UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-KT

(Mark One)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2017

OR

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

FOR THE TRANSITION PERIOD FROM JANUARY 1, 2018 TO MARCH 31, 2018

Commission file number: 000-55759

AIT THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**47-3812456**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
500 Mamaroneck Avenue, Suite 320 Harrison, NY 10528	**7403635**
(Address of Principal Executive Offices)	**(Zip Code)**

+516.665.8200
(Registrant's Telephone Number, Including Area Code)

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

Title of each class:	**Name of each exchange on which registered:**
None	**None**

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

Common Stock, par value $0.0001

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KT or any amendment to this Form 10-KT. [ ]

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	[ ]	(Do not check if a smaller reporting company)	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]

Aggregate market value of the voting stock held by non-affiliates as of June 30, 2017: $0 as there was no reported price on the OTC Markets prior to that date. The voting stock held by non-affiliates on that date consisted of 6,150,725 shares of Common Stock.

As of June 15, 2018, the registrant had 8,406,657 shares of common stock ($0.0001 par value) outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

AIT Therapeutics, Inc..

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FORWARD-LOOKING STATEMENTS AND MARKET DATA

This Transition Report on Form 10-KT 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 Transition 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," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential", or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this Transition 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 Transition 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 Transition 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; and

- our ability to successfully manage our growth.

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 Transition Report and the documents that we reference in this Transition 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.

AIT Therapeutics, the AIT logo, and other trademarks or service marks of AIT Therapeutics appearing in this Transition Report are the property of AIT Therapeutics. This Transition 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 Transition 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

Change in Fiscal Year End

On May 10, 2018, our board of directors approved a change in our fiscal year end from December 31st to March 31st. As a result of this change, we are filing this Transition Report on Form 10-KT for the three-month transition period ended March 31, 2018. References to any of our previous fiscal years mean the fiscal years ending on December 31st.

Overview

We are an emerging medical device company developing a nitric oxide (NO) delivery system, or the AIT NO Delivery System, that is capable of generating NO from ambient air. The AIT NO Delivery System can generate up to 400 parts per million (ppm) for delivery to a patient's lung. The AIT NO Delivery System can deliver NO either continuously or for a fixed amount of time and has the ability to either titrate dose on demand or maintain a constant dose. We believe that there is a high unmet medical need for patients suffering from certain severe lung infections for which our system can be used. Our current product candidates will be subject to premarket reviews and approvals by the FDA, as well as similar regulatory agencies in other countries or regions. If approved, our System will be marketed as a medical device in the U.S. (U.S.).

In contrast to approved NO delivery systems, our novel AIT NO Delivery System is designed to deliver not only low concentrations of NO, but also high concentrations of NO to the lungs, which we believe has the potential to eliminate microbial infections, including bacteria, fungi and viruses. Current FDA approved NO delivery systems are approved for persistent pulmonary hypertension of the newborn, or PPHN, which requires a NO concentration of 20 ppm and is not intended to treat microbial infections. The body produces NO naturally as an innate immunity mechanism. Based on our clinical studies, we believe that 160 ppm is the minimum therapeutic dose to achieve the desired pulmonary antimicrobial effect of NO. To date, the FDA, nor any other major regulatory agency in other countries or regions, has not approved any NO formulation and/or delivery system for the delivery of 160 ppm or higher to the lungs.

We were incorporated in Delaware on April 28, 2015 under the name "KokiCare, Inc." and operated as a healthcare software company prior to the Merger (as defined below). Concurrent with the closing of the Merger, we abandoned our pre-Merger business plan in the healthcare software industry and we are now solely pursuing our business in the medical device industry.

The Merger and Reverse Acquisition

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, Inc., , 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, Inc., 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.

Prior to consummation of the Merger, effective as of January 9, 2017, we amended and restated our Certificate of Incorporation to (i) change our name from "KokiCare, Inc." to "AIT Therapeutics, Inc.", (ii) increase our capitalization to provide for the issuance of up to 100,000,000 shares of common stock and up to 10,000,000 shares of preferred stock, par value $0.0001 per share; and (iii) effect a one-for-100 reverse stock split of our common stock. On January 9, 2017, our Board of Directors declared a $2.50 per share cash dividend to our stockholders of record as of January 9, 2017, and we repurchased 90,000 shares of common stock (on a post-reverse stock split basis) at a price of $0.2667 per share from our principal stockholder, Jason Lane.

The Merger was accounted for as a reverse merger and recapitalization. AIT Ltd. is the acquirer for financial reporting purposes, and we are the acquired company.

Unless otherwise indicated, all information contained in this Transition Report on Form 10-KT with respect to periods prior to the date on which we consummated the Merger relates solely to Kokicare, Inc., without regard to the Merger.

Our offices are located at 500 Mamaroneck Avenue, Suite 320 Harrison, NY 10528, telephone number 516.665.8200.

Business Overview

We are an emerging medical device company developing our AIT NO Delivery System, which is capable of generating NO from ambient air. The AIT NO Delivery System can generate NO up to 400 ppm for delivery to a patient's lung. The AIT NO Delivery System can deliver NO either continuously or for a fixed amount of time and has the ability to either titrate dose on demand or maintain a constant dose. We believe the AIT NO Delivery System can be used to treat patients on a ventilator that require NO, as well as patients with chronic lung disease or acute severe lung infections via delivery through a breathing mask. Furthermore, we believe that there is a high unmet medical need for patients suffering from certain severe lung infections that our AIT NO Delivery System can potentially address. Our initial areas of focus are PPHN, bronchiolitis and nontuberculous mycobacteria, or 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.

With respect to PPHN, our novel AIT NO Delivery System 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 our AIT NO Delivery System has many competitive advantages over the current approved NO delivery systems in the U.S., European Union, Japan and other markets. For example, our AIT NO Delivery System 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 AIT NO Delivery System can also deliver a high dosage 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 160 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 160 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	Phase 2 double blind randomized (n=43)	Bronchiolitis (all causes)	Safety & Efficacy	● No SAEs ● Length of hospital stay reduced by 24 hours in hospitalized infants
2013 – 2014	Phase 2 open label (n=9)	Cystic Fibrosis (CF)	Safety & Efficacy	● No SAEs ● Lowered bacterial load
2016	Compassionate use Israel (n=2)	Nontuberculous Mycobacteria(NTM) in CF patients	Efficacy	● No SAEs ● Improvements in clinical and surrogate endpoints
2017	Compassionate use National Institute of Health (n=1)	NTM in CF patient	Efficacy	● No SAEs ● Improvements in clinical endpoints
2017	Pilot open label (N=9)	Refractory NTM *abscessus*	Safety	● No SAEs ● Improvements in clinical and surrogate endpoints
2018	Pilot double blind randomized (n=68)	Bronchiolitis (all causes)	Efficacy	● No SAEs ● Dosing complete, results pending

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

Product	Indication	Development Status	Further Information
AIT-PH (Pulmonary Hypertension)	In-Hospital Use	Commercial system in development	Regulatory filings expected ~year end 2018
AIT-BRO (Bronchiolitis)	Bronchiolitis in Infants (elderly to follow)	94 patient study ongoing	Data expected in 2Q18
AIT-NTM (Nontuberculous Mycobacteria)	Mycobacterium Abscessus Complex (MABSC)	9 patient pilot study dosing complete	Meet with FDA by mid-year to discuss potential pivotal trial design

We plan to submit a 510(k) premarket notification to the FDA around year end 2018 for the use of AIT NO Delivery System in PPHN. We also expect to make certain regulatory filings outside of the U.S. beginning in 2019. According to the 2017 year end report from Mallinckrodt Pharmaceuticals, aggregate sales of low concentration NO in the U.S. were $505 million in 2017, while sales outside of the U.S., where there are multiple market participants, were considerably lower than in the U.S.

With respect to bronchiolitis, we expect to initiate a pivotal trial for infants hospitalized due to bronchiolitis in the fourth quarter of 2019. The trial would last approximately 6 months after initiation. If the trial is successful, we would submit a premarket approval or 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.

Our NTM program has produced data from three compassionate use subjects and patients from a multi-center pilot study completed earlier this year. All patients suffered from NTM *Abscessus* infection and had underlying cystic fibrosis (CF). One compassion patient was treated with our NO generator based delivery system 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. We expect to meet with the FDA during the second calendar quarter of 2018 to discuss a pivotal trial design for the use of the AIT NO Delivery System (generator based) for patients suffering from the effects of NTM and potentially other serious, chronic, and refractory lung infections.

For our high concentration platform, the initial target is lower respiratory tract infections, or LRTI. Our initial two target indications are infants hospitalized due to bronchiolitis (mainly caused by RSV) and patients suffering from NTM *abscessus* and other severe, chronic, refractory infections. There are over 1.5 million hospitalizations related to LRTI annually in the U.S., and LRTI is the third leading cause of death worldwide.

NTM *abscessus* 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. The *abscessus* form of NTM comprises approximately 25% of all 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,* frequently require lengthy and repeated hospital stays to manage their condition. There are no treatments specifically indicated for the treatment of NTM lung disease in North America, Europe or Japan. 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 two years or more. 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). 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).

Over 150 million new cases of bronchiolitis are reported worldwide each year. In the U.S., there are more than 100,000 annual bronchiolitis hospitalizations among children two years of age or younger.

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 eliminate microbes and reduce hospital length of stay.

We believe, based on the currently understood mechanisms of action of NO, that our AIT NO Delivery System can deliver NO at 160 ppm and higher to potentially eliminate bacteria, viruses, fungi and other microbes from the lungs and may also be effective against antibiotic-resistant bacteria. Because our product candidates are not antibiotics, we believe there is a reduced risk of the development of resistant bacteria and there could be synergy with co-administration of antibiotics.

In addition, our NO Delivery System can deliver NO at concentrations of 1 – 80 ppm consistent with currently approved NO delivery systems for the treatment of PPHN while providing significant advantages associated with the elimination of the use of high-pressure cylinders.

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 seven issued patents and their continuations and foreign counterparts, which we have obtained through a non-exclusive worldwide license from SensorMedics Corporation, a subsidiary of CareFusion, 17 issued patents which we acquired pursuant to the exercise of an option in 2017 granted to us by Pulmonox Technologies Corporation (“Pulmonox”) and 22 patent applications developed by us internally. Eight of the Pulmonox patents that we acquired are jointly owned by CareFusion and Pulmonox, five of which are covered by our non-exclusive license with CareFusion. Our royalty and other license obligations to CareFusion with respect to these five patents will remain in effect as long as our CareFusion license remains in effect. In January 2018, we entered into a global, exclusive, transferable license to the eNOGenerator and all associated patents from NitricGen, Inc., or NitricGen.

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 muccocilary clearance, and low levels of nasal NO correlate with impaired muccociliary 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 muccolytics. In addition to treating CF infections, 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 160 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.

AIT Technology

We have developed the AIT NO Delivery System, a novel and precise delivery system that uses NO generated from ambient air with a novel NO generator. We believe 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.

Our novel AIT NO Delivery System is designed to provide patients with a gaseous dose of NO (ranging from 10.5 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 for concentrations of 160 ppm and higher. Our AIT NO Delivery System 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, methemoglobin and the fraction of inspired oxygen, or FiO_2 , blood oxygen saturation and heart rate, all of which are important parameters .. A dedicated screen allows for monitoring of the gas mixture and the patient's vital signs. Further, our product candidates resemble other inhalation systems, making it user friendly, with operation and maintenance that we believe will be familiar to medical staff. Our novel delivery system for use with a mask has been manufactured at commercial scale with a contract manufacturer.

Our novel NO delivery system, when programmed for lung infections, is designed to specifically deliver a NO dosage of 160 ppm and higher, and we believe that it has a number of advantages over other NO formulation delivery systems. For example, it is:

- optimized to deliver 160 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) as well as patient parameters (e.g. vital signs, MetHemoglobin and OxyHemoglobin percentages);
- capable of providing constant flow of our NO formulation, 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 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 18 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 have entered into a definitive agreement to acquire a global, exclusive, transferable license to the eNOGenerator and associated critical assets including intellectual property, know-how, trade secrets and confidential information (the "License") from NitricGen.

The AIT NO delivery 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 1 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 have also agreed to issue to NitricGen or its designees options to purchase 100,000 shares of our Common Stock at an exercise price of $6.90.

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, COPD, and CF. 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 completed a double blind, randomized, placebo controlled pilot study conducted in Israel in infants with bronchiolitis. We commenced an Israeli-based clinical trial in the first quarter of 2017 that will complete in the second quarter of 2018 which will serve as another pilot study. We intend to submit an Investigational Device Exemption ("IDE") to the FDA in 2018 and expect to commence a pivotal clinical trial in 2019 in the U.S.

- *NTM*. Three patients with CF who suffer from NTM infections (specifically, *M. Abscessus*) have been treated under compassionate use, comprising two patients at the Rambam healthcare campus in Israel and one patient in the U.S., treated with our AIT generator based NO Delivery System, at the National Heart, Lung and Blood Institute (NHLBI). A pilot study of nine CF patients infected with NTM *Abscessus* in Israel were treated with our AIT NO Delivery System using cylinder gas was completed in the fourth quarter of 2017. In addition, we intend to speak with the FDA in 2018 to get agreement on a pivotal trial design. We expect that the pivotal study will use our generator based NO delivery system and treat patients infected with NTM and other severe, refractory lung infections with and without CF. Endpoints are expected to include 6-minute walk, bacterial load, forced expiratory volume in one second (FEV1), quality of life and safety. The study is anticipated to commence in 2019.

- *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 and patients infected by NTM Abscessus.

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 $505m in 2018 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 115,000 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.

According to the American Academy of Pediatrics, in 2009, almost 3,000 children in the U.S. with bronchiolitis needed mechanical ventilation, and the average length of hospital stay for previously healthy infants was 2.5 days. The mortality in children less than one year of age was 0.25%. In 2009, the total direct cost of bronchiolitis related hospitalization was $545 million.

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 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 NTM Abscessus, which is a limited portion of the market discussed above.

There are no approved products in the U.S. and Europe to treat NTM 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 to three 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 160 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 study was performed at the UBC and was published in 2012 in the Journal of Cystic Fibrosis.

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, were 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 related to NO reported. We are awaiting further evaluation at this time and may treat the patient again in the near future.

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 or AEs, 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. 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 thera py). At day 81 (60 days after the cessation of therapy) bacterial load was 65% lower than baseline. 1 of 9 patients saw culture conversion.

We are currently completing a study in bronchiolitis. The prospective, randomized, double-blind, controlled pilot study is expected to enroll 94 patients, aged 0-12 months, who are hospitalized due to bronchiolitis. The patients will receive either standard-of-care (typically oxygen and hydration) or standard-of-care plus inhaled NO at a concentration of 160 ppm for 30 minutes 5 times per day for up to 5 days. The primary endpoint is hospital length-of-stay (LOS). Secondary endpoints are 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. We expect to announce data from the trial in the second quarter of 2018.

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 and inside the U.S. for PPHN, specifically. We are still determining whether to attempt to collaborate for bronchiolitis and/or NTM in the U.S.

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. 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 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 have patent filings that relate to our NO generator, NO2 filtration, delivery systems and devices configured for delivering NO to patients by inhalation. We also have other patent filings that pertain to methods of exposing patients to inhalation of NO, and to utilizing these methods for treating subjects in need of NO inhalation. In addition, we are in possession of trade secrets and know-how regarding the practice of these methods.

Our intellectual property portfolio consists of seven issued patents and one patent application, as well as their continuations and foreign counterparts, which we have obtained through a non-exclusive worldwide license from CareFusion, 17 issued patents that we acquired from Pulmonox and 21 patent applications developed internally, including PCT patent applications. Additionally, we acquired one issued patent and one patent application in connection with the NitricGen license.

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 one U.S. patent application, including corresponding foreign counterparts - including patents granted in Australia, Mexico and China. Our intellectual property licensed from CareFusion, for which the earliest expiring patent term is 2019, covers devices and methods for delivering NO formulations to a patient at steady and alternating concentrations, including intermittent delivery of NO. Our CareFusion license also covers patents relating to devices and methods for delivering alternating concentrations of NO topically, nasally and to an upper respiratory tract, for which the expiring patent terms range from 2020 to 2025. 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. Pursuant to the agreement, we are required to pay CareFusion, in addition to a one-time up-front fee of $150,000 already paid, 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 for $25,000 the option, referred to as the Option, to purchase certain intellectual property assets, including Pulmonox's rights in 17 issued U.S. patents, 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.

On January 24, 2017, we exercised the Option and, for a purchase price of $500,000, 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 our first product candidate.

Of the 17 Pulmonox patents, eight U.S. patents are jointly owned by CareFusion and Pulmonox. Pursuant to an agreement with CareFusion, we currently have a non-exclusive world-wide license to five of the eight U.S. patents and their corresponding foreign counterparts jointly owned by CareFusion and Pulmonox, including patents granted in China and Canada, and pending applications in China and Europe. Following the exercise of the option, six patents directed to devices and methods for delivering NO formulations to a patient; one patent directed to systems and methods for using NO to reduce pathogens in blood; one patent directed to use of NO as a mucolytic agent; and one patent directed to methods of using NO for treatment and disinfection of biofilms will be solely owned by us. In addition, four patents 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; and four patents directed to a device and methods for treatment of surface infections will be jointly owned by CareFusion and us.

Patent Applications. We have filed 21 patent applications, including one in Canada, eight in the U.S., one in Israel, five in Europe, three PCT patent applications and three provisional patent applications in the U.S.

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.

In January 2018 we entered into a definitive agreement with NitricGen which granted us an exclusive global license to one issued patent and one pending patent application covering the NO generator and the NO2 filter.

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 devices by 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. Additionally, the FCPA and local laws of other countries potentially implicate the sale and marketing of devices internationally. This complex patchwork of laws can change rapidly with relatively short notice.

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

European Regulation. 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 an 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.

Available Information

We file electronically with the Securities and Exchange Commission, or SEC, our annual reports, this transition report on Form 10-KT, 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.ait-therapeutics.com, 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 15, 2018, we had 13 full-time employees, 8 of whom were primarily engaged in research and development activities. A total of 2 employees have either one or both an M.D. or Ph.D. degree. 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 Transition Report on Form 10-KT. 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 income of $1 million for the three months ended March 31, 2018, and an accumulated deficit of approximately $30.6 million as of March 31, 2018, 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 have no source of revenue, 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 is 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 mean nothing. 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 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. RSV or the winter cannot be predicted. 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 are heavily dependent on the Aeronox system to conduct our trial outside the U.S., and we may be required to seek an alternative delivery system for our proprietary 160 ppm NO formulation if we were to conduct a clinical trial within the U.S.

We are heavily dependent on the Aeronox system and the company that manufactures it, International Biomedical, located in Texas. If International Biomedical decides not to continue to support the Aeronox system (for example, selling parts and providing repair services for the device), then we might not be able to conduct our U.S. trial. This system is not manufactured specifically for us, and we have no agreement with International Biomedical for the continued manufacture or support of this Aeronox system. Additionally, the Aeronox system is not currently approved for use in the U.S. at the 160 ppm concentration required by our proprietary 160 ppm NO formulation, and we currently engage a third-party contractor to modify the Aeronox system in order for it to monitor our NO formulation at 160 ppm. Unless the Aeronox system obtains such approval, of which we have no current expectation, we would be required to seek an alternative delivery system in order to conduct a clinical trial of our formulation within the U.S.

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 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 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, Ikaria, Inc. 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. 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 EMA for the use of inhaled NO-based treatments in treating CF. 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 Ikaria and Novoteris are planning 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.

We have a non-exclusive license to certain patents owned by CareFusion that relate to methods and devices for delivering 80-400 PPM NO formulations to patients. CareFusion may grant additional non-exclusive licenses to third parties.

Absent any agreement with CareFusion to the contrary, each of the joint owners may make, use, offer to sell, or sell the patented invention within the U.S., or import the patented invention into the U.S., without the consent of and without accounting to the other owner. While we are unaware of any other licenses issued by CareFusion to third parties granting rights in the patents CareFusion licensed to us, we cannot be sure other licenses have not already been granted, or will not be granted in the future, by CareFusion to third parties.

Any such licenses may enable third parties to develop and market products competitive with ours, provided that they do not infringe our other intellectual property rights. The terms of our non-exclusive license with CareFusion leaves full control of any and all enforcement of the licensed patents with CareFusion. If CareFusion elects to not enforce any or all of the licensed patents it could significantly undercut the value of any of our product candidates, which would materially adversely affect our revenue, financial condition and results of operations.

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. For example, our existing license agreement with CareFusion imposes the following milestones, which comport with the plans we discuss under "Business—Our Strategy": completion of a Phase II study by September 2017; completion of a Phase III study by September 2018; FDA approval for a licensed product by September 2020; and the first sale of a licensed product by September 2021. We have completed the Phase II, double blind, randomized study conducted in Israel in infants with bronchiolitis discussed under "Business—Our Strategy", and we have commenced the "Phase III" study referenced under "Business—Our Strategy". Obtaining FDA approval by September 2020 of a licensed product will most likely not occur. If we fail to comply with our obligations under the CareFusion agreement or other agreements, or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose our license or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license.

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 we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. To the extent that our employees have not effectively waived the right to compensation with respect to inventions that they helped create, they may be able to assert claims for compensation with respect to our future revenue may be successful. As a result, we may receive less revenue from future products if such claims are successful which in turn could impact our future profitability.

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

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

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

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

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

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

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 thirteen 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 will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, such as the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank Act"), was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and pay parity. Recent legislation permits smaller "emerging growth companies" to implement many of these requirements over a longer period and up to five years from the pricing of our initial offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we will be required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report, commencing in our Current Report on Form 8-K, as filed with the SEC on January 20, 2017, on the effectiveness of our internal controls over financial reporting, if then required by Section 404 of the Sarbanes-Oxley Act. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 of the Sarbanes-Oxley Act will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner or if we identify or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

New laws and regulations as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act and rules adopted by the SEC, would likely result in increased costs to us as we respond to their requirements. Similarly, in the future, we may attempt to list our Common Stock on the Nasdaq Capital Market, the NYSE MKT or another national securities exchange, which would subject us to additional rules and regulations, as well as additional costs.

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 U.S. Foreign Corrupt Practices Act ("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.

Risks Related to the Ownership of our Common Stock

There is a limited liquid and orderly trading market for our Common Stock, which may make it difficult for you to sell your shares of our Common Stock.

There is limited trading activity in our Common Stock and an active trading market for our shares may never develop or be sustained. As a result, investors in our Common Stock must bear the economic risk of holding those shares for an indefinite period of time.

Our Common Stock is subject to only limited quotation on the OTC Pink, and it is not otherwise regularly quoted on any other over-the-counter market.

Although our Common Stock is quoted on the OTC, trading of our Common Stock is extremely limited and sporadic and at very low volumes. We do not now, and may not in the future, meet the initial listing standards of any national securities exchange. We presently anticipate that our Common Stock will continue to be quoted on OTC Pink or another over-the-counter quotation system in the foreseeable future. In those venues, our stockholders may find it difficult to obtain accurate quotations as to the market value of their shares of our Common Stock, and may find few buyers to purchase their stock and few market makers to support its price. As a result of these and other factors, you may be unable to resell your shares of our Common Stock at or above the price for which you purchased them, or at all. Further, an inactive market may also impair our ability to raise capital by selling additional equity in the future, and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of Common Stock as consideration.

Our share price is volatile and may be influenced by numerous factors, some of which may be beyond our control.

The trading price of our Common Stock is likely to be highly volatile, and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Transition Report on Form 10-KT, these factors include:

- 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.

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.

Our Common Stock may be a "penny stock."

Generally, a "penny stock" is an equity security that is not listed on a national securities exchange and has a market price of less than $5.00 per share, subject to specific exceptions. Our Common Stock presently has, and since our inception has had, no trading activity to support a market price, but many historical sales of our Common Stock have been at a price per share less than $5.00. As a result, our Common Stock may be considered to be a penny stock. Regulations imposed by the SEC and other regulatory authorities requiring, among other things, that broker-dealers effecting transactions in a penny stock make certain disclosures to and obtain a written suitability statement from potential purchasers, could restrict the ability of broker-dealers to sell our Common Stock if it were to be considered a penny stock, which could affect the ability of our stockholders to sell their shares of our stock. In addition, if our Common Stock continues to be quoted on the "OTC Pink Current Information" tier of OTC Markets, then our stockholders may find it difficult to obtain accurate quotations for our Common Stock, and may find few buyers to purchase our Common Stock and few market makers to support its price.

FINRA sales practice requirements may limit a stockholder's ability to buy and sell our stock.

In addition to rules applicable to "penny stock," the Financial Industry Regulatory Authority, or FINRA, has adopted rules requiring that, in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA has indicated its belief that there is a high probability that speculative low-priced securities will not be suitable for at least some customers. These FINRA requirements make it more difficult for broker-dealers to recommend that at least some of their customers buy our Common Stock, which may limit the ability of our stockholders to buy and sell our Common Stock and could have an adverse effect on the market for and price of our shares.

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 may be exposed to additional risks as a result of "going public" by means of a reverse merger transaction.

We may be exposed to additional risks because the business of AIT Ltd. has become a public company through a "reverse merger" transaction. There has been increased focus by government agencies on transactions such as the Merger in recent years, and we may be subject to increased scrutiny by the SEC and other government agencies and holders of our securities as a result of the completion of that transaction. Further, since we existed as a "shell company" under applicable rules of the SEC prior to the closing of the Merger on January 13, 2017, we are subject to certain restrictions and limitations for certain specified periods of time relating to potential future issuances of our securities and compliance with applicable SEC rules and regulations. Additionally, our "going public" by means of a reverse merger transaction may make it more difficult for us to obtain coverage from securities analysts of major brokerage firms following the Merger because there may be little incentive to those brokerage firms to recommend the purchase of our Common Stock. The occurrence of any such event could cause our business or stock price to suffer.

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 that AIT Ltd. did not incur as a private company. 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.

AIT Ltd. was not subject to requirements to establish, and did not establish, internal control over financial reporting and disclosure controls and procedures prior to the Merger. Our management team and Board of Directors currently do and in the future will need to devote significant efforts to maintaining adequate and effective disclosure controls and procedures and internal control over financial reporting in order to comply with applicable regulations, which may include hiring additional legal, financial reporting and other finance staff. Additionally, any of our efforts to improve our internal controls and design, implement and maintain an adequate system of disclosure controls may not be successful and will require that we expend significant cash and other resources.

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 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.

Shares of our Common Stock that have not been registered under federal securities laws are subject to resale restrictions imposed by Rule 144, including those set forth in Rule 144(i) which apply to a former "shell company."

Prior to the closing of the Merger, we were deemed a "shell company" under applicable SEC rules and regulations, because we had no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets. Pursuant to Rule 144 ("Rule 144"), promulgated under the Securities Act, sales of the securities of a former shell company, such as us, under that rule are not permitted until at least 12 months have elapsed from the date on which the Current Report on Form 8-K, filed by us on January 20, 2017, reflecting our status as a non-shell company, was filed with the SEC. As a result, most of our stockholders will be forced to hold their shares of our Common Stock for at least that 12-month period before they are eligible to sell those shares, and even after that 12-month period, sales may not be made under Rule 144 unless we and the selling stockholders are in compliance with other requirements of Rule 144. Further, it will be more difficult for us to raise funding to support our operations through the sale of debt or equity securities unless we agree to register such securities under the Securities Act, which could cause us to expend additional time and cash resources. Additionally, our previous status as a shell company could also limit our use of our securities to pay for any acquisitions we may seek to pursue in the future (although none are currently planned). The lack of liquidity of our securities as a result of the inability to sell under Rule 144 for a longer period of time could cause the market price of our securities to decline.

If we issue additional shares of our capital stock in the future, our existing stockholders will be diluted.

Our Amended and Restated Certificate of Incorporation authorize the issuance of up to 100,000,000 shares of our Common Stock and up to 10,000,000 shares of preferred stock with the rights, preferences and privileges that our Board of Directors may determine from time to time. In addition to capital raising activities, which we expect to pursue in order to raise the funding we will need in order to continue our operations, other possible business and financial uses for our authorized capital stock include, without limitation, future stock splits, acquiring other companies, businesses or products in exchange for shares of our capital stock, issuing shares of our capital stock to partners or other collaborators in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our equity compensation plans, or other transactions and corporate purposes that our Board of Directors deems are in the best interest of our company. Additionally, shares of our capital stock could be used for anti-takeover purposes or to delay or prevent changes in control or our management. Any future issuances of shares of our capital stock may not be made on favorable terms or at all, they may not enhance stockholder value, they may have rights, preferences and privileges that are superior to those of our Common Stock, and they may have an adverse effect on our business or the trading price of our Common Stock. The issuance of any additional shares of our Common Stock will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our Common Stock. Additionally, any such issuance will reduce the proportionate ownership and voting power of all of our current stockholders.

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 significant 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 the 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.

Comprehensive tax reform bills could adversely affect our business and financial condition.

The U.S. government recently enacted comprehensive federal income tax legislation that includes significant changes to the taxation of business entities. These changes include, among others, (i) a permanent reduction to the corporate income tax rate, (ii) a partial limitation on the deductibility of business interest expense, (iii) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a territorial system (along with certain rules designed to prevent erosion of the U.S. income tax base) and (iv) a one-time tax on accumulated offshore earnings held in cash and illiquid assets, with the latter taxed at a lower rate. Notwithstanding the reduction in the corporate income tax rate, the overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected. This Transition Report on Form 10-KT does not discuss any such tax legislation or the manner in which it might affect holders of our common stock. We urge our stockholders to consult with their legal and tax advisors with respect to any such legislation and the potential tax consequences of investing in our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

As of March 31, 2018, our executive offices were located at 500 Mamaroneck Avenue, Suite 321, Harrison, New York 10528 under a lease that expires in June 2018. We expect to relocate and expand our offices in New York in the second fiscal quarter of 2019. We also lease office space at 12 Eli Horovitz Street, Rehovot, 7414002 Israel.

On March 16, 2018, the Company entered into an office lease agreement for office space at 175 East Badger Road, Madison, Wisconsin, for a term of three years and two months, effective March 1, 2018, with a monthly lease payment of $1,728. Future minimum non-cancelable rental payments under the operating lease are $64 thousand through April 30, 2021.

ITEM 3. LEGAL PROCEEDINGS

On March 16, 2018, Empery Asset Master, Ltd., Empery Tax Efficient, LP and Empery Tax Efficient II, LP (together, "Empery"), and each a holder of certain of our warrants issued January 13, 2017 (the "January 2017 Warrants"), filed a complaint in the Supreme Court of the State of New York, (the "Empery Suit"), relating to the notice of adjustment of both the exercise price of, and the number of warrant shares issuable under, Empery's January 2017 Warrants. We were notified of the Empery Suit on April 26, 2018. The Empery Suit alleges that, as a result of certain circumstances of our offering of additional warrants, which closed on February 16, 2018, the January 2017 Warrants issued to Empery provide for adjustments to both the exercise price of the warrants and the number of warrant shares issuable upon such exercise. Empery seeks money damages and declaratory relief under theories of breach of contract or contract reformation predicated on mutual mistake.

We intend to vigorously defend against the Empery Suit and believe that it is unlikely that the ultimate resolution of the matter will have a material adverse effect on our financial condition, results of operations or near-term liquidity. However, we do expect to incur legal expenses as we pursue a vigorous defense against this claim. Given the early stage of the litigation, it is too early to determine or assess the probability of any particular outcome.

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 is publicly traded on the OTC Pink. Our Common Stock was originally listed on the OTC Pink in 2016 under the symbol "KKIC". After the Merger, the symbol was changed to "AITB." There was no trading volume for our common stock until July 2017, and there remains a generally low level volume of trading for our common stock in the public market. There can be no assurance that a liquid market for our common stock will develop in the foreseeable future. Transfer of our common stock may also be restricted under the securities or blue sky laws of certain states and foreign jurisdictions. Consequently, investors may not be able to liquidate their investments and should be prepared to hold the common stock for an indefinite period of time. The following table sets forth, for the periods indicated, the high and low bid prices per share of our Common Stock as reported by the OTC Pink. The following quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

	High	Low
Year Ended December 31, 2016		
Fourth Quarter (beginning December 31, 2016)	NA—	NA—
Year Ended December 31, 2017		
First Quarter	NA—	NA—
Second Quarter	NA—	NA—
Third Quarter	$ 7.50	$ 5.00
Fourth Quarter	$ 10.00	$ 3.51
For three month Ended March 31, 2018		
First Quarter	$ 5.23	$ 2.80

Authorized Capital Stock; Issued and Outstanding Capital Stock

As of June 15, 2018, there were 8,406,657 shares of our common stock outstanding.

Warrants

Immediately prior to the Merger, AIT Ltd. consummated a private placement pursuant to which it issued to investors an aggregate of 1,701,616 of its ordinary shares, together with warrants to purchase an aggregate of 3,403,232 ordinary shares, referred to as the January 2017 Warrants, for gross proceeds of approximately $10,210 thousand. In connection with the Merger, we assumed AIT Ltd.'s obligations under the purchase agreements with respect to such private placement, including the registration rights contained therein. In connection with the closing of the Merger, all outstanding ordinary shares, warrants and options of AIT Ltd. were converted into shares of our Common Stock, warrants for our Common Stock and options for our Common Stock, respectively, at a ratio of 1:1.

On March 31, 2017 we consummated a private placement in which we issued and sold an aggregate of 110,494 units, each composed of one share of our Common Stock and a five-year warrant to purchase two shares of Common Stock at an exercise price of $6.90 per share, referred to as the March 2017 Warrants. We issued and sold the units to certain investors at a purchase price of $6.00 per unit, for which we received approximately $663 thousand of gross proceeds. An additional 11,050 warrants in substantially the same form were issued to Laidlaw & Co. (UK) in connection with the March 31, 2017 private placement, referred to as the Laidlaw Warrants and, together with the January 2017 Warrants and the March 2017 Warrants, referred to as the Existing Warrants.

The Existing Warrants contain anti-dilution provisions in the case of a subdivision or combination of our shares of Common Stock, stock dividends, any reclassification of Common Stock, and corporate events such as a reorganization, consolidation, merger, or sale of all or substantially all of our assets. Additionally, subject to certain exceptions, if we issue or sell, or are deemed to have issued or sold, any Common Stock for a consideration per share, referred to as the New Issuance Price, less than a price equal to the exercise price then in effect immediately prior to such issuance or sale, then immediately after such issuance or sale the Exercise Price then in effect would be reduced to the New Issuance Price. If any sale or issuance, or deemed issuance, is for no consideration, then the New Issuance Price is deemed to be $0.01 per share and the number of shares of Common Stock for which the warrant is exercisable would be increased to the number of shares determined by multiplying the exercise price in effect immediately prior to such adjustment by the number of shares of Common Stock issuable upon exercise of the warrant immediately prior to such adjustment and dividing the product thereof by the Exercise Price resulting from such adjustment.

On February 16, 2018, we consummated the February 2018 Offering in which we issued and sold an aggregate of 4,599,604 warrants, referred to as the February 2018 Warrants and, together with the Existing Warrants, referred to as the Warrants, being comprised of (i) 2,299,802 Tranche A Warrants to purchase one share of Common Stock at an exercise price of $4.25 per Tranche A Warrant Share, exercisable within three days from the issue date of the Tranche A Warrants and (ii) an equal number of Tranche B Warrants to purchase one share of Common Stock at an exercise price of $4.25 per Tranche B Warrant Share, exercisable within three years from the issue date of the Tranche B Warrants. Immediately following the consummation of February 2018 Offering, each Purchaser exercised the full amount of their Tranche A Warrants resulting in gross proceeds to us from the sale of the February 2018 Warrants for $0.01 per underlying Warrant Share, together with the exercise price of the Tranche A Warrants, of approximately $9,820 thousand.

Upon close of the February 2018 Offering, the exercise price of all Existing Warrants detailed above was adjusted pursuant to the terms and conditions of those warrants, resulting in the adjustment of the exercise price to $4.25.

Dividend Policy

On January 9, 2017, in connection with the Merger, our Board of Directors declared a $2.50 per share cash dividend to our stockholders of record as of January 9, 2017, and we agreed to repurchase 90,000 shares of our Common Stock (on a post-reverse stock split basis) at a price of $0.2667 per share from our principal stockholder, Jason Lane. We do not expect to pay any further cash dividends for the foreseeable future. We expect that that any future earnings will be retained for use in developing and/or expanding our business.

Unregistered Sales of Equity Securities

From January 1, 2017 through December 31, 2017, we issued and sold the equity securities described below:

1. Immediately prior to the Merger, AIT Ltd. consummated a private placement pursuant to which it issued to investors an aggregate of 1,701,616 of its ordinary shares, together with warrants to purchase an aggregate of 3,403,232 ordinary shares, referred to as the January 2017 Warrants, for gross proceeds of approximately $10,210 thousand. In connection with the Merger, we assumed AIT Ltd.'s obligations under the purchase agreements with respect to such private placement, including the registration rights contained therein. In connection with the closing of the Merger, all outstanding ordinary shares, warrants and options of AIT Ltd. were converted into shares of our Common Stock, warrants for our Common Stock and options for our Common Stock, respectively, at a ratio of 1:1.

2. On March 31, 2017 we consummated a private placement in which we issued and sold an aggregate of 110,494 units, each composed of one share of our Common Stock and a five-year warrant to purchase two shares of Common Stock at an exercise price of $6.90 per share, referred to as the March 2017 Warrants. We issued and sold the units to certain investors at a purchase price of $6.00 per unit, for which we received approximately $663 thousand of gross proceeds. An additional 11,050 warrants in substantially the same form were issued to Laidlaw & Co. (UK) in connection with the March 31, 2017 private placement, referred to as the Laidlaw Warrants and, together with the January 2017 Warrants and the March 2017 Warrants, referred to as the Existing Warrants.

3. The Existing Warrants contain anti-dilution provisions in the case of a subdivision or combination of our shares of Common Stock, stock dividends, any reclassification of Common Stock, and corporate events such as a reorganization, consolidation, merger, or sale of all or substantially all of our assets. Additionally, subject to certain exceptions, if we issue or sell, or are deemed to have issued or sold, any Common Stock for a consideration per share, referred to as the New Issuance Price, less than a price equal to the exercise price then in effect immediately prior to such issuance or sale, then immediately after such issuance or sale the Exercise Price then in effect would be reduced to the New Issuance Price. If any sale or issuance, or deemed issuance, is for no consideration, then the New Issuance Price is deemed to be $0.01 per share and the number of shares of Common Stock for which the warrant is exercisable would be increased to the number of shares determined by multiplying the exercise price in effect immediately prior to such adjustment by the number of shares of Common Stock issuable upon exercise of the warrant immediately prior to such adjustment and dividing the product thereof by the Exercise Price resulting from such adjustment.

4. On February 16, 2018, we consummated the February 2018 Offering in which we issued and sold an aggregate of 4,599,604 warrants, referred to as the February 2018 Warrants and, together with the Existing Warrants, referred to as the Warrants, being comprised of (i) 2,299,802 Tranche A Warrants to purchase one share of Common Stock at an exercise price of $4.25 per Tranche A Warrant Share, exercisable within three days from the issue date of the Tranche A Warrants and (ii) an equal number of Tranche B Warrants to purchase one share of Common Stock at an exercise price of $4.25 per Tranche B Warrant Share, exercisable within three years from the issue date of the Tranche B Warrants. Immediately following the consummation of February 2018 Offering, each Purchaser exercised the full amount of their Tranche A Warrants resulting in gross proceeds to us from the sale of the February 2018 Warrants for $0.01 per underlying Warrant Share, together with the exercise price of the Tranche A Warrants, of approximately $9,820 thousand.

5. Upon close of the February 2018 Offering, the exercise price of all Existing Warrants detailed above was adjusted pursuant to the terms and conditions of those warrants, resulting in the adjustment of the exercise price to $4.25.

6. In 2017 we granted stock options to purchase an aggregate of 371,500 shares of our Common Stock at a weighted average exercise price of $4.25 per share to certain of our employees, consultants and directors in connection with services provided to us by such persons.

7. The securities described in paragraphs (1) and (2) above were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All purchasers of Common Stock and Warrants to purchase Common Stock described above represented to us in connection with their purchase that they were accredited investors and were acquiring the shares for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

The stock options and the common stock issuable upon the exercise of such options as described in paragraph (3) were issued pursuant to written compensatory plans or arrangements with our employees and directors, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(a)(2) under the Securities Act and Regulation D promulgated thereunder relative to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All of the foregoing securities included appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer. No underwriters were involved in the foregoing transactions.

Issuer Repurchases 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 Transition Report on Form 10-KT. This discussion and other parts of this Transition Report on Form 10-KT 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 company developing a nitric oxide (NO) delivery system, or the AIT NO Delivery System (the "System"), that is capable of generating NO from ambient air. The AIT NO Delivery System can generate up to 400 parts per million (ppm) for delivery to a patient's lung. The AIT NO Delivery System can deliver NO either continuously or for a fixed amount of time and has the ability to either titrate dose on demand or maintain a constant dose. We believe that there is a high unmet medical need for patients suffering from certain severe lung infections for which our system can be used. Our current product candidates will be subject to premarket reviews and approvals by the FDA, as well as similar regulatory agencies in other countries or regions. If approved, our System will be marketed as a medical device in the U.S.

In contrast to approved NO delivery systems, our novel AIT NO Delivery System is designed to deliver not only low concentrations of NO, but also high concentrations of NO to the lungs, which we believe has the potential to eliminate microbial infections, including bacteria, fungi and viruses. Current FDA approved NO delivery systems are approved for persistent pulmonary hypertension of the newborn, or PPHN, which requires a NO concentration of 20 ppm and is not intended to treat microbial infections. The body produces NO naturally as an innate immunity mechanism. Based on our clinical studies, we believe that 160 ppm is the minimum therapeutic dose to achieve the desired pulmonary antimicrobial effect of NO. To date, the FDA, nor any other major regulatory agency in other countries or regions, has not approved any NO formulation and/or delivery system for the delivery of 160 ppm or higher to the lungs.

We were incorporated in Delaware on April 28, 2015 under the name "KokiCare, Inc." and operated as a healthcare software company prior to the Merger (as defined below). Concurrent with the closing of the Merger, we abandoned our pre-Merger business plan in the healthcare software industry and we are now solely pursuing our business in the medical device industry.

To date, we have not generated revenue from the sale of any product, and we do not expect to generate revenue unless and until we obtain marketing approval of, and commercialize, our product candidates. As of March 31, 2018, we had an accumulated deficit of $30.6million. Our financing activities are described below under "Liquidity and Capital Resources."

Financial Operations Overview

Operating Expenses

Our current operating expenses consist of three components: research and development expenses; general and administrative expenses; and manufacturing.

Research and Development Expenses

Our research and development expenses consist primarily of the cost of third party clinical consultants and expenses related to conducting clinical and preclinical trials, patent maintenance, expenses related to the development of our generator and delivery system, salaries and related personnel expenses, share-based compensation expenses, regulatory expenses, travel expenses and other research and development expenses.

We expect that our research and development expenses will reduce as our clinical activity will decrease in anticipation of our regulatory filing, which we expect will be partially offset by costs related to the development of our delivery system and increased manufacturing activity.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, share-based compensation expense, professional service fees for accounting, legal, bookkeeping and facilities, travel expenses and other general and administrative expenses.

We expect our general and administrative expenses, such as accounting and legal fees, to increase in connection with our operations as a U.S. public company, and we expect increases in the number of our executive, accounting and administrative personnel due to our anticipated growth.

Financial Expense, net

Financial expense, net mainly consists of expenses in respect of the revaluation of warrants to purchase common stock, amortization of the beneficial conversion feature ("BCF") in respect of our convertible notes, issuance cost related to warrants issued to investors. For more information refer to Note 13 to the consolidated financial statements as of March 31, 2018 contained herein.

Taxes on Income

Taxes on income comprise taxes incurred as result of the implementation of the cost plus method between AIT Ltd. and its wholly-owned subsidiary, Advanced Inhalation Therapies (AIT) Inc., referred to as AIT Inc. AIT Inc. provides certain services to AIT Ltd., for which AIT Ltd. remunerates AIT Inc. based on a cost plus methodology. The Company applied the comparative profits method ("CPM") for transfer pricing purposes. The CPM method compares the profit of the tested party to that of comparable companies that perform similar functions.

The markup on total costs, or "cost plus", was selected as the profit level indicator, which reflects the remuneration by AIT Ltd. to AIT Inc. for services performed. Cost plus is defined as the ratio of operating profit to total costs.

Critical Accounting Estimates and Policies

We describe our significant accounting policies more fully in Note 2 to our consolidated financial statements for the three month period ended March 31, 2018 and for the years ended December 31, 2017 and 2016.

Stock-based compensation and fair value of ordinary shares

We account for stock-based compensation in accordance with ASC 718, "Compensation - Stock Compensation", ("ASC 718") and ASC 505-50, "Equity-Based Payment to Non-Employees" ("ASC 505"). For more information refer to Note 2(q) to the consolidated financial statements as of March 31, 2018 contained herein.

Beneficial conversion feature with respect to convertible notes

Starting in December 2013 and continuing until December 31, 2016, AIT entered into Convertible Notes Agreements and received an aggregate amount of $3,342 in proceeds from these convertible notes.

On January 13, 2017, upon the Closing of the Merger all Convertible Notes and the accrued interest were converted into shares of Common Stock of the Company. With respect to the Convertible Notes, AIT applied ASC 470, "Debt with Conversion and Other Options". For more information refer to Note 7 to the consolidated financial statements as of March 31, 2018 contained herein.

Warrants to purchase Common Stock

The Company accounted for warrants to purchase shares of its Common Stock held by investors which include down round protective provisions as a liability according to the provisions of ASC 815-40, "Derivatives and Hedging Contracts in Entity's Own Equity" ("ASC 815"). The Company measures the warrants at fair value by using the Black-Scholes model in each reporting period until they are exercised or expired, with changes in the fair values being recognized in the Company's statement of comprehensive loss as financial expense (income), net. For more information refer to Note 2(n) and Note 8 to the consolidated financial statements as of March 31, 2018 contained herein.

Results of Operations

Comparison of the Three months Ended March 31, 2018 Compared to Three months Ended March 31, 2017

	For the Three months Ended	
	2018	2017
	(in thousands)	
Research and development expenses	$ 1,637	$ 1,439
General and administrative expenses	803	2,121
Operating loss	2,440	3,560
Financial expense, net	6	1,409
Revaluation of warrants to purchase Common Stock	(3,494)	1,308
Loss (Income) before taxes on Income	(1,048)	6,277
Taxes on income	-	6
Net (income) loss	$ (1,048)	$ 6,283

The following table discloses the breakdown of research and development expenses for the three months ended March 31, 2018 and 2017.

	For the Three months Ended March 31,	
	2018	2017
	(in thousands)	
Costs to third-party related to conducting clinical and preclinical trials, manufacturing and other R&D subcontractors	$ 1,267	$ 360
Purchase of certain intellectual property assets	-	500
Salaries and related personnel	138	37
Stock-based compensation and warrants	50	501
Other	182	41
Total	$ 1,637	$ 1,439

For the three months ended March 31, 2018 and 2017, we incurred research and development expenses in the aggregate of $1,637 thousand and $1,439 thousand, respectively. The increase was primarily due to an increase in costs of $907 thousand related to clinical trials, subcontractors, consultants, manufacturing of our delivery system by a third-party contract manufacturer and $243 thousand for increase in compensation related and other expenses. The increase was partially offset by a decrease in purchase of certain intellectual property in the amount of $500 thousand and expenses of $451 thousand related to Stock-based compensation and warrants.

Our research and development expense is highly dependent on the execution of clinical trials and therefore is expected to fluctuate significantly from period to period. We expect that our research and development expenses will reduce as our clinical activity will decrease in anticipation of our regulatory filing, which we expect to be partially offset by costs related to the development of our delivery system and increased manufacturing activity.

General and Administrative Expenses

General and administrative expenses consist primarily of payroll expenses, stock-based compensation expense, costs related to the Merger and recapitalization, professional service fees for accounting and legal advisors, facilities, travel expenses and other general and administrative expenses.

We expect our general and administrative expenses, such as accounting and legal fees, to increase in connection with our operations as a U.S. public company, and we expect increases in the number of our executive, accounting and administrative personnel due to our anticipated growth.

For the three months ended March 31, 2018 and 2017, we incurred general and administrative expenses of $803 thousand and $2,121 thousand, respectively. The decrease of $1, 318 thousand for the three months ended March 31, 2018 as compared to the three months ended March 31, 2017 resulted primarily from a decrease of approximately $1,276 thousand in stock-based compensation expense mainly due to restricted shares to board members and a service provider, and a decrease of $164 thousand for issuance fees in connection with the Merger.

Operating loss

Our operating loss for the three months ended March 31, 2018, was $2,440 thousand, as compared to an operating loss of $3,560 thousand for the three months ended March 31, 2017, a decrease of $1,120 thousand.

Financial Expense, Net

Financial expense, net consists of expenses in respect of the revaluation of warrants to purchase common stock, amortization of the BCF in respect of our convertible notes, issuance cost related to warrants issued to investors, foreign currency translation adjustments and other financial expenses. For more information, refer to note 13 to our consolidated financial statements as of March 31, 2018 contained herein.

For the three months ended March 31, 2018 we incurred financial income, net of $3,488 and for the three months ended March 31, 2017 we incurred financial expenses, net of $2,717 thousand. The increase resulted primarily from income of $3,494 related to the issuance and revaluation of warrants granted to investors in connection with private placements for the three months ended March 31, 2018, as compared to expenses $1,308 thousand for the three months ended March 31, 2017.

Net Income / Loss

As a result of the foregoing, our net income for the three months ended March 31, 2018, was $1,048 thousand, as compared net loss for the three months ended March 31, 2017 was $6,283 thousand, a decrease of $7,331 thousand.

Comparison of the Year Ended December 31, 2017 Compared to Year Ended December 31, 2016

	For the Year ended December 31	
	2017	2016
	(in thousands)	
Research and development expenses	$ 4,438	$ 673
General and administrative expenses	6,629	1,039
Costs related to aborted IPO	-	621
Operating loss	11,067	2,333
Financial expense, net	1,565	1,360
Revaluation of warrants to purchase Common Stock	5,412	–
Loss before taxes on Income	18,044	3,693
Taxes on income	-	27
Net loss	$ 18,044	$ 3,720

Research and Development Expenses

The following table discloses the breakdown of research and development expenses for the years ended December 31, 2017 and 2016.

	For the Year ended December 31	
	2017	2016
	(in thousands)	
Costs to third-party related to conducting clinical and preclinical trials, manufacturing and other R&D subcontractors	$ 2,694	$ 157
Purchase of certain intellectual property assets	500	-
Salaries and related personnel	378	198
Stock-based compensation and warrants	618	109
Other	248	209
Total	$ 4,438	$ 673

For the years ended December 31, 2017 and 2016, we incurred research and development expenses in the aggregate of $4,438 thousand and $673 thousand, respectively. The increase was primarily due to an increase in costs of $2,537 thousand related to clinical trials, subcontractors, consultants, manufacturing of our delivery system by a third party contract manufacturer, purchase of certain intellectual property in the amount of $500 thousand and expenses of $480 thousand related to the warrants.

Our research and development expense is highly dependent on the execution of clinical trials and therefore is expected to fluctuate significantly from period to period. We expect that our R&D expenses will decrease due to the completion of our clinical studies , which will be partially offset by higher cost for manufacturing of our NO Generator and Delivery System and filing the necessary submission with the FDA.

General and Administrative Expenses

General and administrative expenses consist primarily of payroll expenses, stock-based compensation expense, costs related to the Merger and recapitalization, professional service fees for accounting and legal advisors, facilities, travel expenses and other general and administrative expenses.

We expect our general and administrative expenses, such as accounting and legal fees, to increase in connection with our operations as a U.S. public company, and we expect increases in the number of our executive, accounting and administrative personnel due to our anticipated growth.

For the years ended December 31, 2017 and 2016, we incurred general and administrative expenses of $6,629 thousand and $1,039 thousand, respectively. The increase of $5,590 thousand for the year ended December 31, 2017 as compared to the year ended December 31, 2016 resulted primarily from an increase of approximately $3,664 thousand in stock-based compensation expense mainly due to restricted shares to board members and a service provider, an increase in costs of $523 thousand related to legal, accounting and issuance fees in connection with the Merger, and an increase in payroll expenses of $695 thousand due to the hiring of general and administrative employees.

Costs Related to Aborted IPO

Costs related to our aborted initial public offering in the year ended December 31, 2016 consisted of direct and incremental costs such as accounting, consulting, legal and printing fees that were incurred in connection with an initial public offering process pursuant to which we had planned to register and quote our Common Stock on the OTCQB, the over-the-counter trading marketplace for securities of early-stage or developing companies run by the OTC Markets Group, Inc., which we did not complete.

Operating loss

Our operating loss for the year ended December 31, 2017, was $11,067 thousand, as compared to an operating loss of $2,333 thousand for the year ended December 31, 2016, an increase of $8,734 thousand.

Financial Expense, Net

For the years ended December 31, 2017 and 2016 we incurred financial expenses, net of $6,977 thousand and $1,360 thousand, respectively. The increase of $5,617 thousand resulted primarily from expenses of $5,412 thousand related to the issuance and revaluation of warrants granted to investors in connection with private placements, a decrease of $273 thousand in imputed interest in respect of our convertible notes and issuance costs of $457 thousand related to cost associated with warrants issued to investors in the first quarter of 2017.

Net Loss

As a result of the foregoing, our net loss for the year ended December 31, 2017, was $18,044 thousand, as compared to $3,720 thousand for the year ended December 31, 2016 an increase of $14,324 thousand.

Liquidity and Capital Resources

Overview

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 in the next several years. Since our inception through March 31, 2018, we have funded our operations principally with $22,464 thousand from the issuance of our equity securities and $3,721 from loans from related parties and convertible promissory notes.

Private Placements

Immediately prior to the Merger, AIT Ltd. consummated a private placement pursuant to which it issued to investors an aggregate of 1,701,616 of its ordinary shares, together with warrants to purchase an aggregate of 3,403,232 ordinary shares, referred to as the January 2017 Warrants, for gross proceeds of approximately $10,210 thousand. In connection with the Merger, we assumed AIT Ltd.'s obligations under the purchase agreements with respect to such private placement, including the registration rights contained therein. In connection with the closing of the Merger, all outstanding ordinary shares, warrants and options of AIT Ltd. were converted into shares of our Common Stock, warrants for our Common Stock and options for our Common Stock, respectively, at a ratio of 1:1.

On March 31, 2017 we consummated a private placement in which we issued and sold an aggregate of 110,494 units, each composed of one share of our Common Stock and a five-year warrant to purchase two shares of Common Stock at an exercise price of $6.90 per share, referred to as the March 2017 Warrants. We issued and sold the units to certain investors at a purchase price of $6.00 per unit, for which we received approximately $663 thousand of gross proceeds. An additional 11,050 warrants in substantially the same form were issued to Laidlaw & Co. (UK) in connection with the March 31, 2017 private placement, referred to as the Laidlaw Warrants and, together with the January 2017 Warrants and the March 2017 Warrants, referred to as the Existing Warrants.

The Existing Warrants contain anti-dilution provisions in the case of a subdivision or combination of our shares of Common Stock, stock dividends, any reclassification of Common Stock, and corporate events such as a reorganization, consolidation, merger, or sale of all or substantially all of our assets. Additionally, subject to certain exceptions, if we issue or sell, or are deemed to have issued or sold, any Common Stock for a consideration per share, referred to as the New Issuance Price, less than a price equal to the exercise price then in effect immediately prior to such issuance or sale, then immediately after such issuance or sale the Exercise Price then in effect would be reduced to the New Issuance Price. If any sale or issuance, or deemed issuance, is for no consideration, then the New Issuance Price is deemed to be $0.01 per share and the number of shares of Common Stock for which the warrant is exercisable would be increased to the number of shares determined by multiplying the exercise price in effect immediately prior to such adjustment by the number of shares of Common Stock issuable upon exercise of the warrant immediately prior to such adjustment and dividing the product thereof by the Exercise Price resulting from such adjustment.

On February 16, 2018, we consummated the February 2018 Offering in which we issued and sold an aggregate of 4,599,604 warrants, referred to as the February 2018 Warrants and, together with the Existing Warrants, referred to as the Warrants, being comprised of (i) 2,299,802 Tranche A Warrants to purchase one share of Common Stock at an exercise price of $4.25 per Tranche A Warrant Share, exercisable within three days from the issue date of the Tranche A Warrants and (ii) an equal number of Tranche B Warrants to purchase one share of Common Stock at an exercise price of $4.25 per Tranche B Warrant Share, exercisable within three years from the issue date of the Tranche B Warrants. Immediately following the consummation of February 2018 Offering, each Purchaser exercised the full amount of their Tranche A Warrants resulting in gross proceeds to us from the sale of the February 2018 Warrants for $0.01 per underlying Warrant Share, together with the exercise price of the Tranche A Warrants, of approximately $9,820 thousand.

Upon close of the February 2018 Offering, the exercise price of all Existing Warrants detailed above was adjusted pursuant to the terms and conditions of those warrants, resulting in the adjustment of the exercise price to $4.25.

Future Funding Requirements

We have devoted substantially all of our efforts to business planning and research and development. We have incurred a net income of $1,048 thousand and had negative cash flow of $1 thousand, for the three month period ended March 31, 2018, and had an accumulated deficit of $30,569 thousand as of March December 31, 2018. As of March 31, 2018, we had $9,043 thousand in cash, cash equivalents, restricted cash and short-term marketable securities. Currently, our only source of liquidity is our current cash on hand. Our ability to continue to operate is dependent upon raising additional funds to finance our activities, and we do not currently have any commitments for future additional funding. 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 management and the Board of Directors believe that the Company's existing financial resources are adequate to satisfy its expected liquidity requirements through the end of June 2019. The Company adopted a contingency plan, which was approved by the Board of Directors, to be effected, in whole or in part, at its discretion, to allow the Company to continue its operations and meet its cash obligations, all to the extent required. The contingency plan consist of cost reduction, which include mainly the following steps: reduction in consultants' expenses, headcount, compensation paid to key management personal and overhead expenses. The Company and the Board of Directors believes that its existing capital resources and other future measures that may be implemented, if so required, will be adequate to satisfy its expected liquidity requirements.

We have based this assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the 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

For the Three months Ended March 31, 2018 Compared to Three months Ended March 31, 2017 and For the Year Ended December 31, 2017 Compared to Year Ended December 31, 2016.

	For the Three month ended 31, 2017		For the Year ended December 31,	
	2018	2017	2017	2016
		Unaudited		
Net cash provided by (used in):				
Operating activities	$ (1,748)	$ (2,212)	$ (7,119)	$ (692)
Investing activities	$ (7,704)	$ (320)	$ (1,143)	$ 14
Financing activities	$ 8,984	$ 9,666	$ 9,462	$ 556
Net (increase) decrease in cash and cash equivalents	$ (468)	$ 7,134	$ 1,120	$ (122)

Operating Activities

For the three months ended March 31, 2018 and 2017, net cash used in operations was $1,748 thousand and $2,212 thousand, respectively.

For the years ended December 31, 2017 and 2016, net cash used in operations was $7,119 thousand and $692 thousand, respectively. In 2017 cash was used primarily for expenses related to the Merger, private placements, payroll, clinical trials conducted in Israel, services from subcontractors and third parties.

Investing Activities

For the three months ended March 31, 2018 net cash used in investing activities was $7,704 thousand and for the three months ended March 31, 2017 net cash used in investing activities was $320 thousand. The increase resulted primarily from net investment of $7,704 thousand in short-term marketable securities.

For the year ended December 31, 2017 net cash used in investing activities was $1,149 thousand and for the year ended December 31, 2016 net cash provided by investing activities was $14 thousand. The increase resulted primarily from net investment of $604 thousand in short-term marketable securities, $244 thousand related to purchasing property and equipment and $295 thousand related to our acquisition of AIT Ltd. in the Merger.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2018 and 2017, was $8,984 thousand and $9,666 thousand, respectively. The Company received $682 thousand in higher proceeds for the three months ended March 31, 2018, when compared to March 31, 2017.

Net cash provided by financing activities for the years ended December 31, 2017 and 2016, was $9,462 thousand and $556 thousand, respectively. The increase resulted primarily from proceeds from the issuance of units, consisting of common stock and warrants for common stock, net of issuance costs, which totaled $9,889 thousand.

Sources of Liquidity and Current Outlook

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 revenues from sale of our products in the next several years. We have financed our operations to date primarily through proceeds from sales of our equity and equity-linked securities, including pursuant to the Israeli Private Placement the March 2017 Private Placement and the February 2018 Private Placement. Currently, our only source of liquidity is our current cash on hand. We do not currently have any commitments for future external funding.

We will require significant additional financing in the future to fund our operations if and when we obtain regulatory approval and commercialize our products. 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 candidates;
- 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 candidates;
- 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 candidates.

Potential sources of liquidity may include our issuance of equity or debt securities or our obtaining a credit facility from one or more financial institutions or otherwise. The sale of equity or convertible debt securities may result in dilution to our existing stockholders, and the incurrence of indebtedness would result in increased fixed obligations and could also subject us to covenants that restrict our operations. Additional equity or debt financing may not be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate all or a portion of our operations.

Off-Balance Sheet Arrangements

We currently do not have any off-balance sheet arrangements.

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. Approximately 14% of our expenses are denominated in NIS. 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 Transition Report on Form 10-KT. An index of those consolidated financial statements is found in Item 15 of this Transition Report on Form 10-KT.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Limitations on effectiveness of controls and procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Transition Report on Form 10-KT, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2018.

Management's Transition Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on this assessment, our management concluded that, as of March 31, 2018, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

This Transition Report does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

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

Name	Age	Position
Steven A. Lisi	47	Chief Executive Officer and Chairman of the Board of Directors
Amir Avniel	44	President, Chief Operating Officer and Director
Stephen DiPalma	59	Chief Financial Officer
Ron Bentsur	50	Director
David Grossman	42	Director
Erick J. Lucera	50	Director
Ari Raved	62	Director
Yoori Lee	45	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 and was formerly on the Board of Incysus Ltd, a transformational cell therapy company targeting solid tumors. 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.

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 ™ (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.

Ari Raved, Director

Mr. Ari Raved served as a Senior Vice President of IDB Development Corporation Limited., a subsidiary of IDB Holding Corp. Ltd. from 2004 to 2014. Mr. Raved served as the Vice President of IDB Development Corporation. He served as the Chairman of Bartan Holdings and Investments Ltd. from 2006 to 2014. He serves as a Director of Modiin Energy Limited Partnership. Mr. Raved has been a Director of the Company. since 2012. He served as a Director of Property & Building Corp. Ltd., from May 15, 2012 to December 14, 2015. He served as a Director of Gav-Yam Land Corporation Ltd. He served as a Director of Modiin Energy - LP.from 2006 until 2014 he was the Chairman of the Board at Bartan Holdings and Investments Ltd. Mr. Raved holds a Degree in Social Sciences and Masters of Arts in Labor Studies from Tel Aviv University. Ari's history from company inception is critical for our future success.

David Grossman, Director and Secretary

David Grossman has served on AIT Ltd's board since February 2016 and our Board since January 13, 2017.. Since 2017, Mr. Grossman has served as a member of the board of directors at Gefen Biomed Investments Ltd. (TASE: GEFEN).Since 2016 until 2017, Mr. Grossman has served as Chairman of the Board and Chief Executive Officer at D-Pharm Ltd. (TASE: DPRM)Since 2015, Mr. Grossman has served on the board of Amnis Therapeutics Ltd. (TASE: AMNS) (formerly ITGI Medical Ltd.) and since 2014 is an External Director at Cellect Biotechnology Ltd. (NASDAQ, TASE: APOP). From 2014 to 2016, Mr. Grossman served as the Chairman of Algomizer Ltd. (TASE: ALMO). Mr. Grossman previously served as Chief Executive Officer at XTL Biopharmaceuticals Ltd. (NASDAQ: XTLB, TASE: XTL), from 2009 until 2014 and was also a member of the board from 2009 until 2013. He served as a Vice President of Eurocom Investments LP, a private equity fund, from 2006 to 2009. Also during that time, Mr. Grossman served as Vice President of Sahar Investments Ltd, (TASE: ENLT; formerly SAIN) which focused on investments in the life sciences arena. Prior to that, Mr. Grossman was a Senior Analyst at Israel Health Care Ventures (IHCV), an Israeli healthcare venture capital fund. Mr. Grossman has previously served on a number of boards of public companies including Proteologics Ltd. (TASE: PRTL) and InterCure Ltd. (TASE: INCR) from 2012 to 2013, Rosetta Green Ltd. (TASE: RSTG) from 2011 to 2014, Bio Light Israeli Life Science Investments Ltd. (TASE: BOLT) from 2009 to 2011, and Gilat Satcom Ltd. (AIM: GLT) from 2007 to 2008. Mr. Grossman received a BA in Business Administration with a focus on information technology, from the Interdisciplinary Center Herzliya. David's experience in the industry, especially Israel, is a necessity for a company of our structure.

Erick J. Lucera, Director

Erick J. Lucera joined AIT's Board of Directors in August 2017 and serves on our Audit Committee. He is the Chief Financial Officer of Valeritas, a U.S. NASDAQ traded commercial stage company developing new technology for diabetes. 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.

Yoori Lee, Director

Ms. Yoori Lee joined AIT's Board of Directors in January 2018. She currently serves as Co-founder and President of Trio Health Advisory Group, Inc. 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 AIT with a distinct advantage over other companies of our size and stage of development.

Stephen DiPalma, Chief Financial Officer

Mr. DiPalma has been our Interim Chief Financial Officer since April, 2018. Mr. DiPalma is Managing Director at Danforth Advisors, LLC, where he has served since April 2014. He brings more than 30 years of experience in life sciences and healthcare, including founding two start-ups, working with venture-backed companies, subsidiaries of Fortune 100 firms and publicly traded companies, and his work with Danforth Advisors clients. Previously, he served as the CFO of two public companies, and as CFO, COO, CEO or Director of eight privately held companies, in addition to his consulting clients. Mr. DiPalma participated in the successful reorganization of Cambridge Biotech from Chapter 11 bankruptcy protection into Aquila BioPharmaceuticals, led the effort to take RXi Pharmaceuticals public, and has extensive experience in international fund raising and corporate structuring. He was formerly Chairman of the Board of Cognoptix Inc., and is on the Board of Directors of Phytera, Inc. Mr. DiPalma received his M.B.A. from Babson College and his B.S. from the University of Massachusetts-Lowell.

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 Ari Raved, 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 J. Lucera, Yoori Lee and Ari Raved.

Our Board of Directors has determined that Erick Lucera, Ron Bentsur and Ari Raved 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 during the transition period ended March 31, 2018. 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 Directorsin 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.

ITEM 11. EXECUTIVE COMPENSATION

Executive Compensation

ITEM 11. EXECUTIVE COMPENSATION

Executive Compensation

The following table sets forth all of the compensation awarded to, earned by or paid to our named executive officers for the three months ended March 31, 2018 and for the years ended December 31, 2017 and 2016.

Name and Principal Position	Year	Salary Cost (1)	Stock-based compensation	Bonus	Total
			(in thousands)		
Steven A. Lisi. (2)	2018	$ 130	$ -	$	$ 130
Chief Executive Officer and Chairman of the Board	2017	$ 163	$ -	$ -	$ 163
Amir Avniel	2018	$ 85	$ 27	$ -	$ 112
President, Chief Operating Officer and Director	2017	$ 286	$ 89	$ 50	$ 425
	2016	$ 220	$ -	$ -	$ 220
Hai Aviv	2017	$ 160	$ 39	$ -	$ 199
Chief Financial Officer					

(1) Salary cost includes the Covered Executive's gross salary plus payment of social benefits made by the Company on behalf of such Covered Executive. Such benefits may include, to the extent applicable to the Covered Executive, payments, contributions and/or allocations for savings funds (*e.g.,* Managers' Life Insurance Policy), education funds (referred to in Hebrew as " *keren hishtalmut* "), pension, severance, risk insurances (*e.g.,* life, or work disability insurance), payments for social security and tax gross-up payments, vacation, car, medical insurances and benefits, phone, convalescence or recreation pay and other benefits and perquisites consistent with the Company's policies.

(2) Mr. Lisi was appointed as the Company's CEO on June 14, 2017. The costs presented in the above table include payments which were paid to Mr. Lisi since his appointment as the Company's CEO.

Outstanding Equity Awards as of March 31, 2018

	Equity awards						
Name	Date of Grant	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	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	-	-	-	-	-	-	-
Amir Avniel	02/20/2017	33,333	66,667	-	4.25	02/20/2027	-
Hai Aviv	05/15/2017	12,500	37,500	-	4.25	05/15/2027	-

Director Compensation

Persons serving as both an Officer and a Director of the Company are only included in the Executive Compensation Table above.

Name	Fees earned or paid in cash ($)	Stock awards ($)	Option awards ($)	Non-equity incentive plan compensation ($)	Nonqualified deferred compensation earnings ($)	All Other Compensation ($)	Total ($)
				(in thousands)			
Steven A. Lisi	-	17	-	-	-	-	17
Ron Bentsur	-	-	-	-	-	-	-
David Grossman	15	-	7	-	-	-	22
Erick J. Lucera	-	-	-	-	-	-	-
Ari Raved	-	-	-	-	-	-	-
Yoori Lee	-	-	-	-	-	-	-

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 8,406,657 shares of our Common Stock outstanding as of June 15, 2018

Under the terms of the Warrants 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		
Deerfield Special Situations Fund, L.P.	1,228,930[3]	9.99%[4]
Pulmonox Technologies Corporation	982,733[5]	4.99%[6]
Allianz Biotechnologie	954,779[7]	9.99%[4]
M. Kingdon Offshore Master Fund, L.P.	968,385[8]	4.99%[6]
Executive Officers and Directors		
Steven A. Lisi	723,511[9]	4.99%[6]
Amir Avniel	572,623[10]	4.99%[6]
Ron Bentsur	356,918[11]	4.21%
Yossef Av-Gay	378,843[12]	4.50%
David Grossman	40,166[13]	*
Ari Raved	768,260[14]	4.99%[6]
Hai Aviv	16,667[15]	*
Erick Lucera	2,342[16]	*
Yoori Lee	4,684[17]	*
Executive Officers and Directors as a Group (Nine persons)	2,920,005	23.68%

* Less than one percent (1.0%).

(1) The address of these persons, unless otherwise noted, is c/o AIT Therapeutics, Inc., 500 Mamaroneck Avenue, Suite 321, Harrison, New York 10528.

(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 15, 2018. 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 February 16, 2018 by Deerfield Mgmt, L.P. Deerfield Management Company, L.P., Deerfield Special Situations Fund, L.P. and James E. Flynn. Includes 856,863 shares of Common Stock issuable upon exercise of the January 2017 Warrants and the February 2018 Warrants. James E. Flynn is the President of J.E. Flynn Capital, LLC, which is the general partner of Deerfield Mgmt, L.P., which is the general partner of Deerfield Special Situations Fund, L.P. Flynn Management LLC is the general partner of Deerfield Management Company, L.P., which is the investment advisor to Deerfield Special Situation Fund, L.P. The reporting persons' business address is 780 Third Avenue, 37th Floor, New York, NY 10017.

(4) The provisions of the warrants 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 9.985% (subject to an increase of such percentage to 9.99%) of the total number of our then-outstanding shares of Common Stock.

(5) Includes 675,652 shares of Common Stock issuable upon exercise of the January 2017 Warrants and the February 2018 Warrants.

(6) The provisions of the warrants 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.

(7) Based, in part, on information provided on Schedule 13G filed with the SEC on March 9, 2018 by Allianz Global Investors U.S. Holdings LLC and Allianz Global Investors GmbH. Includes 560,723 shares of Common Stock issuable upon exercise of the January 2017 Warrants and the February 2018 Warrants. Allianz Global Investors U.S. Holdings LLC and Allianz Global Investors GmbH are investment advisors to Allianz Biotechnologie. The business address for Allianz Global Investors U.S. Holdings LLC is 1633 Broadway, New York, NY 10019. The business address for Allianz Global Investors GmbH is Bockenheimer Landstrasse 42-44, Frankfurt, 2M 60323 Germany.

(8) Based, in part, on information provided on Schedule 13G filed with the SEC on February 14, 2018 by M. Kingdon Capital Management, L.L.C, M. Kingdon Offshore Master Fund L.P. and Mark Kingdon. Includes 567,526 shares of Common Stock issuable upon exercise of the January 2017 Warrants and the February 2018 Warrants. Mark Kingdon is the Managing Member of Kingdon GP, LLC, which is the general partner of M. Kingdon Offshore Master Fund L.P. The business address for the reporting persons is 152 West 57th Street, 50th Floor, New York, NY 10019.

(9) Includes 200,446 shares of Common Stock issuable upon exercise of the January 2017 Warrants and the February 2018 Warrants.

(10) Includes 87,343 shares of Common Stock issuable upon exercise of the January 2017 Warrants and the February 2018 Warrants, as well as options held by Mr. Avniel. Also includes 32,666 shares of Common Stock held by Dandelion Investments Ltd., over which Mr. Avniel has sole voting and dispositive power.

(11) Includes 73,419 shares of Common Stock issuable upon exercise of the January 2017 Warrants and the February 2018 Warrants.

(12) Includes 9,186 shares of Common Stock issuable upon exercise of the January 2017 Warrants and the February 2018 Warrants.

(13) Includes 36,158 shares of Common Stock issuable upon exercise of the January 2017 Warrants and the February 2018 Warrants, as well as options held by Mr. Grossman.

(14) Includes 128,375 shares of Common Stock issuable upon exercise of the January 2017 Warrants and the February 2018 Warrants.

(15) Includes 16,667 shares of Common Stock issuable upon exercise of options held by Mr. Aviv.

(16) Includes 1,171 shares of Common Stock issuable upon exercise of the February 2018 Warrants.

(17) Includes 2,342 shares of Common Stock issuable upon exercise of the February 2018 Warrants.

Equity Compensation Plan Information

The following table summarizes securities available under our equity compensation plans as of March 31, 2018.

	Equity Compensation Plan Information		
Plan category	**Number of securities to be issued upon exercise of outstanding stock options**	**Weighted-average exercise price of outstanding stock options**	**Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))**
	(a)	(b)	(c)
Equity compensation plans approved by security holders			
2013 Equity Incentive Plan	410,906	$ 4.17	55,770
Total	410,906	$ 4.17	55,770

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

Transactions with Related Persons

Due to the small size of our company, we do not at this time have a formal written policy regarding the review of related party transactions, and rely on our full Board of Directors to review, approve or ratify such transactions and identify and prevent conflicts of interest. Pursuant to Delaware law, no director having an interest in a particular transaction is permitted to vote upon such transaction. Our Board of Directors reviews any such transaction in light of the particular affiliation and interest of any involved director, officer or other employee or stockholder and, if applicable, any such person's affiliates or immediate family members. Management aims to present transactions to our Board of Directors for approval before they are entered into or, if that is not possible, for ratification after the transaction has occurred. If our Board of Directors finds that a conflict of interest exists, then it will determine the appropriate action or remedial action, if any. Our Board of Directors approves or ratifies a transaction if it determines that the transaction is consistent with our best interests and the best interest of our stockholders.

Director Independence

In connection with the closing of the Merger, our Board of Directors undertook a review of the composition of our Board of Directors and independence of each director. Based upon information requested from and provided by each director concerning his background, employment and affiliations, including family relationships, Mr. Lucera, Mr. Bentsur, Mr. Raved and Ms. Lee would qualify as "independent" as that term is defined by Nasdaq Listing Rule 5605(a)(2).

Employment or Service Agreements with Executive Officers; Consulting and Directorship Services Provided by 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 U.S. ("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, 2018 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.

Employment Agreement with Mr. Amir Avniel, CEO

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.

In October 31, 2016, the Company's Chief Executive Officer has waived all his requirements for certain debts of the Company to him in total 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.

Directors Agreement with David Grossman

On February 4, 2016, the Board of Directors approved the appointment of Mr. Grossman as a Director of the Company. Mr. Grossman shall be entitled to (i) 14,476 options of the Company with annual period over three years and (ii) an annual retainer of $25,000 subject to the consummation of an IPO.

Employment Agreement with Hai Aviv, CFO

On January 26, 2017, the Board of Directors of the Company, appointed Mr. Hai Aviv to serve as the Company's Chief Financial Officer, effective as of February 28, 2017.

Mr. Aviv, who is 35 years old, joined the Company from Babylon Ltd., a publicly-traded Israeli company listed on the Tel Aviv Stock Exchange, operating in the fields of Internet, risk capital investments and software, where he has served as Chief Financial Officer from 2013 to the present. From 2010 to 2013, Mr. Aviv served as Babylon's corporate controller. Mr. Aviv is a certified public accountant and, from 2005 to 2010, served as manager at the Ernst & Young Accounting Firm, Kost Forer, Gabbay & Kasierer, working predominantly with the high-tech team.

In connection with Mr. Aviv's appointment as CFO, Mr. Aviv entered into an employment agreement with the Company's wholly owned subsidiary, Advanced Inhalation Therapies, Ltd., providing for annual compensation in an amount equal to NIS 420,000, or approximately $113,400, based on an exchange rate of $0.27 per NIS. Severance and disability benefits are generally provided as required under Israeli law. Additionally, Mr. Aviv is entitled to a grant of options to purchase 50,000 shares of the Company's Common Stock, par value $0.0001, per share, subject to the Board's adoption of an equity compensation plan and due authorization of such grant. Under the employment agreement, Mr. Aviv has also agreed to customary non-disclosure and non-competition covenants, and either party may terminate the employment agreement upon 90-days prior written notice to the non-terminating party.

Mr. Aviv resigned from the Company as of April 30, 2018, and as such his employment agreement has been terminated. The Company will pay Mr. Aviv any compensation that is earned but unpaid prior to resignation. Mr. Aviv's stock options for 50,000 shares of common stock were accelerated and vested and shall be exercisable at any time up to April 30, 2018. His resignation is not the result of any disagreement with the Company.

Under current applicable Israeli employment laws, we may not be able to enforce (either in whole or in part) covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees. Please see "Risk factors-Risks Relating to Intellectual Property" for a further description of the enforceability of non-competition clauses. See "Management-Agreements and Arrangements with, and Compensation of, Directors and Executive Officers" for additional information.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Audit Fees

The aggregate fees billed for the transition period ended March 31, 2018 and the fiscal years December 31, 2017 for professional services rendered by Kost Forer Gabbay & Kasierer, a Member of Ernst & Young Global for the audit of our annual financial statements, 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 these fiscal periods were as follows:

	Three Months Ended March 31, 2018	Year Ended December 31, 2017
	(in thousand)	
Audit Fees	$ 36	$ 82
Audit Related Fees	$ -	$ 20
Tax Fees	$ -	$ 2
All Other Fees	$ -	$ -
Total	**$ 36**	**$ 124**

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-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 Kost Forer Gabbay & Kasierer, a Member of Ernst & Young Global and believes that the provision of services for activities unrelated to the audit is compatible with maintaining Kost Forer Gabbay & Kasierer's independence.

PART IV

ITEM 15. SUBSEQUENT EVENTS

ITEM 16. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

1. Financial Statements.

The following financial statements of AIT Therapeutics, Inc., together with the report thereon of Kost Forer Gabbay & Kasierer, a Member of Ernst & Young Global, an independent registered public accounting firm, are included in this Transition Report on Form 10-KT:

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.
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.

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	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.
10.4+	Personal Employment Agreement, dated as of September 9, 2012, by and between Advanced Inhalation Therapies Ltd. and Mrs. Racheli Vizman, filed as Exhibit 10.6 to our Current Report on Form 8-K, as amended and filed with the SEC on March 15, 2017 and incorporated herein by reference.
10.5+	Addendum to Personal Employment Agreement, dated as of May 30, 2013, by and between Advanced Inhalation Therapies Ltd. and Mrs. Racheli Vizman, filed as Exhibit 10.7 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	Addendum #2 to Personal Employment Agreement, dated as of April 8, 2014, by and between Advanced Inhalation Therapies Ltd. and Mrs. Racheli Vizman, filed as Exhibit 10.8 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+	Addendum #3 to Personal Employment Agreement, dated as of July 12, 2015, by and between Advanced Inhalation Therapies Ltd. and Mrs. Racheli Vizman, filed as Exhibit 10.9 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	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.
10.9^	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.
10.10	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.
10.11	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.
10.12+	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.
10.13+	Employment Agreement, effective as of February 28, 2017 by and between Advanced Inhalation Therapies Ltd. and Hai Aviv, filed as Exhibit 10.1 to our Current Report on Form 8-K, filed with the SEC on January 31, 2017 and incorporated herein by reference
10.14+	Consulting Agreement, dated as of December 15, 2012, by and between Advanced Inhalation Therapies Ltd. and Yossef Av-Gay, filed as Exhibit 10.15 to our Registration Statement on Form S-1 (File No. 333-216287), and incorporated herein by reference.

10.15+		Amendment to Consulting Agreement, dated as of October 21, 2014, by and between Advanced Inhalation Therapies Ltd. and Yossef Av-Gay, filed as Exhibit 10.16 to our Registration Statement on Form S-1 (File No. 333-216287), and incorporated herein by reference.
10.16+		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.
10.17+		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.
10.18+		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.
10.19		Advanced Inhalation Therapies (AIT) Ltd. 2013 Share Option Plan, as amended and restated as of the closing of the Merger as a Stock Incentive Plan of AIT Therapeutics, Inc., filed as Exhibit 10.4 to our Current Report on Form 8-K, as amended and filed with the SEC on March 15, 2017 and incorporated herein by reference.
10.20		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.
10.21		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.
10.22		Form of loan agreement between the Company and Ari Raved.***
21.1		List of AIT Therapeutics, Inc. Subsidiaries, filed as Exhibit 21.1 to our Current Report on Form 8-K, filed with the SEC on January 20, 2017 and incorporated herein by reference.
23.1	*	Consent of Kost Forer Gabbay & Kasierer, a Member of Ernst & Young Global.*
31.1	*	Rule 13a-14(a) / 15d-14(a) Certification of Chief Executive Officer
31.2	*	Rule 13a-14(a) / 15d-14(a) Certification of Chief Financial Officer
32.1	****	Section 1350 Certification of Chief Executive Officer
32.2	****	Section 1350 Certification of Chief Financial Officer

+ Management contract or compensation plan arrangement

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

* Filed herewith.

** Previously filed with our Registration Statement on Form S-1 filed with the SEC on February 27, 2017.

*** Previously filed with our Amendment No. 1 to Registration Statement on Form S-1 filed with the SEC on May 2, 2017.

**** Furnished herewith.

Item 16. Form 10-KT Summary

None.

AIT THERAPEUTICS, INC. AND ITS SUBSDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

AS OF MARCH 31, 2018

U.S. DOLLARS IN THOUSANDS

INDEX

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Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of AIT Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of AIT Therapeutics, Inc. and its subsidiaries (the Company) as of March 31, 2018, December 31, 2017 and December 31, 2016, the related consolidated statements of comprehensive loss, changes in shareholders' equity (deficiency) and cash flows for the period from January 1, 2018 to March 31, 2018, and each of the two fiscal years in the period ended December 31, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at March 31, 2018, December 31, 2017 and December 31, 2016, and the results of its operations and its cash flows for the period from January 1, 2018 to March 31, 2018, and each of the two fiscal years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

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 provide a reasonable basis for our opinion.

/s/ KOST FORER GABBAY & KASIERER
A Member of EY Global

We have served as the Company's auditor since 2014.
June 15, 2018
Tel-Aviv, Israel

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands, except share and per share data

	As of March 31, 2018	As of December 31, 2017	As of December 31, 2016
ASSETS :			
CURRENT ASSETS:			
Cash and cash equivalents	$ 733	$ 1,201	$ 7
Restricted cash	6	6	-
Marketable securities	8,304	606	-
Other accounts receivable and prepaid expenses	59	109	78
Total current assets	9,102	1,922	85
NON-CURRENT ASSETS:			
Deferred private placement costs	-	-	90
Property and equipment, net	253	267	61
Total non-current assets	253	267	151
TOTAL ASSETS	$ 9,355	$ 2,189	$ 236

The accompanying notes are an integral part of the consolidated financial statements.

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands, except share and per share data

	As of March 31, 2018	As of December 31, 2017	As of December 31, 2016
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIENCY)			
CURRENT LIABILITIES:			
Bank loan	$ -	$ -	$ 39
Trade payables	842	669	528
Other accounts payable	1,257	694	1,093
Loans from related parties and others	33	33	379
Total current liabilities	2,132	1,396	2,039
NON-CURRENT LIABILITIES:			
Liability related to warrants	5,678	9,172	-
Convertible notes	-	-	2,895
TOTAL LIABILITIES	7,810	10,568	4,934
COMMITMENTS AND CONTINGENCIES			
SHAREHOLDERS' EQUITY (DEFICIENCY)			
Common Stock, $0.0001 par value per share - 100,000,000 and 11,665,085 shares authorized at March 31, 2018, December 31, 2017 and 2016; 8,397,056 , 6,097,254 and 2,207,449 shares issued and outstanding at March 31, 2018, December 31, 2017 and 2016, respectively	1	1	1
Preferred Stock, $0.0001 par value per share - 10,000,000 shares authorized at March 31, 2018 , December 31, 2017and 2016; 0 issued and outstanding shares at March 31, 2018 ,December 31, 2017 and 2016	-	-	-
Accumulated other comprehensive income	(3)	2	-
Treasury shares	(25)	(25)	-
Additional paid- in capital	32,141	23,260	8,874
Deficit accumulated	(30,569)	(31,617)	(13,573)
Total shareholders' equity (deficiency)	1,545	(8,379)	(4,698)
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIENCY)	$ 9,355	$ 2,189	$ 236

The accompanying notes are an integral part of the consolidated financial statements.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS (INCOME)

U.S. dollars in thousands, except share and per share data

	For the Three months Ended	For the Twelve months Ended	
	March 31, 2018	December 31, 2017	December 31, 2016
Operating expenses:			
Research and development expenses	$ 1,637	$ 4,438	$ 673
General and administrative expenses	803	6,629	1,039
Costs related to aborted IPO	-	-	621
Operating loss	2,440	11,067	2,333
Financial (income) expense, net	(3,488)	6,977	1,360
Loss (Income) before taxes on income	(1,048)	18,044	3,693
Taxes on income	-	-	27
Net (income) loss	$ (1,048)	$ 18,044	$ 3,720
Net unrealized loss (gain) on available-for-sale investments	5	(2)	-
Total comprehensive (income) loss	$ (1,043)	$ 18,042	$ 3,720
Net basic earnings (loss) per share of common stock	0.15	(3.01)	(2.69)
Net diluted earnings (loss) per share of common stock	0.14	(3.01)	(2.69)
Weighted average number of shares used in computing net basic earnings (loss) per share of common stock	7,196,048	6,002,052	1,448,363
Weighted average number of shares used in computing net diluted earnings (loss) per share of common stock	7,250,194	6,002,052	1,448,363

The accompanying notes are an integral part of the consolidated financial statements.

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (DEFICIENCY)

U.S. dollars in thousands, except share and per share data

	Common Stock		Treasury Shares	Additional Paid-in Capital	Accumulated Deficit	Other Comprehensive income	Total stockholders' Equity (Deficiency)
	Number	Amount					
Balance as of January 1, 2016	2,207,449	$ 1	$ -	$ 8,028	$ (9,853)	$ -	$ (1,824)
Modification of Consultants' warrants to purchase Common Stock	-	-	-	94	-	-	94
Waiver of salary by the Company's officer	-	-	-	304	-	-	304
Stock-based compensation related to options granted to employees and non-employees	-	-	-	243	-	-	243
Stock-based compensation related to RSUs granted to Board of Directors' member	-	-	-	28	-	-	28
Beneficial conversion feature in respect to Convertible Notes	-	-	-	177	-	-	177
Net loss	-	-	-	-	(3,720)	-	(3,720)
Balance as of December 31, 2016	2,207,449	1	-	8,874	(13,573)	-	(4,698)
			-				
Shares issued with respect to reverse merger of AITT Inc.	103,200	*)	-	(295)	-	-	(295)
Treasury shares	(90,000)	*)	(25)	-	-	-	(25)
Stock-based compensation related to options granted to employees and non-employees	-	-	-	536	-	-	536
Stock-based compensation related to RSUs granted to Board of Directors' member	3,927	*)	-	(24)	-	-	(24)
Stock-based compensation related to RSs granted to members of the Board of Directors	856,910	*)	-	2,549	-	-	2,549
Cancellation of RSs to members of the Board of Directors	(246,312)	*)	-	844	-	-	844
Issuance of warrants to service provider	-	-	-	480	-	-	480
Issuance of Common Stock, net of issuance costs	1,812,110	*)	-	6,322	-	-	6,322
Conversion of Convertible Notes into Common Stock upon the merger	1,397,068	*)	-	3,973	-	-	3,973
Issuance of shares upon exercise of options	52,902	*)		1	-	-	1
Net unrealized gains on available-for-sale investments	-	-	-	-	-	2	2
Net loss	-	-	-	-	(18,044)	-	(18,044)
Balance as of December 31, 2017	6,097,254	$ 1	$ (25)	$ 23,260	$ (31,617)	$ 2	$ (8,379)

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (DEFICIENCY) (Cont.)

U.S. dollars in thousands, except share and per share data

	Common Stock		Treasury Shares	Additional Paid-in Capital	Accumulated Deficit	Other Comprehensive income	Total stockholders' Equity (Deficiency)
	Number	Amount					
Balance as of January 1, 2018	6,097,254	$ 1	$ (25)	$ 23,260	$ (31,617)	$ 2	$ (8,379)
Stock-based compensation related to options granted to employees and non-employees	-	-	-	130	-	-	130
Stock-based compensation related to RSs granted to members of the Board of Directors	-	*)	-	17	-	-	17
Issuance of Common Stock, net of issuance costs	2,299,802	*)	-	8,734	-	-	8,734
Net unrealized loss on available-for-sale investments	-	-	-	-	-	(5)	(5)
Net Income	-	-	-	-	1,048	-	1,048
Balance as of March 31, 2018	8,397,056	$ 1	$ (25)	$ 32,141	$ (30,569)	$ (3)	$ 1,545

*) Represents an amount lower than $1.

The accompanying notes are an integral part of the consolidated financial statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	For the three months ended March 31,	For the twelve months ended December 31,	
	2018	**2017**	**2016**
Cash flows from operating activities			
Net income (loss)	$ 1,048	$ (18,044)	$ (3,720)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	15	38	25
Capital loss in respect to property and equipment	-	-	5
Stock-based compensation related to warrants, RSs and RSUs	147	4,385	365
Issuance of Common Stock to finder upon the conversion of Convertible Notes	-	18	-
Amortization of beneficial conversion feature and debt issuance costs related to Convertible Notes	-	1,046	1,050
Issuance cost related to warrants liability	-	457	-
Adjustment of liability warrants	-	2,434	-
Revaluation of warrants to purchase Common Stock	(3,494)	2,978	-
Imputed interest on Convertible Notes, loans from related parties and others	-	33	299
Waiver of salary by the Company's officer	-	-	304
Change in:			
Other accounts receivables and prepaid expenses	50	(31)	(67)
Trade payables	173	141	404
Other accounts payable	313	(574)	291
Deferred IPO costs that was aborted	-	-	352
Net cash used in operating activities	(1,748)	(7,119)	(692)
Cash flows from investing activities			
Investment in marketable securities	(9,403)	(2,000)	-
Proceeds from redemption of marketable securities	1,700	1,396	-
Selling of property and equipment	-	-	12
Purchase of property and equipment	(1)	(244)	2
Purchase price that has been paid upon the reverse merger	-	(295)	-
Net cash (used in) provided by investing activities	(7,704)	(1,143)	14
Cash flows from financing activities			
Proceeds from issuance of units consisting of Common Stock and warrants, net of issuance costs	8,984	9,889	-
Proceeds from loan from related parties and others	-	57	340
Maturity of loan and interest from related parties and others	-	(418)	-
Proceeds from bank loan	-	-	467
Repayment of bank loan	-	(42)	(431)
Treasury shares	-	(25)	-
Proceeds from issuance of Convertible Note	-	-	184
Deferred private placement costs that were paid	-	-	(4)
Exercise of options	-	1	-
Net cash provided by financing activities	8,984	9,462	556
Increase (decrease) in cash, cash equivalents and restricted cash	(468)	1,120	(122)
Cash, cash equivalents and restricted cash at beginning of year	1,207	7	129
Cash, cash equivalents and restricted cash at end of year	$ 739	$ 1,207	$ 7
Supplemental disclosure of non-cash financing activities:			
Conversion of Convertible Notes into Common Stock	$ -	$ 3,955	$ -
Capitalization of deferred private placement costs	$ -	$ -	$ 86
Issuance costs related to warrants	$ 250	$ -	$ -

NOTE 1:- GENERAL

a. AIT Therapeutics, Inc. ("AITT" or the "Company") was incorporated on April 24, 2015 as KokiCare, Inc. under the laws of the State of Delaware. On January 9, 2017, the name of the Company was changed to AIT Therapeutics, Inc.

Advanced Inhalation Therapies (AIT) Ltd. ("AIT") was incorporated in Israel on May 1, 2011 and commenced its operations in May 2012. In December 2016, through a merger transaction, AIT became a wholly-owned subsidiary of the Company.

The Company is an emerging medical device company that is developing a Nitric Oxide (NO) delivery system that generates NO from ambient air. The system can generate up to 400 parts per million (ppm) of NO for delivery to a patient's lung. The system can deliver continuously or for a fixed amount of time and can titrate dose on demand or maintain a constant dose. Hence the system can be used to treat patients on a ventilator requiring NO, those with chronic lung disease or acute severe lung infections via delivery through a breathing mask.

On August 29, 2014, AIT established a wholly-owned subsidiary, Advanced Inhalation Therapies (AIT) Inc. ("Inc."), a Delaware corporation.

b. Reverse merger:

On December 29, 2016, KokiCare Inc. entered into an Agreement and Plan of Merger (as subsequently amended, the "Merger Agreement"), together with Red Maple Ltd., a wholly owned subsidiary of KokiCare Inc., ("Merger Sub"), and AIT. The Merger Agreement provided for (i) the merger of Merger Sub with and into AIT pursuant to the laws of the State of Israel (the "Israeli Merger"), and (ii) the conversion of the ordinary shares and other outstanding securities of AIT into the right to receive shares and other applicable securities of AITT, with AIT surviving as a wholly owned subsidiary of AITT (the "Merger"). The Israeli Merger became effective on December 29, 2016 and the Merger closed on January 13, 2017 (the "Closing").

Prior to consummation of the Merger:

1. The Company received a $320 cash purchase price (the "Purchase Price") from AIT and used the cash purchase price to (i) pay off all the liabilities of the Company as of the Closing of the Merger, (ii) issue a cash dividend of $2.50 per share to its stockholders as of immediately prior to the Closing of the Merger, and (iii) acquire 90,000 (on a post-reverse stock split basis) shares of its common stock, par value $0.0001 per share ("Common Stock") from the Company's prior sole officer and director, for $25.

2. KokiCare Inc. adopted its Amended and Restated Certificate of Incorporation ("COI") to (i) change its name from "KokiCare Inc." to "AIT Therapeutics Inc.", (ii) increase its capitalization to provide for the issuance of up to 100,000,000 shares of its Common Stock and up to 10,000,000 shares of Preferred Stock, par value $0.0001 per share; and (iii) effect a one-for-100 reverse stock split of the Common Stock.

   In connection with the Closing of the Merger, all outstanding ordinary shares, warrants and options of AIT were converted into the rights to receive shares of AITT's Common Stock, warrants for AITT's Common Stock and stock options for AITT's Common Stock, respectively, at a ratio of 1:1.

NOTE 1:- GENERAL (Cont.)

3. On December 31, 2016, Kokicare's Common Stock was quoted on the Pink Open Market of the OTC Markets (the "OTC Pink") under the symbol "KKIC". After the Merger, the symbol changed to "AITB".

The Merger was accounted for as a reverse recapitalization which is outside the scope of ASC 805, "Business Combinations". Under reverse capitalization accounting, AIT is considered the acquirer for accounting and financial reporting purposes and acquired the assets and assumed the liabilities of the Company. Assets acquired and liabilities assumed are reported at their historical amounts. Consequently, the consolidated financial statements of the Company reflect the operations of the acquirer for accounting purposes together with a deemed issuance of shares, equivalent to the shares held by the former stockholders of the legal acquirer and a recapitalization of the equity of the accounting acquirer. These consolidated financial statements include the accounts of the Company since the effective date of the reverse capitalization and the accounts of AIT since inception.

c. Since its inception, the Company has devoted substantially most of its effort to business planning, research and development. The Company generated net income of $1,048 and negative cash flow of $1,748 from operating activities in the three month period ended March 31, 2018, and has an accumulated deficit of $30,569 as of March 31, 2018. The Company management and the Board of Directors believe that the Company's existing financial resources are adequate to satisfy its expected liquidity requirements through the end of June 2019. The Company adopted a contingency plan, which was approved by the Board of Directors, to be effected, in whole or in part, at its discretion, to allow the Company to continue its operations and meet its cash obligations, all to the extent required. The contingency plan consist of cost reduction, which include mainly the following steps: reduction in consultants' expenses, headcount, compensation paid to key management personal and overhead expenses. The Company and the Board of Directors believes that its existing capital resources and other future measures that may be implemented, if so required, will be adequate to satisfy its expected liquidity requirements

The Company is also continuing to evaluate additional sources of capital and financing. However, there is no assurance that additional capital and/or financing will be available to the Company, and even if available, whether it will be on terms acceptable to the Company or in amounts required.

d. Change in Fiscal Year end:

On May 10, 2018, the Company's board of directors approved a change in the Company's fiscal year end from December 31 to March 31. The change in the Company's fiscal year end resulted in a three month transition period that began on January 1, 2018 and ended on March 31, 2018.

In the Consolidated Statements of Operations, the Company compares the three months ended March 31, 2018 with the previously reported fiscal years ended December 31, 2017 and 2016.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

The consolidated financial statements have been prepared in accordance with United States Generally Accepted Accounting Principles ("U.S. GAAP").

a. Use of estimates:

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company evaluates on an ongoing basis its assumptions. The Company's management believes that the estimates, judgment and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Actual results could differ from those estimates.

b. Principles of consolidation:

The consolidated financial statements include the accounts of the Company and its subsidiaries. Inter-company balances, and transactions including profits from inter-company sales not yet realized have been eliminated upon consolidation.

c. Financial statements in U.S. dollars in thousands:

The majority of AIT's operations are currently conducted in Israel and in the United States while a significant part of AIT's expenses and financing activities are denominated and determined in U.S. dollars. 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 (ASC) 830, "Foreign Currency Matters". All transaction gains and losses from re-measurement of monetary balance sheet items denominated in non-dollar currencies are reflected in the statements of comprehensive loss as financial income or expenses, as appropriate.

d. Cash equivalents:

Cash equivalents are short-term highly liquid investments that are readily convertible to cash with original maturities of three months or less at acquisition.

e. Restricted cash:

Restricted cash are invested in bank deposit. These deposits serve as securities for the Company's vehicle lease.

f. Investment in marketable securities:

The Company accounts for investments in marketable securities in accordance with ASC No. 320, "Investments- Debt and equity Securities". Management determines the appropriate classification of its investments at the time of purchase and reevaluates such determinations at each balance sheet date.

The Company classified its investment in marketable securities as available-for-sale securities. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in "Accumulated other comprehensive income" in shareholders' equity (deficiency). Realized gains and losses on sales of investments are included in financial income, net and are derived using the specific identification method for determining the cost of securities.

The Company recognizes an impairment charge when a decline in the fair value of its investments below the cost basis is judged to be other-than-temporary. The factors considered in making such a determination include the duration and severity of the impairment, the reason for the decline in value, the potential recovery period and the Company's intent to sell, including whether it is more likely than not that the Company will be required to sell the investment before recovery of cost basis. For securities that are deemed other-than-temporarily impaired, the amount of impairment recognized in the statement of income (loss) is limited to the amount related to credit losses, while impairment related to other factors is recognized in other comprehensive income (loss).

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

g. Property and equipment, net:

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets at the following rates:

	%
Computers and electronic equipment	33
Clinical and medical equipment	10-15

h. Impairment for long-lived assets:

The Company's long-lived assets are reviewed for impairment in accordance with ASC 360, whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell. For the three month period ended March 31, 2018 and for the twelve month ended December 31, 2017 and 2016, no impairment losses have been identified.

i. Research and development expenses:
Research and development expenses are charged to the statement of comprehensive loss as incurred.

j. Severance pay:

AIT's liability for severance pay is pursuant to Section 14 of the Severance Compensation Act, 1963 ("Section 14"). All AIT employees are included under this section, and are entitled only to monthly deposits, at a rate of 8.33% of their monthly salary, made in the employee's name with insurance companies. Payments in accordance with Section 14 release AIT from any future severance payments in respect of those employees. The fund is made available to the employee at the time the employer-employee relationship is terminated, regardless of cause of termination. The severance pay liabilities and deposits under Section 14 are not reflected in the balance sheet as the severance pay risks have been irrevocably transferred to the severance funds.

k. Income taxes:

The Company accounts for income taxes in accordance with ASC 740, "Income Taxes". This topic prescribes the use of the liability method whereby deferred tax assets and liability account balances are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides full valuation allowance, to reduce deferred tax assets to the amount that is more likely than not to be realized.

The Company implements a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% (cumulative basis) likely to be realized upon ultimate settlement. As of March 31, 2018, and as of December 31, 2017 and 2016, the Company has recorded a liability for uncertain tax position under other accounts payable.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

The Company classifies interest and penalties on income tax (which includes uncertain tax positions) as taxes on income.

l. Concentrations of credit risk:

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, cash equivalents, restricted cash and marketable securities. Cash, cash equivalents and restricted cash are invested in major banks in Israel and U.S. Management believes that the financial institutions that hold the Company's investments are financially sound and, accordingly, minimal credit risk exists with respect to these investments.

The Company's marketable securities include investments in mutual funds which management believes bear minimal credit risk

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

m. Legal and other contingencies:

The Company accounts for its contingent liabilities in accordance with ASC 450 "Contingencies". A provision is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. With respect to legal matters, provisions are reviewed and adjusted to reflect the impact of negotiations, estimated settlements, legal rulings, advice of legal counsel and other information and events pertaining to a particular matter.

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 the February 2018 Offering, the January 2017 Warrants issued to Empery 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. The Company intends to vigorously defend all claims.

Given the early stage of the litigation, it is not possible to determine or assess the probability of any particular outcome.

n. Warrants to purchase Common Stock:

The Company accounted for warrants to purchase shares of its Common Stock held by investors which include down round protective provisions as a liability according to the provisions of ASC 815-40, "Derivatives and Hedging Contracts in Entity's Own Equity" ("ASC 815"). The Company measures the warrants at fair value by using the Black-Scholes model in each reporting period until they are exercised or expired, with changes in the fair values being recognized in the Company's statement of comprehensive loss as financial expense (income), net.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

o. Treasury shares:

Shares held by the Company are presented as a reduction of equity, at their cost to the Company, until such shares are retired and removed from the account.

p. Basic and diluted net earnings (loss) per share:

Basic net earnings (loss) per share is computed based on the weighted average number of Common Stock outstanding during each year. Diluted net earnings (loss) per share is computed based on the weighted average number of Common Stock outstanding during each year plus dilutive potential equivalent Common Stock considered outstanding during the year, in accordance with ASC 260.

For the twelve month periods ended December 31, 2017 and 2016, all outstanding stock options, warrants, restricted shares and restricted share units have been excluded from the calculation of the diluted net loss per share as all such securities are anti-dilutive for all periods presented. For the three month period ended March 31, 2018 all outstanding convertible notes, options and warrants have been excluded from the calculation of the diluted net loss per share since their effect was anti-dilutive, excluding 54,146 stock option which are dilutive and included in the weighted average number of shares used in computing net diluted earnings loss per share of common stock.

q. Stock-based compensation:

The Company accounts for stock-based compensation in accordance with ASC 718, "Compensation Stock Compensation", ("ASC 718"), which requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite or derived service period in the Company's consolidated statement of comprehensive loss.

The Company recognizes compensation expense for the value of its awards granted based on the accelerated method over the requisite or derived service period of each of the awards.

The Company estimates the fair value of stock options granted using the Black-Scholes-Merton option-pricing model which requires a number of assumptions, of which the most significant are the fair value of the underlying Common Stock, expected stock price volatility and the expected option term. Fair Value of the underline Common Stock in the three months ended March 31, 2018 was calculated based on last funding price and terms. Expected volatility was calculated based upon historical volatilities of similar entities in the related sector index. The expected option term represents the period that the Company's stock options are expected to be outstanding and is determined based on the simplified method until sufficient historical exercise data will support using expected life assumptions. The risk-free interest rate is based on the yield from U.S. treasury bonds with an equivalent term. The expected dividend yield assumption is based on AIT's historical experience and expectation of no future dividend payouts. The Company has historically not paid cash dividends and has no foreseeable plans to pay cash dividends in the future.

The fair value for options granted in 2017 and 2016 to employees and directors of the Company is estimated at the date of grant using a Black-Scholes-Merton Options pricing model with the following weighted average assumptions:

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)'

	For the Three months Ended	For the twelve months Ended	
	March 31 2018	December 31 2017	December 31 2016
Dividend yield (1)	0%	0%	0%
Expected volatility (2)	84.54%	75%	75.2%
Risk-free interest (3)	2.38%-2.63%	2.1%-3.5%	2.1%-3.6%
Expected life (years) (4)	3.5-5.75	5.5-6	5.5-6.25

(1) Dividend yield - was based on the fact that the Company has not paid dividends to its stockholders in the past and does not expect to pay dividends to its stockholders in the future.

(2) Expected volatility - was calculated based on actual historical stock price movements of comparable companies in the same industry over a term that is equivalent to the expected term of the option.

(3) Risk-free interest rate - based interest rates on three to five years US treasury bond rates

(4) Expected life - the expected life was based on the expiration date of the warrants.

The Company measures the fair value of restricted share and restricted share unit based on the market value of the underlying shares at the date of grant.

The Company applies ASC 505-50, "Equity-Based Payments to Non-Employees" ("ASC 505") with respect to options and warrants issued to non-employees which requires the use of option valuation models to measure the fair value of the options and warrants at the measurement date.

r. Impact of recently issued accounting standards:

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, Leases (Topic 842) (ASU 2016-02), which generally requires companies to recognize operating and financing lease liabilities and corresponding right-of-use assets on the balance sheet. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those annual periods. Early adoption is permitted.

The Company is still evaluating the effect that this guidance will have on its consolidated financial statements and related disclosures.

In November 2016, the FASB issued Accounting Standards Update No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (ASU 2016-18), which requires companies to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted the standard commencing January 1, 2018. The Impact of the adoption was immaterial to the financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of certain Cash Receipts and Cash Payments (ASU 2016-15). The new authoritative guidance addressing eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain transactions are presented and classified in the statement of cash flows. The guidance will generally be applied retrospectively and is effective for financial statements issued for annual reporting periods beginning after December 15, 2018. The Company adopted the standard commencing January 1, 2018. The Company is still evaluating the effect that this guidance will have on its consolidated financial statements and related disclosures.

NOTE 3:- OTHER ACCOUNTS RECEIVABLE

	March 31, 2018	December 31, 2017	December 31, 2016
Prepaid expenses	$ 7	$ 46	$ 73
Government authorities	52	63	5
	$ 59	$ 109	$ 78

NOTE 4:- PROPERTY AND EQUIPMENT, NET

	March 31, 2018	December 31, 2017	December 31, 2016
Cost:			
Computers and electronic equipment	$ 33	$ 32	$ 28
Clinical and medical equipment	359	359	119
	392	391	147
Accumulated depreciation:			
Computers and electronic equipment	29	27	20
Clinical and medical equipment	110	97	66
	139	124	86
Depreciated cost	$ 253	$ 267	$ 61

Depreciation expenses for the three month period ended March 31, 2018 and for the years ended December 31, 2017 and 2016 were $15, $38 and $25 respectively.

NOTE 5:- OTHER ACCOUNTS PAYABLE

	March 31, 2018	December 31, 2017	December 31, 2016
Accrued expenses	$ 999	$ 450	$ 851
Employees and payroll accruals	104	90	88
Income tax	154	154	154
	$ 1,257	$ 694	$ 1,093

NOTE 6:- BANK LOAN

On September 15, 2016, AIT entered into a loan agreement with a commercial bank for a loan ("Loan") in an aggregate principal amount of $52 with imputed interest at an average rate of 5.1% with monthly payments over 12 installments. On May 21, 2017 the remaining balance of the Loan including the accrued interest was paid by the Company.

NOTE 7:- CONVERTIBLE NOTES

Starting in December 2013 and continuing until December 31, 2016, AIT entered into Convertible Notes Agreements ("Notes Agreement") and received an aggregate amount of $3,342 in proceeds from these convertible notes - ("Convertible Notes"), of which $892 was received from related parties as of December 31, 2016.

With respect to the Convertible Notes, AIT applied ASC 470, "Debt with Conversion and Other Options", pursuant to which AIT recognized and measured the Beneficial Conversion Feature ("BCF") in the Convertible Notes at the commitment date by allocating a portion of the proceeds equal to the intrinsic value of the feature to additional paid-in-capital. The intrinsic value of the feature is calculated on the commitment date using the effective conversion price. The discount resulting from the BCF is amortized over the life of the Convertible Notes and is contained in financial expenses (income), net in the Company's statements of consolidated comprehensive loss unless mandatorily converted earlier.

In September and October 2016, the Convertible Notes' terms were modified such that subject to and effective immediately upon the consummation of a transaction whereby AIT's ordinary shares were to become quoted on the OTC Market, the holders of the Convertible Notes had the right to convert the Convertible Notes and the outstanding accrued interest into ordinary shares of AIT. Following the consummation of the Merger, the holders of the Convertible Notes elected to change the conversion terms such that the Convertible Notes and the outstanding accrued interest will convert into 1,397,068 ordinary shares of AIT. Following the conversion, the holders will no longer have any rights or claims under the Notes Agreement. AIT accounted for this amendment as modification according to ASC 470-50 "Modifications and Extinguishments".

On January 13, 2017, upon the Closing of the Merger (see Note 1b) all Convertible Notes and the accrued interest were converted into 1,397,068 shares of Common Stock of the Company (including 6,473 shares that were issued as a finders' fee), and the remaining BCF and capitalized debts issuance costs were amortized immediately into statement of comprehensive loss as finance expenses (see also Note 13).

The Convertible Notes balance consists of the following:

	December 31, 2017	2016
Opening balance	$ 2,895	$ 1,552
Receipt of Convertible Notes	-	184
BCF in respect of Convertible Notes	-	(177)
Amortization of BCF	1,031	1,034
Amortization of debts issuance costs	15	16
Imputed interest	14	286
Conversion of Convertible Notes into Common Stock	(3,955)	-

	$ -	$ 2,895

NOTE 8:- FAIR VALUE MEASUREMENT

ASC 820, "Fair Value Measurements and Disclosures" ("ASC 820"), defines fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required to be recorded at fair value, the Company considers the principal or most advantageous market in which it would transact and considers assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions and risk of nonperformance.

ASC 820 also establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. A financial instrument's categorization within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. ASC 820 establishes three levels of inputs that may be used to measure fair value.

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.

The Company accounted for the warrants issued to investors which included, among others, down round protective provisions as a non-current liability according to provisions of ASC 815. The Company will measure the warrants at fair value in each reporting period until they are exercised or expired, with changes in the fair value being recognized in the Company's statement of comprehensive loss as financial income or expense, as appropriate. Under ASC 820, the warrants are classified as Level 3 (See also Note 2n).

Under ASC 820, the marketable securities invested in mutual funds are classified as Level 1 (See also Note 2f).

The Company used the following assumptions to estimate the fair value of the warrants:

	March 31, 2018
Risk-free interest rate (1)	2.49%-2.51%
Expected volatility (2)	84.54%
Expected life (in years) (3)	3.79-4
Dividend yield (4)	0%
Fair value per warrant	$ 1.55-1.59

NOTE 8:- FAIR VALUE MEASUREMENT (Cont.)

(5) Risk-free interest rate - based on yield rates of non-index linked U.S. Federal Reserve treasury bonds.

(6) Expected volatility - was calculated based on actual historical stock price movements of comparable companies in the same industry over a term that is equivalent to the expected term of the option.

(7) Expected life - the expected life was based on the expiration date of the warrants.

(8) Dividend yield - was based on the fact that the Company has not paid dividends to its stockholders in the past and does not expect to pay dividends to its stockholders in the future.

The changes in Level 3 liabilities associated with the warrants that were issued to investors are measured at fair value on a recurring basis. The following tabular presentation reflects the components of the liability associated with such warrants as of March 31, 2018:

	Number of warrants	Fair value of liability related to warrants
Balance at January 1, 2018	3,635,270	$ 9,172
Revaluation of warrants to purchase Common Stock	-	(3,494)
Balance at March 31, 2018	3,635,270	$ 5,678

As of March 31, 2018, none of the warrants granted have been exercised.

The fair value of the warrants was estimated using the Monte-Carlo method. The significant unobservable inputs are the expected term and volatility.

Upon close of the February 2018 offering, the exercise price of all Existing Warrants detailed above was adjusted pursuant to the terms and conditions of those warrants, resulting in the adjustment of the exercise price to $4.25 from $6.9. Such adjustment is included in the revaluation of the warrants and described above.

In addition, the Company's financial instruments also include cash and cash equivalents, restricted cash, marketable securities, other accounts receivable, trade payables and other accounts payables. As of March 31, 2018, the fair value of these financial instruments was not materially different from their carrying values due to the short-term maturities of such instruments.

NOTE 9:- TAXES ON INCOME

a. Tax rates applicable to AIT:

1. Taxable income of AIT is subject to a corporate tax rate as follow: 2018 – 23%, 2017 - 24% and 2016 - 25%.

2. In 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.

b. AITT and Inc.:

AITT and Inc. are subject to U.S. income taxes. The tax rates are compounded from a progressive federal tax of 21% in addition to a state and local taxes.

The U.S. Tax Cuts and Jobs Act (Tax Act) was enacted on December 22, 2017 and introduces significant changes to U.S. income tax law. Effective in 2018, the Tax Act reduces the U.S. statutory tax rate from 35% to 21% and creates new taxes on certain foreign-sourced earnings and certain related-party payments, which are referred to as the global intangible low-taxed income tax and the base erosion tax, respectively.

As the Company collects and prepares necessary data and interpret the Tax Act and any additional guidance issued by the U.S. Treasury Department, the IRS, and other standard-setting bodies, the Company may make adjustments to provisional amounts. Those adjustments may impact the Company's provision for income taxes and effective tax rate in the period in which the adjustments are made. The accounting for the tax effects of the Tax Act will be completed in 2018.

NOTE 9:- TAXES ON INCOME (Cont.)

c. Net operating losses carry forward:

AIT has accumulated losses for tax purposes as of March 31, 2018 in the amount of approximately $10,141 which may be carried forward and offset against taxable income in the future for an indefinite period.

As of March 31, 2018, AITT has net operating loss carryforwards for federal and state income tax purposes of approximately $2,095 of $1,068 which expire in the year 2037. Utilization of the U.S. net operating losses may be subject to substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses before utilization.

d. Deferred income taxes:

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows:

	March 31, 2018	December 31, 2017	2016
Deferred tax assets:			
Operating loss carry forward	$ 2,909	$ 2,584	$ 1,381
Reserves and allowances	10	7	5
Research and development	762	667	153
Net deferred tax asset before valuation allowance	3,681	3,258	1,539
Valuation allowance	(3,681)	(3,258)	(1,539)
Net deferred tax asset	$ -	$ -	$ -

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that all or some portion of the deferred tax assets will not be realized. The ultimate realization of the deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences are deductible and net operating losses are utilized. Based on consideration of these factors, the Company recorded a full valuation allowance at March 31, 2018, December 31, 2017 and 2016

e. Loss (income) before taxes on income consists of the following:

	For the three months ended March 31, 2018	Year ended December 31, 2017	2016
Foreign	$ 1,887	$ 10,574	$ 3,727
Domestic	(2,935)	7,470	(34)
	$ (1,048)	$ 18,044	$ 3,693

NOTE 9:- TAXES ON INCOME (Cont.)

f. The main reconciling item between the statutory tax rate of the Company and the effective tax rate is the recognition of valuation allowances in respect to deferred taxes relating to accumulated net operating losses carried forward due to the uncertainty of the realization of such deferred taxes.

g. Accounting for uncertainty in income taxes:

A reconciliation of the beginning and ending amount of unrecognized tax benefits related to uncertain tax positions is as follows:

	For the three months ended March 31,	Year ended December 31,	
	2018	2017	2016
Balance at beginning of year	$ 154	$ 154	$ 127
Additions for current year's tax position	-	-	27
Balance at the end of year	$ 154	$ 154	$ 154

The Company does not expect a reversal of unrecognized tax benefits in the next 12 months.

AITT and Inc. file income tax returns in the U.S, AIT file income tax returns in Israel. As of March 31, 2018, the tax returns of AIT are open to examination by the tax authorities from the year of 2013 through 2017 and the tax return of Inc. are open to examination by the tax authorities from inception through 2017.

NOTE 10:- CONTINGENT LIABILITIES AND COMMITMENTS

a. On October 22, 2013, AIT entered into a patent license agreement with a third party, pursuant to which AIT agreed to pay to the third party a non-refundable upfront fee of $150 and is obligated to pay 5% royalties of any licensed product revenues, but at least $50 per annum during the royalty period as defined in the agreement. As of March 31, 2018, AIT did not record any revenues and therefore no royalties were paid or accrued.

b. In August 2015, AIT entered into an Option Agreement (the "Option Agreement") with a third party whereby AIT acquired on September 7, 2016 for $25 the Option to purchase certain intellectual property assets and rights (the "Option"). According to the Option Agreement, the Option was originally exercisable for a period of six months, starting August 2015 (which was extended in 2016 for a period that ended January 2017). AIT exercised the Option in January 2017 and paid an exercise price of $500. Additionally, AIT is required to make certain one-time development and sales milestone payments to the third party, starting from the date on which AIT receives regulatory approval for the commercial sale of its first product candidate.

In addition, immediately prior to the Merger, on January 13, 2017, AIT issued to a third party a warrant (the "Third Party Warrant") to purchase up to 178,570 ordinary shares of AIT at an exercise price of $4.80 for each share. This warrant was exchanged for a warrant to acquire shares of the Common Stock of the Company upon consummation of the Merger. The warrant is exercisable, in whole or in part, until the seventh anniversary as of the date of grant of the warrant. During the year ended December 31, 2017, AIT recorded research and development expenses of $480 in respect to such warrant (see also Note 11j2).

NOTE 10:- CONTINGENT LIABILITIES AND COMMITMENTS (Cont.)

c. On January 31, 2018 the Company entered into an agreement ("Agreement") with NitricGen, Inc. ("NitricGen") to acquire a global, exclusive, transferable license and associated assets including intellectual property, know-how, trade secrets and confidential information from NitricGen related to NO delivery systems ("Delivery System").

According to the Agreement, the Company agreed to pay NitricGen a total of $2,000 in several future payments depending on achieving certain milestones, as defined in the Agreement, and to pay NitricGen royalties on sales of the Delivery System. In addition, the Company agreed to grant NitricGen warrants to purchase 100,000 shares of AITT common stock at an exercise price of $6.90 per share.

On March 1, 2018 the Company paid NitricGen $200 for achieving the first millstone as defined in the Agreement. Which was recorded as research and development expenses in the three months period ended March 31, 2018

d. As of March 31, 2018 AIT Ltd is engaged in an operating lease agreement for its office facility in Israel. Future minimum non-cancelable rental payments under the operating lease are $42 for the year ending March 31, 2019.

e. On March 16, 2018, Empery Asset Master, Ltd., Empery Tax Efficient, LP and Empery Tax Efficient II, LP, (collectively, "Empery"), filed a complaint against the Company.

Given the early stage of the litigation, it is not possible to determine or assess the probability of any particular outcome and the Company didn't accrue any amount (For further details refer to Note 2m).

f. On March 16, 2018, the Company entered into an office lease agreement, which expires on April 2021. Future minimum commitments under the new lease as of March 31, 2018, are as follows:

Year ended March 31,	Operating leases
2019	21
2020	21
2021	21
2022	1
	$ 64

NOTE 11:- STOCKHOLDERS' EQUITY (DEFICIENCY)

a. Share capital:

The Common Stock confers upon the holders the right to receive notice to participate and vote in general meetings of the Company, and the right to receive dividends, if declared, and to participate in the distribution of the surplus assets and funds of the Company in the event of liquidation, dissolution or winding up of the Company.

b. Effective December 29, 2016, the Company's Board of Directors and the stockholders approved a reverse stock split of the outstanding Common Stock, at the ratio of 1 for 100.

For accounting purposes, all Common Stock, warrants to purchase Common Stock and options to purchase Common Stock and earnings (loss) amounts have been adjusted to give retroactive effect to this reverse stock split for all periods presented in these consolidated financial statements. Any fractional shares that resulted from the reverse share split have been rounded up to the nearest whole share.

c. Issuance of Common Stock:

1. In December 2016, AIT entered into a Securities Purchase and Registration Rights Agreement (the "SPA") pursuant to which AIT agreed to issue and sell purchased units in the minimum aggregate amount of $10,000 and up to a maximum aggregate amount of $25,000.

   Each purchased unit (each a "Unit") comprised one ordinary share, NIS 0.01 par value per share, and one five-year warrant to purchase one ordinary share at an exercise price of $6.90 per share but eligible to be exercised on a cashless basis in the sole discretion of the holder.

NOTE 11:- STOCKHOLDERS' EQUITY (DEFICIENCY) (Cont.)

Each Unit sold at a price of $6.00. The exercise price and the number of warrants are subject to non-standard anti-dilution protections clauses and therefore are accounted as non-current liability in the consolidated financial statements.

Immediately prior to the Closing of the Merger, AIT received gross proceeds of approximately $10,210 ("Total Purchase Price") from new and existing investors ("Investors") (including $1,170 from certain principal shareholders, a member of its Board of Directors and its chief executive officer) under the SPA by issuance of an aggregate 1,701,616 Units. Direct and incremental costs related to the SPA amounted to $1,049. Such costs have been allocated between shares of Common Stock and the issued Warrants.

Under the SPA, AIT was obligated to file, as soon as reasonably practicable, but in no event later than the 45th day following January 13, 2017, which was February 27, 2017 (the "Filing Deadline"), with the SEC, a registration statement on Form S-1, (the "Registration Statement"), providing for the resale from time to time by the Investors of any and all registrable securities issued pursuant to the SPA. The registration statement was filed on February 27, 2017.

In addition, AIT agreed to use its reasonable best efforts to cause the Registration Statement to be declared effective by the SEC as soon as practicable following such filing, but in no event later than the earlier of the 90th day following the date on which the Registration Statement was initially filed with the SEC and the fifth day following the date on which AIT is notified by the SEC that the Registration Statement will not be reviewed or will not be subject to further review (such earlier date, the "Effectiveness Deadline"). The Registration Statement was declared effective by the SEC on May 26, 2017.

2. In addition, based on the terms of the SPA, because the issuance of Units by AIT, together with issuances of Units by the Company following the Merger, failed to raise aggregate gross proceeds of at least $15,000, the Company adjusted the number of warrants and issued an additional 1,701,616 liability warrants to the Investors. Consequently, the Company recorded in 2017 additional finance expenses amounting to $2,434.

3. On January 13, 2017, the principal and accrued interest on all of AIT's outstanding Convertible Notes, amounting to $3,955 were converted into 1,390,595 shares of Common Stock. In addition, the Company issued 6,473 shares of Common Stocks as a finders' fee upon the conversion of the Convertible Notes. Consequently, the Company recorded in 2017 finance expenses amounting to $18.

4. In March 2017, the Company raised additional gross funds amounting to approximately $663 from new investors by issuance of an aggregate of 110,494 purchased units, each of which comprised one share of Common Stock and a warrant to acquire two shares of Common Stock at an exercise price of $6.9 per share. Direct and incremental costs related to such investment round amounted to $199. In addition, the Company incurred additional costs amounted to $15 with respect to warrants that the Company is obligated to issue to the placement agent. These costs were allocated between the Common Stock and the issued Warrants.

5. On February 16, 2018, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with several purchasers (the "Purchasers").

   Pursuant to the Purchase Agreement, the Company agreed to sell to the Purchasers (the "Offering") warrants to purchase 4,599,604 shares of its common stock, par value $0.0001 per share (the "Common Stock") at a purchase price of $0.01 per underlying warrant share. The warrants are comprised of an aggregate of (i) 2,299,802 Tranche A Warrants (the "Tranche A Warrants") to purchase one share of Common Stock (the "Tranche A Warrant Shares") at an exercise price of $4.25 per Tranche A Warrant Share, exercisable within three days from the issue date of the Warrants and (ii) an equal number of Tranche B Warrants (the "Tranche B Warrants" and, together with the Tranche A Warrants, the "Warrants") to purchase one share of Common Stock at an exercise price of $4.25 per Tranche B Warrant Share, exercisable within three years from the issue date of the Warrants.

NOTE 11:- STOCKHOLDERS' EQUITY (DEFICIENCY) (Cont.)

The closing of the Offering occurred on February 16, 2018 (the "Closing") and was subject to the satisfaction of specified customary closing conditions. Immediately following the Closing, each Purchaser exercised the full amount of their Tranche A Warrants resulting in gross proceeds to the Company from the sale of the Warrants to the Investors, together with the exercise price of the Tranche A Warrants, of $9,820.

d. Treasury shares:

Following to Note 1b1, the Company acquired 90,000 (on a post-reverse stock split basis) shares of its Common Stock from the Company's prior sole officer and director, for $25.

e. Stock options granted to employees:

In September and December 2013, AIT authorized through its 2013 Incentive Option Plan (the "2013 Plan"), the grant of options and Restricted Share Units ("RSU's") to officers, directors, advisors, management and other key employees. The options granted have generally between 2 to 4 years vesting terms and expire 10 years after the grant date. Certain options will be accelerated upon fulfillment of certain conditions. The Company assumed the 2013 plan upon consummation of the Merger.

The total amount of Common stock reserved for issuance under the Share Plans is 466,676. As of March 31, 2018, 55,770 options were available for future grants.

A summary of the Company's options activity for employees and directors is as follows:

	For the Three months ended March 31, 2018		
	Number of options	Weighted average exercise price	Weighted average remaining contractual life
Options outstanding at beginning of period	292,891	$ 6.18	9
Granted	-	-	
Exercised	-	-	
Forfeited	(37,367)	5.46	
Options outstanding at end of period	255,524	4.32	8.96
Options exercisable at end of period	99,699	$ 4.37	8.95

As of March 31, 2018, the aggregated intrinsic value of outstanding and exercisable options was $0. The aggregate intrinsic value represents the total intrinsic value (the difference between the deemed fair value of the Common Stock on the last day of March 31, 2018 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on March 31, 2018. This amount is impacted by the changes in the fair market value of the Company's shares of Common Stock.

NOTE 11:- STOCKHOLDERS' EQUITY (DEFICIENCY) (Cont.)

f. Options granted to non-employees:

The Company has granted options to certain non-employees under the 2013 Plan and accounted for these options in accordance with ASC 505-50.

The outstanding options granted to non-employees are as follows:

Grant date	Number of options	Exercise price	Expiration date
September 8, 2013	17,081	$ 4.01	September 8, 2023
September 8, 2013	2,340	$ *)	September 8, 2023
December 29, 2013	3,511	$ 4.01	December 29, 2023
April 8, 2014	9,158	$ *)	April 8, 2024
July 24, 2014	1,246	$ 5.46	July 24, 2024
March 1, 2015	57,779	$ 5.46	March 1, 2025
October 20, 2015	12,456	$ *)	October 20, 2025
December 1, 2015	11,210	$ 5.46	December 1, 2025
November 8, 2016	9,601	$ *)	November 8, 2026
June 30, 2017	131,000	$ 4.25	June 30, 2027
	255,382		

*) Represents an amount lower than $1.

g. Stock-based compensation:

The stock-based compensation expense recognized in the consolidated financial statements for services received from employees, directors and non-employees is shown in the following table:

	For the Three months ended March 31,	Year ended December 31,	
	2018	2017	2016
Research and development expenses	$ 50	$ 138	$ 109
General and administrative expenses	97	3,767	134
	$ 147	$ 3,905	$ 243

On February 13, 2018, the Company's Board of Directors approved the issuance of warrants with an exercise price of $4.25. Along with the aforementioned issuance, the Board of Directors of the company decided that all stock option grants to employees or consultants made in the year 2017 would continue to be priced equivalently to that of said investors, as adjusted, to an exercise price of $4.25 per share.

The Company accounted for such benefit pursuant to ASC 718 as a modification. Accordingly, additional compensation of $59 was calculated as the fair value of the modified award in excess of the fair value of the original award measured immediately before its terms have been modified based on current circumstances and should be recognize as an expense over the remaining vesting period.

As of March 31, 2018, the total unrecognized estimated compensation cost related to non-vested stock options granted to employees, directors and non-employees is $157.

NOTE 11:- STOCKHOLDERS' EQUITY (DEFICIENCY) (Cont.)

h. Issuance of Restricted Stock Units ("RSUs"):

On August 31, 2015, AIT's Board of Directors approved a grant of 11,781 RSUs to one member of the Board of Directors with a vesting schedule of three years from September 3, 2015. As of December 31, 2017, 3,927 shares of Common Stock have been issued upon vesting of equivalent amount of RSUs. During the year of 2017, 7,854 RSUs were forfeited due to the board member's termination.

i. Issuance of Restricted Shares ("RSs"):

1. On January 13, 2017, the Company issued 492,624 RSs to one of the directors of the Company, of which 246,312 were to vest on the six-month anniversary of the grant date and the remaining vest on the 18-month anniversary of the grant date. During the second quarter of 2017, 246,312 RSs were cancelled. During the year ended 2017, the Company recorded general and administrative expenses of $1,961 in connection with the above grant, out of which $844 were recorded with respect to the RSs cancellation.

2. On June 24, 2016, AIT entered into an agreement with an individual to serve on AIT's Board of Directors pursuant to which AIT agreed to pay as compensation and benefits upon the consummation of a financing round in the United States (the "Financing Round") (i) an annual retainer of $40 to be paid in equal monthly installments; (ii) a one-time bonus of $150 within 30 days following completion of the Financing Round (the "One-Time Bonus") and (iii) RSs equal to 3% of all issued and outstanding fully diluted shares of AIT after the completion of the Financing Round (including any option to purchase additional shares or similar held by the purchasers in the Financing Round) with a 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 on the 6 month anniversary of the completion of a Financing Round and the remaining 33.33% of such shares on the 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 vest immediately.

   This agreement has a three-year term, subject to earlier termination as defined in the agreement.

   During the first quarter of 2017, the one-time bonus was paid and the Company issued 364,286 RSs. For the three month period ended March 31, 2018 and for the year ended December 31, 2017, the Company recorded expenses in the amount of $17 and $1,433 in respect of this grant, respectively.

j. Warrants:

1. On October 3, 2013 (the "Grant Date"), AIT granted warrants to a strategic adviser to purchase 85,474 ordinary shares of AIT with an exercise price of $8.19 (the "Third-Party Warrant"). Such warrant was fully vested on the Grant Date and eligible for exercise during a period of three years commencing as of the issuance of the warrant and ending on the third anniversary of the Grant Date (the "Exercise Period"). In addition, the warrant expires in the event of an initial public offering (an "IPO") or an acquisition of AIT unless already exercised.

   In January 2016, AIT's Board of Directors approved the extension of the Exercise Period by replacing the aforementioned original warrant with a new warrant exercisable until December 31, 2017 or until the fifth anniversary of the Grant Date in the event an IPO were to occur prior to December 31, 2016. As of December 31, 2017, this warrant was expired.

NOTE 11:- STOCKHOLDERS' EQUITY (DEFICIENCY) (Cont.)

AIT accounted for the extension of the Exercise Period pursuant to ASC 718 as a modification. Accordingly, additional compensation of $94 was calculated as the fair value of the modified award in excess of the fair value of the original award measured immediately before its terms have been modified based on current circumstances and recorded incremental fair value as an immediate compensation expense in the general and administrative expenses in the statements of comprehensive loss in 2016.

2. In respect to the issuance of warrants as further described in note 10 (b). as of January 13, 2017, AIT accounted for the Third-Party Warrant pursuant to ASC 505-50 and measured the warrants at fair value according to the Black-Scholes model for a fair value of approximately $480. Such amount was fully recognized during the year ended December 31, 2017 based on the vesting schedule of the warrant. The value of the Third-Party Warrant was based on the following assumptions: share price of $3.98, exercise price of $4.80, expected dividend rate of 0%, expected standard deviation of 75.23%, risk-free interest rates of 2.20% and expected life until exercise of 7 years.

3. On February 20, 2017, the Company's Board of Directors approved the extension of the exercise period of options granted to one of the Company's officers by an additional nine months from three months to one year from the termination date. The Company accounted for such extension pursuant to ASC 718 as a modification. Accordingly, additional compensation of $13 was calculated as the fair value of the modified award in excess of the fair value of the original award measured immediately before its terms have been modified based on current circumstances and recorded incremental fair value as an immediate compensation expense.

NOTE 12:- RELATED PARTIES BALANCES AND TRANSACTIONS

Balances with related parties:

	March 31,	December 31,	
	2018	2017	2016
Convertible Notes (c)	$ -	$ -	$ 892
Other accounts payable (b)	-	-	65
Loans from related parties (a)	-	-	379
Additional paid in capital (d)	17	3,393	304

Related parties' expenses:

	March 31,	Year ended December 31,	
	2018	2017	2016
Amounts charged to:			
General and administrative expenses (d)	17	3,543	220
Research and Development expenses (b)	-	-	29
Financial expense (a), (c)	$ -	$ 13	$ 82

NOTE 12:- RELATED PARTIES BALANCES AND TRANSACTIONS (Cont.)

a. On February 10, 2014, AIT signed a loan agreement with one of its stockholders for a total amount of $22. The loan bears an interest of 4% per annum.

In 2016 and 2017, AIT entered into loan agreement with existing stockholders pursuant to which AIT received the amounts of $340 and $57 (the "Stockholder Loans"), respectively, which bears an interest rate of 16% per annum and shall be fully repaid in 12 months from the date each was funded. In the event of full payment of the Stockholder Loans at any time within 90 days of the funding, a minimum interest rate of 4% of the Stockholder Loans shall be paid along with the principal.

For the years ended December 31, 2017 and 2016, AIT recorded expenses regarding all aforesaid loans in the amount of $13 and $10, respectively.

On January 13, 2017, upon the closing of the Merger (see also Note 1b), the holdings of certain of the above stockholders were diluted, and they are no longer considered related parties as of December 31, 2017.

b. In previous years, the Company entered into consultancy agreements with certain stockholders.

c. Commencing December 2013, AIT issued the Convertible Notes for which aggregate consideration of $892 was received from related parties (see also Note 7). The Convertible Notes bore an interest rate of 8% per annum compounded annually. Upon the closing of the Merger (see also Note 1b), all of the outstanding Convertible Notes were converted into 1,397,068 shares of Common Stock. For the years ended December 31, 2017 and 2016, the Company recorded finance expenses in the amounts of $0 and $72, respectively.

d. In November 2016, the Company's former CEO waived all of his requirements for certain debts of AIT owed to him for a total amount of $304.

In addition, as described in note 11(i), the Company issued restricted shares as well as paid one-time bonus to two of its directors upon the reverse merger transaction.

NOTE 13:- FINANCIAL EXPENSES, NET

	For the Three months ended March 31,	Year ended December 31,	
	2018	2017	2016
Financial expenses, net:			
Imputed interest in respect to Convertible Notes	-	15	286
Amortization of debt issuance costs	-	14	16
Amortization of BCF in respect to Convertible Notes	-	1,031	1,034
Issuance of Common Stock to finder fee upon the conversion of Convertible Notes	-	18	-
Adjustment of liability warrants (see also Note 11c2)	-	2,434	-
Revaluation of warrants to purchase Common Stock	(3,494)	2,978	-
Issuance cost related to warrants to investors and placement agent	-	457	-
Other financial expenses, net	6	30	24
Total financial (income) expense	$ (3,488)	$ 6,977	$ 1,360

NOTE 14:- BASIC AND DILUTED NET EARNINGS (LOSS) PER SHARE

The following table sets forth the computation of the Company's basic and diluted net earnings (loss) per share of Common stock:

	Three months ended March 31,	Year ended December 31	
	2018	2017	2016
Net comprehensive income (loss)	$ 1,048	$ (18,044)	$ (3,720)
Convertible Preferred A Shares accumulated dividend	-	-	(177)
Net income (loss) attributable to Ordinary shares as reported	$ 1,048	$ (18,044)	$ (3,897)
Net basic earnings (loss) per share of common stock	0.15	(3.01)	(2.69)
Net diluted earnings (loss) per share of common stock	$ 0.14	$ (3.01)	$ (2.69)
Weighted average number of shares used in computing net basic earnings (loss) per share of common stock	7,196,048	6,002,052	1,448,363
Weighted average number of shares used in computing net diluted earnings (loss) per share of common stock	7,250,194	6,002,052	1,448,363

In computing dilutive loss per share for the years ended December 31, 2017 and 2016, all outstanding convertible notes, options and warrants have been excluded from the calculation of the diluted net loss per share since their effect was anti-dilutive. For the three month period ended March 31, 2018 all outstanding convertible notes, options and warrants have been excluded from the calculation of the diluted net loss per share since their effect was anti-dilutive, excluding 54,146 stock option which are dilutive and included in the weighted average number of shares used in computing net diluted earnings loss per share of common stock.

NOTE 15:- TRANSITION PERIOD COMPARATIVE DATA

1. Statements of consolidated comprehensive loss (income)

	For the Three months Ended March 31,	
	2018	(Unaudited) 2017
Operating expenses:		
Research and development expenses	$ 1,637	$ 1,439
General and administrative expenses	803	2,121
Costs related to aborted IPO	-	-
Operating loss	2,440	3,560
Financial (income) expense, net	(3,488)	2,717
Loss (Income) before taxes on income	(1,048)	6,277
Taxes on income	-	6
Net (income) loss	$ (1,048)	$ 6,283
Net unrealized loss (gain) on available-for-sale investments	5	-
Total comprehensive (income) loss	$ (1,043)	$ 6,283
Net basic earnings (loss) per share of common stock	0.15	(1.12)
Net diluted earnings (loss) per share of common stock	0.14	(1.12)
Weighted average number of shares used in computing net basic earnings (loss) per share of common stock	7,196,048	5,617,762
Weighted average number of shares used in computing net diluted earnings (loss) per share of common stock	7,250,194	5,617,762

NOTE 15:- TRANSITION PERIOD COMPARATIVE DATA (Cont.)

2. Statements of consolidated cash flow

	For the three months ended March 31,	
	2018	(Unaudited) 2017
Cash flows from operating activities		
Net income (loss)	$ 1,048	$ (6,283)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	15	6
Stock-based compensation related to warrants, RSs and RSUs	147	1,877
Issuance of Common Stock to finder upon the conversion of Convertible Notes	-	18
Amortization of beneficial conversion feature and debt issuance costs related to Convertible Notes	-	1,046
Issuance cost related to warrants liability	-	457
Adjustment of liability warrants	-	2,434
Revaluation of warrants to purchase Common Stock	(3,494)	(1,308)
Imputed interest on Convertible Notes, loans from related parties and others	-	30
Change in:		
Other accounts receivables and prepaid expenses	50	(99)
Trade payables	173	20
Other accounts payable	313	410
Net cash used in operating activities	(1,748)	(2,212)
Cash flows from investing activities		
Investment in marketable securities	(9,403)	-
Proceeds from redemption of marketable securities	1,700	-
Purchase of property and equipment	(1)	(25)
Purchase price that has been paid upon the reverse merger	-	(295)
Net cash (used in) provided by investing activities	(7,704)	(320)
Cash flows from financing activities		
Proceeds from issuance of units consisting of Common Stock and warrants, net of issuance costs	8,984	9,889
Proceeds from loan from related parties and others	-	57
Maturity of loan and interest from related parties and others	-	(241)
Repayment of bank loan	-	(14)
Treasury shares	-	(25)
Net cash provided by financing activities	8,984	9,666
Increase (decrease) in cash, cash equivalents and restricted cash	(468)	7,134
Cash, cash equivalents and restricted cash at beginning of year	1,207	7
Cash, cash equivalents and restricted cash at end of year	$ 739	$ 7,141
Supplemental disclosure of non-cash financing activities:		
Conversion of Convertible Notes into Common Stock	$ -	$ 3,955
Issuance costs related to warrants	$ 250	$ -

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement Form S-1 dated March 28, 2018 of AIT Therapeutics Inc. and in the related Prospectus of our report dated March 28, 2018, with respect to the consolidated financial statements of AIT Therapeutics Inc. included in this Transition Report (Form 10-KT).

Tel Aviv, Israel
June 15, 2018

Kost Forer Gabbay and Kasierer
KOST FORER GABBAY & KASIERER
A Member of EY Global

Exhibit 31.1

CERTIFICATIONS

I, Steven A. Lisi, certify that:

1. I have reviewed this Transition Report on Form 10-K of AIT Therapeutics, 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 15, 2018

/s/ Steven A. Lisi

Steven A. Lisi

Chairman and Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Stephen DiPalma, certify that:

1. I have reviewed this Transition Report on Form 10-K of AIT Therapeutics, 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 15, 2018

/s/ Stephen DiPalma

Stephen DiPalma
Chief Financial 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 AIT Therapeutics, 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 Transition Report on Form 10-K of the Company for the three month transition period ended March 31, 2018 (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 15, 2018

/s/ Steven A. Lisi
Steven A. Lisi
Chairman and Chief Executive 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, Stephen DiPalma, Chief Financial Officer of AIT Therapeutics, 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 Transition Report on Form 10-K of the Company for the three month transition period ended March 31, 2018 (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 15, 2018

/s/ Stephen DiPalma
Stephen DiPalma
Chief Financial Officer