions.

Directors Agreement with Steven A. Lisi

On June 24, 2016, the board of directors of AIT Ltd., appointed Steven Lisi to serve as a Member of its Board of Directors, effective as of June 24, 2016, and concurrently entered into an agreement with Mr. Lisi to serve as a member of the Board of Directors pursuant to which, among other things, the Company agreed to pay as compensation and benefits upon consummation of a financing round in the United States ("Financing Round") (i) an annual retainer of $40,000 to be paid on equal monthly installments; (ii) one-time bonus amounted to $150,000 with 30 days from completion of the Financing Round ("One-Time Bonus") and (iii) restricted shares equal to 3% of all issued and outstanding fully diluted shares of the Company after the completion of the Financing Round (including any green shoe or similar) with vesting schedule of 33.33% of such shares to be vested immediately upon the completion of a Financing Round, 33.33% of such shares to be vested after 6 month anniversary of the completion of a Financing Round and the remaining 33.33% of such shares after 12 month anniversary of the completion of a Financing Round. Upon the closing of a change of control transaction, as defined in the agreement, the unvested options shall be accelerated and vested immediately. The One-Time Payment was paid on January 27, 2017. The Board of AIT Ltd. determined to issue to Mr. Lisi an aggregate of 364,286 ordinary shares issuable under this agreement in connection with financing transactions contemplated immediately prior to the Merger. The shares were exchanged for shares of our common stock in connection with the Merger.

In January 2017, the board of directors approved a consulting fee payable to Mr. Lisi in an amount equal to $18,000 per month which terminated upon his acceptance of the CEO position in June, 2017 at which time, the Board of Directors approved a salary of $260,000 per annum to Mr. Lisi. In March 2018, the board of directors approved a salary of $450,000 per annum to Mr. Lisi pursuant to an employment agreement.

Effective March 1, 2018, we entered into an employment agreement with Mr. Lisi with an annual salary of $450,000. Pursuant to the terms and conditions of employment, Mr. Lisi will receive 400,000 options to purchase common stock vesting over a period of three years. In the event of termination without cause, Mr. Lisi will be entitled to severance equal to twenty-four months of base salary, a lump sum payment 1.5 times that of the most recent earned short term incentive award and all outstanding options would automatically vest.

Employment Agreement with Amir Avniel

On October 1, 2014, we entered into a service agreement with Amir Avniel, employing him to provide the Company with professional Chief Executive Officer services, effective as of October 1, 2014. As thereafter amended in September, 2015, Mr. Avniel was entitled to a base salary of $15,800 per month. If Mr. Avniel is terminated without cause, he shall be entitled to a salary continuation at the rate then in effect for a period of 90 days from the effective date of termination. In the event Mr. Avniel is terminated within two (2) years following the closing of a change of control of the Company, he shall be entitled to a salary continuation at the rate then in effect for a period of seven (7) months following the effective date of termination.

On October 31, 2016, Mr. Avniel waived the accrued but unpaid salary owed by the Company to him in the total aggregate amount of $304,000.

In February, 2017, the Board of Directors approved a salary to Mr. Avniel of $260,000 per annum, which was thereafter confirmed by the Board of Directors in June 2017 when Mr. Avniel resigned from the position of CEO and assumed the position of COO. In March 2018, the board of directors increased Mr. Avniel's annual salary to $400,000.

Effective March 1, 2018, we entered into an employment agreement with Mr. Avniel with an annual salary of $400,000. Pursuant to the terms and conditions of employment, Mr. Avniel will receive 250,000 options to purchase common stock vesting over a period of three years. In the event of termination without cause, Mr. Avniel will be entitled to severance equal to twenty-four months of base salary, a lump sum payment equal to 1.5 times that of the most recent earned short-term incentive award and all outstanding options would automatically vest.

Offer Letter Agreement with Douglas Beck

Pursuant to the terms of an employment offer letter agreement between the Company and Mr. Beck dated October 17, 2018. Mr. Beck will be paid an annual salary of $250,000 per year. The Company issued Mr. Beck options to purchase 85,000 shares of common stock of the Company at an exercise price of $4.25 per share. Under Mr. Beck's offer letter his employment is at will. In the event of termination without cause he will be entitled to a severance equal to one month's base salary for every six months employed by the Company not to exceed six months of base salary and the options will automatically vest.

Employment Agreement with Adam Newman

Effective March 1, 2018 we entered into an employment agreement with Mr. Newman with an annual salary of $450,000. Pursuant to the terms and conditions of employment, Mr. Newman will receive 150,000 options to purchase common stock vesting over a period of three years. In the event of termination without cause, Mr. Newman will be entitled to severance equal to twenty-four months of base salary, a lump sum payment equal to 1.5 times that of the most recent earned short term incentive award and all outstanding options would automatically vest.

Offer Letter Agreement with Duncan Fatkin

Pursuant to the terms of an employment offer letter agreement between the Company and Mr. Fatkin December 20, 2018, Mr. Fatkin will be paid an annual salary of $250,000 per year. The Company issued Mr. Fatkin options to purchase 85,000 shares of common stock of the Company at an exercise price of $4.25 per share. Under Mr. Fatkin's offer letter his employment is at will. In the event of termination without cause he will be entitled to a severance equal to one month's base salary for every six months employed by the Company not to exceed six months of base salary. In the event of a change of control of the Company, he will receive severance payments equal to six (6) months' base salary and the options will automatically vest.

Equity Compensation Plan Information

We maintain the Second Amended and Restated 2013 Equity Incentive Plan (the "2013 Plan"). The 2013 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance share awards, and other stock-based awards (collectively, the "stock awards"). Stock awards may be granted under the 2013 Plan to our employees, directors and consultants, other than incentive stock options which may only be granted to employees of the Company.

The maximum number of shares of common stock available for issuance under the 2013 Plan is 4,100,000 shares.

The 2013 Plan is scheduled to terminate on August 13, 2028. No stock awards shall be granted pursuant to the 2013 Plan after such date, but Awards theretofore granted may extend beyond that date. The Board may suspend or terminate the Plan at any earlier date pursuant to the 2013 Plan. No stock awards may be granted under the Plan while the Plan is suspended or after it is terminated.

The following table summarizes the total number of outstanding options and shares available for other future issuances of options under the 2013 Plan as of March 31, 2020.

Plan Category	Number of Shares to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Shares Remaining Available for Future Issuance Under the Equity Compensation Plan (Excluding Shares in First Column)
Equity compensation plans approved by stockholders -	785,000	$ 5.54	221,047
Equity compensation plans not approved by stockholders	2,268,589	$ 4.50	-
Total	3,053,589	$ 4.77	221,047

Outstanding Equity Awards as of March 31, 2020

	Equity awards						
Name	**Date of Grant**	**Number of securities underlying unexercised options (#) exercisable**	**Number of securities underlying unexercised options (#) unexcercisable**	**Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)**	**Option exercise price ($)**	**Option expiration date**	**Number of shares or units of stock that have not vested (#)**
Steven A. Lisi	08/31/2018	300,000	100,000	-	4.25	08/13/2029	-
	03/31/2019	187,500	62,500		4.80	03/31/2029	
	03/11/2020	-	70,000		5.32	03/11/2030	
	12/31/2018						70,400
	01/01/2019						9,600
	12/31/2019						104,500
Amir Avniel	08/31/2018	125,000	125,000	-	4.25	08/13/2029	-
	03/31/2019	-	140,000		4.80	03/31/2029	
	03/11/2020	-	40,000		5.32	03/11/2030	
	12/31/2018						36,000
	01/01/2019						9,600
	12/31/2019						50,500
	02/20/2017	100,000	-		4.25	02/20/2027	
Douglas Beck, CPA	11/01/2018	21,250	63,750		4.25	11/01/2028	
	03/31/2019	3,750	11,250		4.80	03/31/2029	
	03/11/2020	-	20,000		5.32	03/11/2030	
	12/31/2019						15,000
Adam Newman	08/31/2018	37,500	112,500	-	4.25	08/13/2029	-
	03/31/2019	25,000	75,000		4.80	03/31/2029	
	03/11/2020	-	40,000		5.32	03/11/2030	
	12/31/2018						30,400
	01/01/2019						9,600
	12/31/2019						45,500
	06/30/2017 (1)	100,000	-		4.25	02/20/2027	
Duncan Fatkin	02/14/2019	21,250	63,750		5.05	02/14/2029	
	03/11/2020	-	35,000		5.32	03/11/2030	
	12/31/2019						25,000

(1) Received for performing legal services for the Company prior to being employed by the Company.

Director Compensation

Persons serving as both an Officer and a Director of the Company are only included in the Executive Compensation Table above for the year ended March 31, 2020.

Name	Fees earned or paid in cash ($)	Stock awards ($)	Option awards ($)	Non-equity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All Other Compensation ($)	Total ($)
Dr. William Forbes	-	-	97,250	-	-	-	97,250
Ron Bentsur	-	-	97,250	-	-	-	97,250
Erick J. Lucera	-	-	97,250	-	-	-	97,250
Yoori Lee	-	-	97,250	-	-	-	97,250
Robert F. Carey	-	-	97,250	-	-	-	97,250

For the year ended March 31, 2020, the Board of Directors received options to purchase 25,000 shares of common and each option expires in ten year from the date of grant. Compensation expense was based upon the grant date fair value of the award in accordance with stock-based compensation rules under Accounting Standards Codification Topic 718.

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

The following table sets forth information with respect to the beneficial ownership of our common stock by each person known by us to beneficially own more than 5.0% of any class of our voting securities together with:

- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

The percentages of common stock beneficially owned are reported on the basis of regulations of the SEC governing the determination of beneficial ownership of securities. Except as indicated in the footnotes to this table, each beneficial owner named in the table below has sole voting and sole investment power with respect to all shares beneficially owned. Percentage computations are based on 16,841,555 shares of our common stock outstanding as of June 19, 2020.

Under the terms of the warrants issued by the Company to the holders listed below, no holder may exercise a warrant to the extent such exercise would cause such holder, together with its affiliates and any other persons acting as a group with such holder or any of its affiliates, to have acquired a number of shares of common stock which would exceed 4.99%, or, in the case of certain holders indicated below, 9.985%, (subject to an increase of such percentage to 9.99% on 61 days' notice by the holder to the Company) of our then outstanding common stock, excluding for purposes of such determination shares of common stock issuable upon exercise of warrants that have not been exercised. We refer to the foregoing limitation applicable to each individual holder or group as the "Ownership Cap." The share numbers in the table below do not reflect the Ownership Cap, but the figures contained in the "Percentage of Outstanding Shares" column reflect the Ownership Cap applicable to each holder.

Name and Address of Beneficial Owner (1)	Number of Shares	Percentage of Outstanding Shares (2)
5% Owners		
Charles Mosseri Marlio	1,524,214(3)	9.0%
Deerfield Partners, L.P.	856,863(4)	5.1%(4)
Executive Officers and Directors		
Steven A. Lisi	1,389,709(6)	8.0%(4)
Amir Avniel	835,218(7)	4.9%(4)
Ron Bentsur	362,918(8)	2.1%
Dr. William Forbes	13,105(9)	*%
Robert F. Carey	25,668(10)	*%
Erick Lucera	19,842(11)	*%
Yoori Lee	25,789(12)	*%
Douglas Beck, CPA	40,460(13)	*%
Executive Officers and Directors as a Group (Eight persons)	2,721,709	16.2%

* Less than one percent (1.0%).

(1) The address of these persons, unless otherwise noted, is c/o Beyond Air, Inc., 825 East Gate Boulevard, Suite 320 Garden City, New York, 11530.

(2) Shares of common stock beneficially owned and, except as limited by the Ownership Cap, the respective percentages of beneficial ownership of common stock includes for each person or entity shares issuable on the exercise of all options and warrants and the conversion of other convertible securities beneficially owned by such person or entity that are currently exercisable or will become exercisable or convertible within 60 days following June 19, 2020. Such shares, however, are not included for the purpose of computing the percentage ownership of any other person.

(3) Based, in part, on information provided on Schedule 13G/A filed with the SEC on March 13, 2020. Includes 108,816 shares of common stock issuable upon exercise of the warrants issued to Mr. Mosseri Marlio in connection with Facility Loan Agreement in March 2020.

(4) Based, in part, on information provided on Schedule 13G/A filed with the SEC on January 23, 2020 by Deerfield Mgmt, L.P., Deerfield Management Company, L.P., Deerfield Partners, L.P., Deerfield Special Situations Fund, L.P. and James E. Flynn. Includes 856,863 shares of common stock issuable upon exercise of the warrants issued to Deerfield Special Situations Fund, L.P. in the Company's 2017 and 2018 offerings and now held by Deerfield Partners, L.P. James E. Flynn is the President of J.E. Flynn Capital, LLC, which is the general partner of Deerfield Partners, L.P., Deerfield Special Situations Fund, L.P. and Deerfield Mgmt, L.P., which is the general partner of Deerfield Special Situations Fund, L.P. and Deerfield Partners L.P. Flynn Management LLC is the general partner of Deerfield Management Company, L.P.. The reporting persons' business address is 780 Third Avenue, 37th Floor, New York, NY 10017.

(5) The provisions of the warrants issued by the Company in its 2017 and 2018 offerings beneficially owned by the holder restrict the exercise of such warrants to the extent that, upon such exercise, the number of shares then beneficially owned by the holder and any other person or entities with which such holder would constitute a Section 13(d) "group" would exceed 4.99% (subject to an increase of such percentage to 9.99%) of the total number of our then-outstanding shares of common stock.

(6) Includes 200,446 shares of common stock issuable upon exercise of the warrants issued to Mr. Lisi in the Company's 2017 and 2018 offerings. Includes 362,5000 vested options to purchase shares of common stock.

(7) Includes 45,676 shares of common stock issuable upon exercise of the warrants issued to Mr. Avniel in the Company's 2017 and 2018 offerings. Includes 275,000 vested options to purchase common stock and 32,666 shares of common stock held by Dandelion Investments Ltd., over which Mr. Avniel has sole voting and dispositive power.

(8) Includes 73,419 shares of common stock issuable upon exercise of the warrants issued to Mr. Bentsur in the Company's 2017 and 2018 offerings. Includes 362,5000 vested options to purchase shares of common stock.

(9) Includes 8,250 vested options to purchase common stock.

(10) Includes 6,250 vested options to purchase common stock.

(11) Includes 1,171 shares of common stock issuable upon exercise of the warrants issued to Mr. Lucera in the Company's 2018 offering, and 17,500 vested options to purchase common stock.

(12) Includes 2,342 shares of common stock issuable upon exercise of the warrants issued to Ms. Lee in the Company's 2018 offering and 16,250 vested options to purchase common stock.

(13) Includes 25,000 vested options to purchase common stock.

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

Transactions with Related Persons

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.

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.

Purchases of Our Securities

On June 3, 2019, Steven Lisi purchased 58,252 shares of our common stock 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 at a purchase price of $3.66 per share, or $697,000.

On June 3, 2019, Charles Mosseri-Marlio purchased 385,000 shares of common stock at a purchase price of $5.00 per share or $1,925,000. On December 12, 2019, Mr. Mosseri-Marlio purchased 150,273 shares of our common stock at a purchase price of $3.66 per share, or $500,000. On March 17, 2020, Mr. Mosseri-Marlio loaned us $3,160,000 pursuant to the terms of the Facility Agreement and we issued him warrants to purchase 108,816 shares of common stock at an exercise price of $7.26 per share.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Audit Fees

The aggregate fees billed for the fiscal year ended March 31, 2019 for professional services rendered by Kost Forer Gabbay & Kasierer, a Member of Ernst & Young Global for quarterly reviews of our interim financial statements and services normally provided by the independent accountant in connection with statutory and regulatory filings or engagements for this fiscal period were as follows:

	Year Ended March 31, 2019
Audit Fees	$ 8,000
Audit Related Fees	
Tax Fees	12,870
All Other Fees	
Total	**$ 20,870**

The aggregate fees billed for the fiscal year ended March 31, 2019 for professional services rendered by Marcum LLP for quarterly reviews of our interim financial statements and services normally provided by the independent accountant in connection with statutory and regulatory filings or engagements for this fiscal period were as follows:

	Year Ended March 31, 2019
Audit Fees	$ 42,900
Audit Related Fees	$ -
Tax Fees	$ -
All Other Fees	$ -
Total	**$ 42,900**

The aggregate fees billed for the fiscal year ended March 31, 2020 and March 31, 2019 for professional services rendered by Friedman LLP for the audit of our annual financial statements provided by the independent accountant in connection with statutory and regulatory filings or engagements for this fiscal period were as follows:

	Year Ended March 31, 2020	Year Ended March 31, 2019
Audit Fees	$ 207,250	$ 92,037
Audit Related Fees	$ -	$ -
Tax Fees	$ -	$ -
All Other Fees	$ -	$ -
Total	**$ 207,250**	**$ 92,037**

In the above table, “audit fees” are fees billed by our company’s external auditor for services provided in auditing our company’s annual financial statements for the subject year. Audit fees also include professional services performed for filing of the Company’s registration statement on Form S-1 and S-3 for equity offerings, Form S-8 for registering restricted stock and stock options and other filings. “Audit-related fees” are fees not included in audit fees that are billed by the auditor for assurance and related services that are reasonably related to the performance of the audit review of our company’s financial statements. “Tax fees” are fees billed by the auditor for professional services rendered for tax compliance, tax advice and tax planning. “All other fees” are fees billed by the auditor 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 auditors. 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 each of Kost Forer Gabbay & Kasierer, a Member of Ernst & Young Global, Marcum LLP and Friedman LLP, respectively, and believes that the provision of services for activities unrelated to the audit, if any, is compatible with maintaining such auditors’ independence.

PART IV

ITEM 15. EXHIBITS, 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 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., 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 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 amended and filed with the SEC on March 15, 2017 and incorporated herein by reference.
4.2	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 amended and filed with the SEC on March 15, 2017 and incorporated herein by reference.
4.3	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 amended and filed with the SEC on April 4, 2017 and incorporated herein by reference.
4.4	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 amended and filed with the SEC on February 22, 2018 and incorporated herein by reference.
4.5	Beyond Air, Inc. Second Amended and Restated 2013 Equity Incentive Plan (included in Appendix A to our Definitive Proxy Statement filed on January 17, 2020 and incorporated herein by reference).
4.6	Warrant to Purchase Common Stock, filed as exhibit 4.1 to our Current Report on Form 8-K filed on March 17, 2020 and incorporated herein by reference.
4.7	Description of the Company's Securities Registered under Section 12 of the Securities Exchange Act of 1934, as amended.

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 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.
10.13	Securities Purchase Agreement, by and among AIT Therapeutics, Inc. and the Investors party thereto, filed as Exhibit 10.1 to our Current Report on Form 8-K, as amended and filed with the SEC on February 22, 2018 and incorporated herein by reference.
10.14	Registration Rights Agreement, by and among AIT Therapeutics, Inc. 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 February 22, 2018 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, filed as Exhibit 10.1 to our Current Report on Form 8-K, 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.
10.20	Underwriting Agreement, dated December 10, 2019, by and between Beyond Air, Inc. and SunTrust Robinson Humphrey, Inc., filed as Exhibit 1.1 to our Current Report on Form 8-K, filed with the SEC on December 10, 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.
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

^ Portions of this exhibit have been omitted pursuant to a request for confidential treatment.

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 the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Date: June 23, 2020

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 23, 2020
/s/ Douglas Beck Douglas Beck	Chief Financial Officer (Principal Financial Officer)	June 23, 2020
/s/ Amir Avniel Amir Avniel	Chief Operating Officer and Director	June 23, 2020
/s/ Erick Lucera Erick Lucera	Director	June 23, 2020
/s/ Yoori Lee Yoori Lee	Director	June 23, 2020
/s/ William Forbes William Forbes	Director	June 23, 2020
/s/ Ron Bentsur Ron Bentsur	Director	June 23, 2020
/s/ Robert Carey Robert Carey	Director	June 23, 2020

BEYOND AIR, INC. AND ITS SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

AS OF MARCH 31, 2020

INDEX

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of Beyond Air, Inc. (formerly: AIT Therapeutics, Inc.) and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Beyond Air, Inc. (formerly: AIT Therapeutics, Inc.) and Subsidiaries (the "Company") as of March 31, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the two-year period ended March 31, 2020, 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 23, 2020

BEYOND AIR, INC. AND ITS SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	March 31, 2020	March 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 19,829,275	$ 1,340,203
Restricted cash	5,635,836	16,934
Marketable securities	-	6,542,667
Other current assets and prepaid expenses	1,149,806	788,409
Right-of-use lease assets	66,970	-
Total current assets	26,681,887	8,688,213
Licensing right to use technology	412,763	495,000
Right-of-use lease assets	128,757	-
Property and equipment, net	211,337	244,872
TOTAL ASSETS	$ 27,434,744	$ 9,428,085
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,256,229	$ 1,164,672
Accrued expenses	1,097,534	1,567,638
Deferred revenue	873,190	2,263,294
Stock to be issued to a vendor	240,000	144,000
Operating lease liability	69,342	-
Loan payable	335,358	263,604
Total current liabilities	4,871,653	5,403,208
Operating lease liability	131,581	-
Facility Agreement loan, net	4,339,065	-
Total liabilities	9,342,299	5,403,208
Commitments and contingencies		
Shareholders' equity		
Preferred Stock, $0.0001 par value per share: 10,000,000 shares authorized, 0 shares issued and outstanding	-	-
Common Stock, $0.0001 par value per share: 100,000,000 shares authorized, 16,056,360 and 8,714,815 shares issued and outstanding as of March 31, 2020 and March 31, 2019, respectively	1,606	871
Treasury stock	(25,000)	(25,000)
Additional paid-in capital	75,702,915	41,693,578
Accumulated deficit	(57,587,076)	(37,644,572)
Total shareholders' equity	18,092,445	4,024,877
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 27,434,744	$ 9,428,085

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, 2020	Year Ended March 31, 2019
License revenue	$ 1,390,104	$ 7,724,001
Operating expenses		
Research and development	(10,648,920)	(3,929,558)
General and administrative	(8,883,119)	(6,852,988)
Operating loss	(18,141,935)	(3,058,545)
Other income (loss)		
Realized and unrealized loss on available for sale marketable securities	(2,075,602)	(3,581,193)
Dividend income	115,716	86,748
Interest expense	(30,543)	(1,506)
Foreign exchange gain (loss)	35,560	(920)
Other expenses	-	(3,034)
Total other loss	(1,954,869)	(3,499,905)
Net loss before income taxes	(20,096,804)	(6,588,450)
Benefit for income taxes	154,300	-
Net loss	$ (19,942,504)	$ (6,558,450)
Deemed dividend from warrant modification	(522,478)	-
Net loss attributed to common shareholder	$ 20,464,982	$ (6,558,450)
Net loss per share – basic and diluted	$ (1.78)	$ (0.77)
Weighted average number of common shares outstanding – basic and diluted	11,506,212	8,498,525

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

BEYOND AIR, INC. AND ITS SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
FOR THE YEAR ENDED MARCH 31, 2019

	Common Stock		Treasury	Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Shareholders'
	Number	Amount	Stock	Capital	Deficit	Income (Loss)	Equity
Balance as of April 1, 2018	8,397,056	$ 840	$ (25,000)	$ 32,141,110	$ (30,569,764)	$ (2,986)	$ 1,544,200
Adjustment due to adoption of ASU-2017 (1)	-	-		6,194,292	(516,358)	-	5,677,934
Adjustment due to adoption of ASU 2016-01	-	-		-	-	2,986	2,986
At the market stock issuance of common stock, net,	297,000	29	-	799,156	-	-	799,185
Issuance of common stock upon exercise of options	20,759	2	-	8,699	-	-	8,701
Stock-based compensation				2,550,321			2,550,321
Net loss	-	-	-	-	(6,558,450)	-	(6,558,450)
Balance as of March 31, 2019	8,714,815	$ 871	$ (25,000)	$ 41,693,578	$ (37,644,572)	-	$ 4,024,877

(A) The Company elected to adopt Accounting Standards Update 2017-11 retrospective to outstanding financial instruments with down round feature by means of cumulative-effect adjustment to the beginning additional paid-in capital of $6,194,292 and accumulated deficit of $(516,358) as of April 1, 2018. This ASU affects all entities that issue financial instruments (for example, warrants or convertible instruments) that include down round features.

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

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

	Common Stock		Treasury	Additional Paid-in	Accumulated	Total Shareholders'
	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	-	3,478,649
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

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, 2020	For The Year Ended March 31, 2019
Cash flows from operating activities		
Net loss	$ (19,942,504)	$ (6,558,450)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities		
Depreciation and amortization	159,403	64,787
Stock-based compensation	3,577,649	2,399,321
Operating lease expense	62,875	-
Payment of operating lease liability	(57,679)	-
Unrealized and realized loss on marketable securities to available for sale marketable securities	2,075,602	3,498,883
Change of management's assessment of prior year research and development to licensing right to use technology	-	(200,000)
Adoption of ASU 2016-01	-	2,986
Amortization of debt issuance cost and deferred financing fees	4,652	-
Changes in:		
Other current assets and prepaid expenses	(361,395)	(729,159)
Accounts payable	1,091,557	322,633
Accrued expenses	(470,105)	276,757
Deferred revenue	(1,390,104)	2,263,294
Net cash (used in) provided by operating activities	(15,250,049)	1,341,052
Cash flows from investing activities		
Investment in available for sale marketable securities	(37,320,235)	(12,222,774)
Proceeds from redemption of marketable securities	41,787,299	10,485,610
Purchase of property and equipment	(43,631)	(56,475)
Net cash provided by (used in) investing activities	4,423,433	(1,793,639)
Cash flows provided by from financing activities		
Issuance of common stock in an underwritten offering and private placement, net of offering costs	10,169,343	-
Issuance of common stock in private placement, net of offering costs	7,839,495	-
Issuance of common stock related to at the market offerings, net of offering costs	7,745,012	-
Issuance of common stock, net of offering cost	-	799,185
Proceeds from credit facility loan	5,000,000	
Proceeds from loan	375,570	292,250
Payment of loan	(303,806)	(28,646)
Proceeds from the exercise of warrants	3,968,944	-
Payment of debt issuance costs	(70,618)	-
Proceeds from the exercise of stock options	210,650	8,701
Net cash provided by financing activities	34,934,590	1,071,490
Increase in cash, cash equivalents and restricted cash	24,107,974	618,903
Cash, cash equivalents and restricted cash at beginning of period	1,357,137	738,234
Cash, cash equivalents and restricted cash at end of period	$ 25,465,111	$ 1,357,137
Supplemental disclosure of non-cash financing and investing activities:		
Right of use assets	$ 258,605	$ -
Operating lease liability	$ 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	$ -
Fair market value of options issued to NitricGen for the licensing right to use technology	$ -	$ 295,000
Supplemental disclosure of cash flow items:		
Interest paid	$ 23,112	$ -
Income taxes paid	$ -	$ -

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

NOTE 1 ORGANIZATION AND BUSINESS

Beyond Air, Inc. ("Beyond Air" or the "Company") was incorporated on April 24, 2015. On June 25, 2019, the Company's name was changed to Beyond Air, Inc. from AIT Therapeutics, Inc. The Company has the following wholly-owned subsidiaries.

Beyond Air, Ltd was incorporated in Israel on May 1, 2011.

Advanced Inhalation Therapies (AIT), a wholly owned subsidiary of Beyond Air, Ltd was incorporated on August 29, 2014, in Delaware.

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

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

The Company is an a clinical-stage medical device and biopharmaceutical company focused on developing inhaled Nitric Oxide (NO) for the treatment of patients with respiratory conditions, including serious lung infections and pulmonary hypertension, and gaseous NO for the treatment of solid tumors. Since its inception, the Company has devoted substantially all of its efforts to research and development.

The Company is developing a nitric oxide ("NO") generator and delivery system (the "LungFit™ system") that is capable of generating NO from ambient air. LungFit™ can generate NO up to 400 parts per million ("ppm") for delivery to a patient's lungs. 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. Our current areas of focus with the LungFit™ are persistent pulmonary hypertension of the newborn ("PPHN"), severe acute respiratory syndrome coronavirus 2 (SARS CoV-2), bronchiolitis ("BRO") and nontuberculous mycobacteria ("NTM"). The Company's current product candidates will be subject to premarket reviews and approvals by the U.S. Food and Drug Administration, or 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.

Liquidity Risks and Uncertainty

The Company has incurred cash used in operating activities of $15.3 million for the year ended March 31, 2020, and has accumulated losses of $57.6 million. The Company has cash, cash equivalents and restricted cash of $25.5 million as of March 31, 2020. Based on management's current business plan, the Company estimates it will have enough cash 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 will depend on many factors, including, but not necessarily limited to, the actual cost and time necessary for clinical studies and other actions needed to obtain regulatory approval of our medical devices in development as well as the cost to launch our first product for PPHN, assuming approval of our Premarketing Application ("PMA") which is expected to be filed in the third quarter of calendar 2020.

The Company will be required to raise additional funds through sale of equity or debt securities or through strategic collaboration and/or licensing agreements, to fund operations and continue our clinical trials 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 growth plans, our results of operations and our financial condition.

On April 2, 2020, Beyond Air, Inc. entered into an At-The-Market Equity Offering for $50 million and utilized the Company's shelf registration statement, see Note 14.

On March 17, 2020, the Company entered into a $25 million unsecured loan facility agreement (the "Facility Agreement") with certain lenders that is unsecured. As of March 31, 2020, the Company has drawn down of the first of five tranches of $5 million which is include in restricted cash. The Company has the ability to drawn down on an additional $5 million tranche prior to the PMA filing, see Note 10.

On May 14, 2020, the Company entered into a $40 million purchase agreement ("New Purchase Agreement") with Lincoln Park Capital Fund, LLC ("LPC"), that replaces the existing $20 million purchase agreement. The New Purchase Agreement provides for the issuance of up to $40 million of the Company's common stock through May 2023 at the Company's discretion., The Company utilized the shelf registration statement, see Note 14.

NOTE 2 SIGNIFICANT ACCOUNTING POLICIES

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 the accompanying financial statements.

Use of Estimates

The preparation of financial statements in conformity with 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's evaluates its significant estimates including accruals for expenses under consulting, licensing agreements, and clinical trials, stock-based compensation, warrant fair value determination and associated debt discount and classification within stockholders' equity, assumptions associated with revenue recognition, and the determination of deferred tax attributes and the valuation allowance thereon.

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, uncertainty of market acceptance of products and the potential need to obtain additional financing. The Company is dependent on third party suppliers, in some cases single-source suppliers.

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.

The Company's products require approval or clearance from the U.S. Food and Drug Administration 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 our product candidates could be further disrupted and adversely affected by the recent outbreak of COVID-19. The spread of SARS CoV-2 from China to other countries has resulted in the Director General of the World Health Organization declaring COVID-19 a pandemic on March 11, 2020. We have addressed 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. However, there can be no assurance that this analysis will enable us to avoid part or all of any impact from the spread of COVID-19 or its consequences. The extent to which the COVID-19 pandemic and global efforts to contain its spread will impact our operations will depend on future developments, which are still uncertain and cannot be predicted at this time.

Concentrations

The Company's license revenue was from two milestone payments from a terminated license for sales and marketing rights agreement, see Note 9. The Company is seeking additional partners.

The Company relies on two vendors to manufacture its delivery system. The Company is reliant on the vendors for commercial manufacturing of our LungFit™ generator and delivery systems and nitrogen dioxide filters for both clinical studies and commercial supply, if regulatory approval is received.

NOTE 2 SIGNIFICANT ACCOUNTING POLICIES (continued)

Financial Instruments

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents and marketable securities. The Company maintains its cash and cash equivalents in bank deposit and other interest-bearing accounts in major banks in Israel 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.

Restricted Cash

As of March 31, 2020, restricted cash includes $5,000,000 of cash in an escrow account from the lenders of the facility agreement loan, See Note 10. Subsequent to March 31, 2020, the Company received the funds from the escrow account into a cash operating cash. In addition, as of March 31, 2020, restricted cash includes $619,000 of cash that is designated for a contract manufacturer. This cash is expected be used for material and parts that require a long lead time. Collateral for vehicle leases are invested in bank deposit accounts which is restricted and as of March 31, 2020 was $16,836 and as of March 31, 2019 was $16,934, respectively.

Cash equivalents are short-term highly liquid investments that are readily convertible to cash with original maturities of three months or less at acquisition. Restricted cash is collateral for vehicle leases and invested in bank deposit accounts.

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:

	For The Year Ended March 31, 2020	For The Year Ended March 31, 2019
Cash and cash equivalents	$ 19,829,275	$ 1,340,203
Restricted cash	5,635,836	16,934
Cash and cash equivalents and restricted cash	$ 25,465,111	$ 1,357,137

Revenue

The Company recognizes revenue when we transfer promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. To determine revenue recognition for contracts with customers we perform 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, we assess the goods or services promised within each contract, assess whether each promised good or service is distinct and identify those that are performance obligations.

The Company must use 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 the contract are satisfied, see, Note 9.

NOTE 2 SIGNIFICANT ACCOUNTING POLICIES (continued)

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.

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, we have viewed our operations and managed our 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, costs incurred by outside laboratories, manufacturer's, consultants, accredited facilities in connection with clinical trials and preclinical studies and stock based-compensation.

Foreign Exchange Transactions

BA Ltd.'s operations are in Israel and Beyond Air's operations are in the United States. The Company's management believes that 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. Thus, the functional and reporting currency of the Company is the U.S. dollar. The Company's transactions and balances denominated in U.S. dollars are presented at their original amounts. Non-dollar transactions and balances have been re-measured to U.S. dollars in accordance with the Accounting Standards Board Codification Topic 830, "Foreign Currency Matters".

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 stock on the date of grant. That cost is recognized over the period during which an 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 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 an implied volatility based on an aggregate of guideline companies. In 2020, the Company began to blend its historical volatility with the peer group in order to obtain expected volatility. The peer companies were based similar publicly traded peer companies. The Company routinely reviews its calculation of volatility based on, the Company's life cycle, its peer group, and other factors. The Company uses the simplified method for share-based compensation to estimate the expected term.

NOTE 2 SIGNIFICANT ACCOUNTING POLICIES (continued)

Compensation expense for options and warrants granted to non-employees is determined by the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured, and is recognized over the service period. The expense was previously adjusted to fair value at the end of each reporting period until such awards vested, and the fair value of such instruments, as adjusted, was expensed over the related vesting period. Adjustments to fair value at each reporting date resulted in income or expense, depending upon the estimate of fair value and the amount of expense recorded prior to the adjustment. In June 2018, the FASB issued ASU No. 2018-07, Stock-based Compensation: Improvements to Nonemployee Share-based Payment Accounting, which amends the existing accounting standards for share-based payments to nonemployees. This ASU aligns much of the guidance on measuring and classifying nonemployee awards with that of awards to employees. Under the new guidance, the measurement of nonemployee equity awards is fixed on the grant date. We adopted this ASU the fourth quarter of fiscal 2019, and as a result, the fair value of all non-employee awards became fixed at the start of the fourth quarter.

Investment in Marketable Securities

Investments in equity marketable securities classified available-for-sale are carried at fair value with the changes in unrealized gains and losses recognized in the Company's results in operations. Realized gains and (losses) from the sale of marketable securities are recognized in the statement of operations using the specific identification method on a trade date basis.

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:

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

NOTE 2 SIGNIFICANT ACCOUNTING POLICIES (continued)

Licensed Right to Use Technology

Licensed right to use technology that is considered platform technology is recorded as an intangible asset which resulted from the NitricGen transaction, see Note 11. The intangible asset was valued based upon the fair value of the options issued to NitricGen and the cash paid for this transaction. The license also contains two future milestone additional payments aggregating $1,800,000. The intangible asset is being amortized on a straight-line method over its estimated useful life of thirteen years. The expected amortization expense for the next five year and thereafter is as follows for the year ended March 31,:

2021	$	38,077
2022		38,077
2023		38,077
2024		38,077
2025		38,077
Thereafter		222,378
Total	$	412,763

Impairment of 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 we consider 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 our use of the acquired assets or the strategy for our overall business,
- significant negative regulatory or economic trends, and
- significant technological changes, which would render equipment and manufacturing processes obsolete.

Recoverability of assets that will continue to be used in our 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, 2020, and March 31, 2019, the Company 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.

The Company files a 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. The Company has recorded a liability in accrued expenses of $0 and $154,300 for uncertain tax positions as of March 31, 2020 and March 31, 2019 and reversed this accrual for the year ended March 31, 2020 which resulted in income, respectively. Tax years 2016 through 2020 remain open to examination by federal and state tax jurisdictions. The Company files tax returns in Israel for which tax years 2014 through 2020 remain open.

NOTE 2 SIGNIFICANT ACCOUNTING POLICIES (continued)

Net Income (Loss) Per Share

Basic and diluted net loss per share attributable to common stockholders is computed by dividing the net loss and a deemed dividend from a warrant modification attributable to common stockholders by the weighted average number of common shares 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 shareholders per share excludes all anti-dilutive common shares. 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 common shares are not assumed to have been issued if their effect is anti-dilutive, see Note 8.

Recently Adopted Accounting Standards

In July 2017, the FASB issued ASU 2017-11, Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815) Accounting for Certain Financial Instruments with Down Round Features. This ASU affects all entities that issue financial instruments (for example, warrants or convertible instruments) that include down round features. This ASU relates to the recognition, measurement, and earnings per share of certain freestanding equity-classified financial instruments that include down round features affect entities that present earnings per share in accordance with the guidance in Topic 260. The Company elected to adopt Update ASU 2017-11 during the third quarter of 2018, retrospective to outstanding financial instruments with down round feature by means of cumulative-effect adjustment by increasing beginning additional paid-in capital by $6,194,292 and decreasing accumulated deficit by $516,358 as of April 1, 2018.

NOTE 2 SIGNIFICANT ACCOUNTING POLICIES (continued)

Recently Adopted Accounting Pronouncements (continued)

On April 1, 2019, the Company adopted Accounting Standards Update No. 2016-02, Leases (Topic 842) (ASU 2016-02), as amended, 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. The Company early adopted the new guidance using the modified retrospective transition approach and practical expedients to all leases existing at the date of initial application and not restating comparative periods. See Note 11. As of April 1, 2019, the adoption date, the Company has identified three operating lease arrangements. The adoption of ASC 842 resulted in the recognition of operating lease liabilities and right-of-use assets of approximately of $264,570 and $258,605, respectively. The right-of use assets and operating lease liability is as follows as of March 31, 2020:

	March 31, 2020
Right of use asset short-term	$ 66,970
Right of use asset long-term	128,757
	$ 195,727
Operating lease liability short-term	$ 69,342
Operating lease liability long-term	131,581
	$ 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 our 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. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates. The weighted average discount rate and remaining term on lease obligation is approximately 8.3% and 3.0 years. Operating lease expense is recognized on a straight-line basis over the lease term and is included in general and administrative expenses. Amortization expense for finance (capital) leases is recognized on a straight-line basis over the lease term and is included in general and administrative expenses and research and development expenses, while interest expense for finance leases is recognized using the effective interest method.

In August 2018, the FASB issued ASU 2018-13, “Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement”, which adds disclosure requirements to Topic 820 for the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. The guidance is effective for the Company’s interim and annual reporting periods beginning with the Company’s fiscal year ended March 31, 2021, and early adoption is permitted. The Company is evaluating the impact of this accounting standard update on the Company’s consolidated financial statements.

NOTE 2 SIGNIFICANT ACCOUNTING POLICIES (continued)

Recently Issued Accounting Standards Not Yet Adopted

In December 2019, the Financial Accounting Standards Board ("FASB") issued ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes." as part of its initiative to reduce complexity in the accounting standards. The standard eliminates certain exceptions related to the approach for intraperiod 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. The standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. 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.

NOTE 3 FAIR VALUE MEASUREMENT

The Company's financial instruments primarily include cash, cash equivalents, restricted cash, marketable securities, accounts payable, loan payable and credit facility loan. Due to the short-term nature of cash and accounts payable, the carrying amounts of these assets and liabilities approximate their fair value. 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 3 FAIR VALUE MEASUREMENT

The Company does not have any marketable securities as of March 31, 2020. As of March 31, 2019, the fair value of the Company's marketable securities was as follows:

	As of March 31, 2019			
	Level 1	Level 2	Level 3	Total
Assets				
Marketable securities -				
Circassia Pharmaceuticals plc (Note 9)	$ 5,649,486	-	-	5,649,486
Mutual funds	893,181	-	-	893,181
	$ 6,542,667	$ -	$ -	$ 6,542,667

NOTE 4 PROPERTY AND EQUIPMENT

Property and equipment consist of the following as of March 31, 2020 and March 31, 2019, respectively:

	March 31, 2020	March 31, 2019
Clinical and medical equipment	$ 357,795	$ 357,795
Computer equipment	73,982	42,782
Furniture and fixtures	53,895	41,464
Leasehold improvements	5,336	5,336
	491,008	447,377
Accumulated depreciation and amortization	(279,671)	(202,505)
	$ 211,337	$ 244,872

Depreciation and amortization expense for the year ended March 31, 2020 and March 31, 2019 was $77,166 and $64,787 respectively

NOTE 5 SHAREHOLDER'S EQUITY

Common stock

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. The Company also entered into a registration rights agreement with LPC whereby the Company filed a registration statement with the SEC and the shares of the Company's common stock that may be issued to LPC under the terms of the Purchase Agreement. The Company may direct LPC, at its sole discretion, and subject to certain conditions, to purchase up to 10,000 shares of common stock on any business day, provided that at least one business day has passed since the most recent purchase. The amount of a purchase may be increased under certain circumstances provided, however that LPC cannot make any single purchase that exceeds $750,000. The purchase price of shares of common stock related to the future funding will be based on the then prevailing market prices of such shares at the time of sales as described in the Purchase Agreement.

From the execution of the Purchase Agreement on August 10, 2018 to March 31, 2019, the Company issued and sold to LPC 297,000 shares of common stock at an average price of $4.53 per shares for net proceeds of $1,344,185. Net proceeds after offering costs for these transactions were $799,185. For the year ended March 31, 2020 the Company issued and sold to LPC 1,420,000 shares of common stock at an average price of $5.45 per shares for net proceeds of $7,745,012. There is $10,910,804 remaining on the Purchase Agreement. This agreement was replaced in May 2020, see Note 14.

On July 2, 2019, the SEC declared effective, the Company's Form S-3 shelf registration statement which allows the Company to sell up to $100 million of equity securities.

On June 3, 2019, the Company entered into a purchase agreement with investors for the issuance of 1,583,743 shares of common stock, resulting in net proceeds of $7,839,495. The Company's CEO invested $300,000 and received 58,253 shares of common stock at $5.15 per share. In addition, certain directors and employees invested $610,000 for an aggregate of 118,254 shares of common stock, representing a purchase price of $5.15 per share. The Company registered the shares sold in June 2019 in a registration statement on Form S-3 that was declared effective in September 2019.

On December 12, 2019, the Company closed on an underwritten 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 underwritten offering shares were registered under the Company's Form S-3 shelf registration statement. There were 532,786 common stock that were sold in a private placement and subsequently registered under an effective Form S-1 on January 23, 2020. In addition, the Company's CEO invested $699,999 for 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.

Stock to be Issued to a Vendor

As of March 31, 2020, and March 31, 2019, the Company was obligated to issue 30,000 shares to a vendor for services related to investor relations. For the year ended March 31, 2020 and March 31, 2019, the Company recorded the fair market value of the shares to be issued and recorded stock-based compensation of $96,000 and $144,000, respectively. The fair market value of the liability as of March 31, 2020 and March 31, 2019 was $240,000 and $144,000, respectively.

NOTE 5 SHAREHOLDER'S EQUITY (continued)

Issuance of Restricted Shares

On December 26, 2018, and December 31, 2019, the Board of directors approved the issuance of 340,000 and 390,000, shares of restricted stock, respectively, to officers, employees and consultants and the fair value for the restricted stock awards was valued at the closing price of the Company's stock on the date of grant. Restricted stock vests annually over five years. The fair market value of the restricted shares for stock-based expense is equal to the closing pricing of the Company's stock at the date of grant. Stock based compensation for the year ended March 31, 2020 and March 31, 2019 was $895,040 and $147,719, respectively.

	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 (a)	(67,000)	4.62
Forfeited	(16,200)	4.65
Outstanding as of March 31 2020	646,800	$ 4.99

Stock Option Plan

The Company has an amended and restated Equity Incentive Option Plan (the "2013 Plan"), pursuant to which the Company may award officers, directors, employees, and non-employees with 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 between two to four years and expire up to ten years after the grant date. On December 26, 2018 and February 13, 2019, the Board of Directors authorized the increase of an additional 600,000 and 1,000,000 under the 2013 Plan, respectively. On March 4, 2020, the shareholders approved 1,000,000 shares of common stock authorized, resulting in a total of 4,100,000 shares eligible for issuance under the 2013 Plan. As of March 31, 2020, there are 191,067 shares available under the 2013 Plan.

NOTE 5 SHAREHOLDER'S EQUITY (continued)

A summary of the Company's options for the year ended March 31, 2020 and March 31, 2019 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, 2018	510,904	$ 4.32	9.0	
Granted	1,919,000	4.54		
Exercised	(20,759)	0.42		
Forfeited	(33,333)	4.25		
Outstanding as of March 31, 2019	2,375,812	$ 4.48	9.2	$ 7,952,643
Granted	815,000	5.51		2,027,240
Exercised	(58,662)	3.59		(101,619)
Forfeited	(78,561)	4.03		-
Outstanding as of March 31, 2020	3,053,589	$ 4.77	8.4	$ 9,878,264
Exercisable as of March 31, 2020	1,235,674	$ 4.39	7.8	$ 6,673,690

As of March 31, 2020, the Company has unrecognized stock-based compensation expense of approximately $4,899,000, related to unvested stock options and is expected to be expensed over the weighted average remaining service period of 2.7 years. The weighted average fair value of options granted during the year ended March 31, 2020 ad March 31, 2019 was approximately $4.03 and $3.11 per share, respectively, on the date of grant using the Black-Scholes option pricing model with the following assumption:

	For the Year Ended March 31, 2020	For the Year Ended March 31, 2019
Risk -free interest rate	0.5% - 3.2%	2.5% - 3.2%
Expected volatility	80.7% - 87.5%	80.7% - 84.5%
Dividend yield	0%	0%
Expected terms (in years)	5-10	5-10

The following summarizes the components of stock-based compensation expense which includes common stock, stock options, warrants and restricted stock in the consolidated statements of operations for the year ended March 31, 2020 and March 31, 2019, respectively

NOTE 5 SHAREHOLDERS' EQUITY (continued)

Stock-based Compensation

	Year Ended March 31, 2020	Year Ended March 31, 2019
Research and development	$ 687,674	$ 572,918
General and administrative	2,889,975	1,977,403
Total stock-based compensation expense	$ 3,577,649	$ 2,550,321

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 December 2019 equity offering described above. As a result, the Company recognized the incremental value of $522,478, as a deemed dividend 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	1.7%

A summary of the Company's outstanding warrants as of March 31, 2020 are as follows:

Warrant Holders	Number Of Warrants	Exercise Price	Date Of Expiration	
January 2017 offering - investors	1,531,782	$ 3.66	January 2022	(a)
January 2017 offering - investors	1,531,782	$ 3.66	February 2022	(a)
March 2017 offering - investors	76,662	$ 3.66	March 2021	(a)
March 2017 offering - placement agent	7,541	$ 3.66	March 2021	(a)
March 2018 offering - investors	1,645,437	$ 4.25	March 2022	
Third-party license agreement	208,333	$ 4.80	January 2024	
March 2020 loan (see Note 10)	172,187	$ 7.26	March 2025	
Total	5,173,724			

(a) These warrants have down round protection.

For the year ended March 31, 2020, there were 985,694 warrants exercised for $3,968,944 and 985,694 common stock were issued at an average price per share of $4.03 per share. Warrant holders exercised 156,154 warrants on a cashless basis and the Company issued 73,461 common stock to the warrant holders. For the year ended March 31, 2019, no warrants were exercised.

NOTE 6 CURRENT ASSETS AND PREPAID EXPENSES

A summary of current assets and prepaid expenses as of March 31, 2020 and March 31, 2019 is as follows:

	March 31, 2020	March 31, 2019
Research and development	$ 266,510	$ 324,063
Insurance	471,182	297,945
Professional	156,259	-
Value added tax receivable	124,127	47,889
Other	131,728	118,512
	$ 1,149,806	$ 788,409

NOTE 7 ACCRUED EXPENSES

A summary of the accrued expenses as of March 31, 2020 and March 31, 2019 is as follows:

	As of March 31, 2020	As of March 31, 2019
Vendors – research and development	$ 484,756	$ 103,320
Professional fees	476,638	780,127
Income taxes payable	-	154,300
Employee salaries and benefits	71,066	183,271
Other	65,074	62,084
Total	$ 1,097,534	$ 1,283,102

NOTE 8 BASIC AND DILUTED NET INCOME (LOSS) PER COMMON SHARE

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:

	Year Ended March 31, 2020	Year Ended March 31, 2019
Common stock warrants	5,173,724	6,143,405
Common stock options	3,053,589	2,375,812
Restricted shares	646,800	340,000
Total	8,874,113	8,859,217

NOTE 9 LICENSE AGREEMENT

On January 23, 2019, the Company entered into an agreement for commercial rights (the "License Agreement") with Circassia Limited and its affiliates (collectively, "Circassia") for persistent pulmonary hypertension of the newborn ("PPHN") and future related indications at concentrations of ≤ 80 ppm in the hospital setting in the United States and China. On December 18, 2019, the Company terminated the License Agreement, see Note 13. The Company would have received payments up to $32.55 million in up front and regulatory milestones, of which $31.5 million was associated with the U.S. market. All such payments were payable in cash or ordinary shares of Circassia, at the discretion of Circassia, with payments in cash discounted by approximately 5%. Royalties are payable only in cash.

This contract was evaluated under ASC 606, which was adopted by the Company during fiscal 2019. Based upon the evaluation, it was determined that the contract consists of five performance obligations:

- Performance Obligation 1: non-exclusive transfer of functional intellectual property rights to Circassia, which includes:
  - the consummation of the License Agreement, which included significant pre-agreement negotiation, product specification, and
  - the successful completion of the pre-submission meeting with the FDA. At this meeting the FDA reinforced their assessment of 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 the approval.
- Performance Obligation 3: launch of the approved product in the field in the USA upon FDA regulatory approval
- Performance obligation 4: FDA approval of the product in the field for use in cardiac surgery
- Performance obligation 5: regulatory approval in China for marketing and sale of the product in China for any indication

NOTE 9 LICENSE AGREEMENT (continued)

In consideration of the rights and licenses granted to Circassia by the Company, five milestones were included:

- $7.35 million upon signing or 12,300,971 ordinary shares of Circassia (received in quarter four of fiscal year ended March 31, 2019);
- $3.15 million payable within five (5) business days following the successful completion of a Food and Drug Administration (the "FDA") pre-submission meeting or 5,271,844 ordinary shares of Circassia (received in quarter four of fiscal year ended March 31, 2019);
- $12.6 million payable on the sooner of ninety (90) days post FDA approval of the Product or the launch of the Product in the United States,
- $8.4 million payable within five (5) business days following the approval by the FDA of the Product in certain hospital and clinic settings for use in cardiac surgery; and
- $1.05 million payable within five (5) business days following approval by the FDA equivalent in China for marketing and sale of the Product.

In addition, Circassia shall pay the Company the following royalty amounts until expiration of all of the applicable patents:

- A one-time 5% royalty on the first cumulative $50 million in gross profit in the United States;
- A one-time 5% royalty on the first cumulative $20 million in gross profit in China;

Thereafter, running royalty amounts of 15% of annual gross profit (United States & China combined) up to and including $100 million and 20% of annual gross profit (United States & China combined) exceeding $100 million.

Following expiration of the patents, Circassia shall pay the Company a 14% royalty on annual gross profits up to and including $100 million and a 19% royalty on annual gross profits exceeding $100 million.

Due to the consideration constraints associated with milestones 3, 4, and 5, only the amounts associated with milestone 1 and 2 have been allocated. During the three months ended March 31, 2019, the Company met the first two milestones under the license agreement and received 17,572,815 ordinary shares 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 recorded as deferred revenue to be recognized over a period of time from the commencement of the agreement to when management expects to submit the PMA. For the year ended March 31, 2020 and March 31, 2019, $1,390,104 and $607,769, respectively of such revenue associated with this second performance obligation has been recognized. As of March 31, 2020, and March 31, 2019, deferred revenue was $873,190 and $2,263,294, respectively.

NOTE 10 FACILITY AGREEMENT LOAN

On March 17, 2020, the Company entered into a facility agreement with certain lenders pursuant to which the lenders shall loan to up to $25,000,000 in five tranches of $5,000,000 per tranche at the option of the Company ("Tranches"), provided however that the Company may only utilize tranches three through five following FDA approval of our 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 first tranche was executed on March 17, 2020 and because the funds were held in escrow as of March 31, 2020 they are classified as restricted cash in the consolidated balance sheet. In connection with this utilization of the first tranche, the Company issued, in March 2020, warrants to the lender 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 percentage of its commitment value divided by the five day the volume weighed 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 percentage of its commitment value divided by the five day the VWAP.

As a result, the Company allocated the fair market value at the date of grant of the warrant to stockholders' equity and debt discount valued at $594,979. The Black-Scholes pricing model was used with 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 facility agreement loan balance as of March 31, 2020 is as follows:

Face value of loan	$	5,000,000
Debt discount		(594,979)
Accretion of interest expense		4,562
Deferred offering costs		(70,518)
Facility agreement loan balance – March 31, 2020	$	4,339,065

Maturity of Facility Agreement Loan	March 31, 2020
2021	$ -
2022	-
2023	1,500,000
2024	2,750,000
2025	750,000
Total	$ 5,000,000

NOTE 11 LOAN PAYABLE

As of March 31, 2020, and March 31, 2019, in connection with the Company's insurance policy, a loan of $374,570 and $292,500, respectively was used to finance part of the premium. For the year ended March 31, 2020 and March 31, 2019, the loan consists of nine payments of $42,366 and ten payment of $29,687 bearing interest at 4.3% and 3.3% per annum, respectively. The outstanding balance as of March 31, 2020 and March 31, 2019 was $335,358 and $263,604, respectively.

NOTE 12 INCOME TAXES

The Company's foreign subsidiary is in Israel and subject to a corporate tax rate as follow: 2019 and 2018 – 23%24%. December 2016, the Israeli Parliament approved the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2017 and 2018 Budget Years), which reduces the corporate income tax rate to 24% (instead of 25%) effective from January 1, 2017 and to 23% effective from January 1, 2018. As of March 31, 2010, there is a net operating loss carry forward of approximately $15,726,000 which offset taxable income for an indefinite period of time.

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.

As of March 31, 2020, the Company has approximately $19,400,000 of unused NOL carryforwards for federal tax purposes. 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 $18,025,000 can be carried forward indefinitely. The Company also has state net operating losses in the amount of approximately $20,187,000 expiring during the years 2035 to 2020. 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.

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

	For the Year Ended March 31, 2020	For the Year Ended March 31, 2019
Domestic	$ (16,685,568)	$ (4,475,659
Foreign	(3,411,236)	(2,082,791
Total	$ (20,096,804)	$ (6,558,450

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 $6,166,000 during the year ended March 31, 2020.

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

NOTE 12 INCOME TAXES (continued)

	March 31, 2020	March 31, 2019
Net operating loss carry forward	$ 9,017,000	$ 4,201,000
Research and development tax credits	524,000	243,000
Other	71,000	120,000
Reserves and allowances - foreign	6,000	6,000
Stock-based compensation	880,000	608,000
Capital loss carry forward	1,571,000	966,000
Research and development - foreign	550,000	550,000
Deferred revenue	241,000	-
Right-of-use asset	(56,000)	-
Lease liability	56,000	-
Net deferred tax	12,860,000	6,694,000
Valuation allowance	(12,860,000)	(6,694,000)
Net deferred tax asset	$ -	$ -

	March 31, 2020	March 31, 2019
Federal income tax at statutory rate	(21.00)%	(21,00)%
State income tax, net of federal benefit	(7.08)	(6.62)
Permanent items	2.48	0.00
Change in valuation allowance	30.67	36.10
Research and development tax credits	(1.39)	(3.71)
Other	(3.69)	(4.77)
Effective income tax expense rate	0.00%	0.00%

For the year ended March 31, 2020 and 2019 the main reconciling item between the effective tax rate is the recognition of valuation allowances in respect to deferred taxes related to accumulated operating net operating losses carried forward due to the uncertainty of the realization of such deferred taxes.

Tax years 2016 through 2020 remain open to examination by federal and state tax jurisdictions. The Company files tax returns in Israel for which tax years 2014 through 2020 remain open.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”) was enacted in response to the COVID-19 pandemic. The CARES Act made various tax law changes including, among other things, (i) increasing the limitation under IRC Section 163(j) for 2019 and 2020 to permit additional expensing of interest, (ii) enacting a technical correction so that qualified improvement property can be immediately expenses under IRC Section 168(k) and (iii) making modification to the federal net operating loss rules including permitting federal net operating losses incurred in 2018, 2019, and 2020 to be carried back to the five preceding taxable years in order to generate a refund of previously paid income taxes. The income tax provisions of the CARES Act had limited applicability to the Company as of March 31,2020, and therefore, the enactment of the CARES Act did not have any impact on the Company’s consolidated financial statements as of March 31,2020.

A reconciliation of the of unrecognized tax benefits related to uncertain tax positions for the year ended March 31, 2020 and March 31, 2019 as follows:

	Year ended March 31,2020	Year Ended March 31, 2019
Balance at beginning of period	$ 154,300	$ 154,300
Decreases for the current year’s tax position	(154,300)	-
Balance at the end of period	$ -	$ 154,300

The Company recorded a federal tax benefit in the amount of $154,300 related to the reversal of uncertain tax positions due to expiration of statute of limitations.

NOTE 13 COMMITMENTS AND CONTINGENCIES

License Agreements

On October 22, 2013, the Company entered into a patent license agreement with CareFusion, pursuant to which it agreed to pay to the third party a non-refundable upfront fee of $150,000 and is obligated to pay 5% royalties of any licensed product net sales, but at least $50,000 per annum through the term of the agreement and the advance is credited against future royalties payments. As of December 31, 2019, the Company did not pay any royalties since the Company did not have any revenues from this license. The term of the 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 agreement, and may be terminated unilaterally by CareFusion with 30 days' prior written notice in the event that we do 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 (the "Option") on September 7, 2016 for $25,000. On January 13, 2017, the Company exercised the Option and paid $500,000. The Company becomes 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 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 an agreement ("Agreement") with NitricGen, Inc. ("NitricGen") acquire a global, exclusive, transferable license and associated assets including intellectual property, know-how, trade secrets and confidential information from NitricGen related to 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 Agreement, and royalties on sales LungFit™. The Company paid NitricGen $100,000 upon the execution agreement, $100,000 upon achieving the next milestone and issued 100,000 options to purchase the Company's stock valued at $295,000 upon executing the agreement. The remaining future milestone payments are $1,800,000 of which $1,500,000 in due after six months after the first approval of LungFit™ by the Food and Drug Administration or the European Medicine Evaluation Agency.

On September 18, 2019, the Company entered into an agreement with a contract research organization to perform a pilot study for bronchiolitis. As of March 31, 2020, the remaining cash commitment under this agreement is approximately $303,000. The Company recorded $754,000 expense for the year ended March 31, 2020.

Employment Agreements

Certain officer agreements contain a change of control provision for payment of severance arrangements.

NOTE 13 COMMITMENTS AND CONTINGENCIES (continued)

Operating Leases

In March 2018, the Company entered into an operating lease for office space in Madison, Wisconsin. The lease commenced in March 2018. The lease agreement expires in April 2021, at which point the Company has the option to renew the lease for one additional five-year term. The renewal period was not included the lease term for purposes of determining the lease liability or right-of-use asset.

In May 2018, the Company entered into an operating lease for office space in Garden City, New York. The lease commenced in July 2018. The lease agreement expires in June 2023, at which point the Company has the option to renew the lease for one additional three-year term. The renewal period was not included the lease term for purposes of determining the lease liability or right-of-use asset.

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, 2020

Cash paid for amounts included in the measurement of lease liabilities:		
Cash paid	$	81,001
Right-of-use assets obtained in exchange for new operating lease liabilities:		-
Weighted-average remaining lease term — operating leases		3.0 years
Weighted-average discount rate — operating leases		8.3%

Maturity of Lease Liabilities		**As of March 31, 2020**
		Operating Leases
2021	$	83,117
2022		64,826
2023		64,693
2024		16,279
Total lease payments		228,915
Less: interest		(27,992)
Present value of lease liabilities	$	200,923

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 Supreme Court of the State of New York, 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 predicated on mutual mistake. 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 Master, 159,869 warrant shares for Empery I and 252,672 warrant shares for Empery II and the exercise price could be reduced from $3.66 to $1.57 per share. While the Company has several meritorious defenses against the claims, the ultimate resolution of the matter, if unfavorable, could result in a material loss. On March 9, 2020, we filed a motion for summary judgment, which remains pending.

On December 18, 2019, the Company terminated the License Agreement with Circassia pursuant to which the Company had granted Circassia an exclusive royalty-bearing license to distribute, market and sell the Company's nitric oxide generator and delivery system in the United States and China. As previously described in Note 9, Circassia had agreed to pay the Company certain milestone and royalty payments, with the remaining milestone and royalty payments payable in cash or ordinary shares of Circassia at Circassia's option. The Company terminated the Agreement pursuant to section 13.3(b) of the Agreement, which provides for termination by either party upon the other party's material breach or default. The Company is evaluating other options for the commercialization of its generator and delivery system. In connection the termination of the license with Circassia, we may be subject to a variety of claims. Adverse outcomes in some or all of these claims, if filed, may adversely affect our ability to conduct business and our financial condition and results of operations.

NOTE 14 SUBSEQUENT EVENTS

On April 2, 2020, Beyond Air, Inc. entered into an At-The-Market Equity Offering for $50 million and utilized the Company's shelf registration statement. The Company may sell shares of our common stock having aggregate sales proceeds of up to $50,000,000 from time to time in this offering. If shares are sold, there is a three 3 percent fee paid to the sales agent.

On May 14, 2020, the Company entered into a $40 million New Purchase Agreement with LPC, that replaced the existing $20 million purchase agreement. The New Purchase Agreement provides for the issuance of up to $40 million of the Company's common stock which we may sell from time to time in our sole discretion to Lincoln Park over the next 36 months, subject to the conditions and limitations in the New Purchase Agreement.

In addition to the Initial Purchase from time to time on any trading day the Company selects that the closing sale price of our common stock is at least $0.25, we have the right, in our sole discretion, subject to the conditions and limitations in the Purchase Agreement, to direct LPC to purchase up to 80,000 shares of our common stock (each such purchase, a "Regular Purchase") over the 36-month term of the New Purchase Agreement; provided, however, that such limit may be increased to up to 100,000 shares if the last closing sale price of our common stock is at least $5.00 on the purchase date, may be increased to up to 120,000 shares if the last closing sale price of our common stock is at least $7.50 on the purchase date, and may be increased to up to 140,000 shares if the last closing sale price of our common stock is at least $10.00 on the purchase date (each subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the Purchase Agreement). The purchase price for shares of common stock to be purchased by Lincoln Park will be the equal to lesser of (i) the lowest sale price on the purchase date, as reported by Nasdaq, or (ii) the arithmetic average of the three lowest closing sale prices for our common stock during the ten trading days prior to the purchase date. Lincoln Park's obligation under each Regular Purchase shall not exceed $2,000,000. The amount of the regular purchases can be modified upon the mutual agreement of the Company and LPC.

Beyond Air can also direct LPC to purchase additional amounts as accelerated purchases and additional accelerated purchases, under certain circumstances and provided the last closing sale price of our common stock is at least $1.00 per share, in an amount up to the lesser of (i) three times the number of shares purchased pursuant to the corresponding Regular Purchase or (ii) 30% of the trading volume on such accelerated purchase date. The purchase price for the additional shares is the lower of:

- the closing sale price for the common stock on the date of sale; and
- ninety-five percent (95%) of the volume weighted average price of the common stock on the Nasdaq Capital Market on the date of sale.

There is no upper or lower limit on the price per share that Lincoln Park must pay for our common stock under the New Purchase Agreement.

Other than as described above, there are no trading volume requirements or restrictions under the New Purchase Agreement. We will control the timing and amount of any sales of our common stock to Lincoln Park. We may at any time, in our sole discretion terminate the New Purchase Agreement without fee, penalty or cost, upon one trading day written notice.

Exhibit 4.7

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES ACT OF 1934

The following description sets forth certain material terms and provisions of our securities that are registered under Section 12 of the Securities Exchange Act of 1934, as amended.

Common Stock

The holders of our common stock are entitled to one vote per share on all matters submitted to vote of our stockholders, including the election of directors. Holders of our common stock are not entitled to cumulate their votes for the election of directors. Except as otherwise required by law, or as otherwise fixed by resolution or resolutions of our Board of Directors with respect to one or more series of our preferred stock, the entire voting power and all voting rights is vested exclusively in our common stock.

Holders of our common stock are not entitled to receive dividends except if declared by our Board of Directors and are not be entitled to a liquidation preference in respect of their shares of common stock. Upon liquidation, dissolution or winding up of our company, the holders of our common stock would be entitled to receive pro rata all assets remaining for distribution to stockholders after the payment of all of our liabilities and of all preferential amounts to which any series of our preferred stock may be entitled.

Holders of our common stock have no preemptive or subscription rights, and have no rights to convert their common stock into any other securities. The common stock is not subject to call or redemption.

Exhibit 21.1

Subsidiary	Jurisdiction of Incorporation
Beyond Air Ltd.	Israel
Advanced Inhalation Therapies Inc.	Delaware
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 23, 2020 relating to the consolidated financial statements of Beyond Air, Inc., which appear in this Form 10-K.

/s/ Friedman LLP

East Hanover, NJ
June 23, 2020

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 23, 2020

/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 23, 2020

/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, 2020 (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 23, 2020

/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 10-K of the Company for the year ended March 31, 2020 (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 23, 2020

/s/ Douglas Beck

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