UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2019

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

For the transition period from _____ to _____

Commission file number 001-38803

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

Nevada	**82-1553794**
(State or jurisdiction of Incorporation or organization)	I.R.S Employer Identification No.
1 Rockefeller Plaza, Suite 1039, New York, New York	**10020**
(Address of principal executive offices)	(Zip code)

(646) 756-2997
(Registrant's telephone number, including area code)

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001 per share	**HOTH**	**The Nasdaq Capital Market LLC**

Securities registered pursuant to Section 12(g) of the Act: None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition of "large accelerated filer," "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 ☒ Smaller Reporting Company ☒ Emerging Growth Company ☒

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

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act) Yes ☐ No ☒

The aggregate market value of the voting stock and non-voting common equity held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter ended June 30, 2019 was $36,213,771 based upon the closing price of the registrant's common stock of $5.81 on The Nasdaq Capital Market as of that date.

Number of shares of common stock outstanding as of February 28, 2020 was 10,118,732.

Documents Incorporated by Reference: None.

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CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). Any statements in this Annual Report on Form 10-K about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. These statements are often, but not always, made through the use of words or phrases such as "believe," "will," "expect," "anticipate," "estimate," "intend," "plan" and "would." For example, statements concerning financial condition, possible or assumed future results of operations, growth opportunities, industry ranking, plans and objectives of management, markets for our common stock and future management and organizational structure are all forward-looking statements. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, levels of activity, performance or achievements expressed or implied by any forward-looking statement.

Any forward-looking statements are qualified in their entirety by reference to the risk factors discussed throughout this Annual Report on Form 10-K. Some of the risks, uncertainties and assumptions that could cause actual results to differ materially from estimates or projections contained in the forward-looking statements include, but are not limited to:

- our business strategies;
- the timing of regulatory submissions;
- our ability to obtain and maintain regulatory approval of our existing product candidates and any other product candidates we may develop, and the labeling under any approval we may obtain;
- risks relating to the timing and costs of clinical trials, the timing and costs of other expenses;
- risks related to market acceptance of products;
- intellectual property risks;
- risks associated with our reliance on third party organizations;
- our competitive position;
- our industry environment;
- our anticipated financial and operating results, including anticipated sources of revenues;
- assumptions regarding the size of the available market, benefits of our products, product pricing and timing of product launches;
- management's expectation with respect to future acquisitions;
- statements regarding our goals, intensions, plans and expectations, including the introduction of new products and markets; and
- our cash needs and financing plans.

The foregoing list sets forth some, but not all, of the factors that could affect our ability to achieve results described in any forward-looking statements. You should read this Annual Report on Form 10-K and the documents that we reference herein and have filed as exhibits to the Annual Report on Form 10-K, completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this Annual Report on Form 10-K is accurate as of the date hereof. Because the risk factors referred to on page 15 of Annual Report on Form 10-K, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and except as required by law, we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of the information presented in this Annual Report on Form 10-K, and particularly our forward-looking statements, by these cautionary statements.

PART I

Throughout this Annual Report on Form 10-K, the "Company," "Hoth," "we," "us," and "our" refers to Hoth Therapeutics, Inc. and its subsidiaries.

ITEM 1. BUSINESS

Overview

We are a clinical-stage biopharmaceutical company incorporated in May 2017 focused on developing new generation therapies for dermatological disorders. We believe that our pipeline has the potential to improve the quality of life for patients suffering from indications including atopic dermatitis (also known as eczema), chronic wounds, psoriasis, asthma and acne.

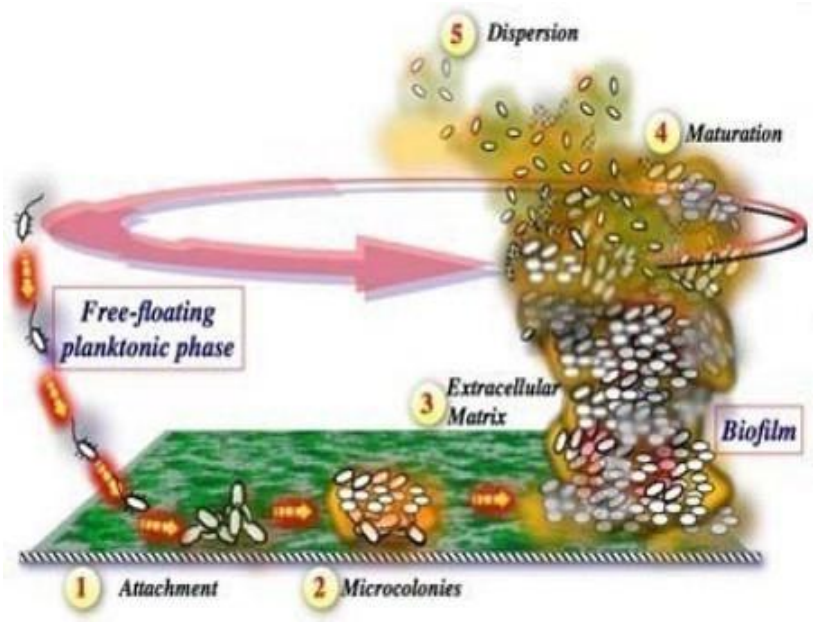
Our primary asset is a sublicense agreement with Chelexa Biosciences, Inc. ("Chelexa") pursuant to which Chelexa has granted us an exclusive sublicense to make, use, have made, import, offer for sale, and sell products based upon or involving the use of (i) topical compositions comprising a zinc chelator and gentamicin and (ii) zinc chelators to inhibit biofilm formation (the "BioLexa Platform" or "BioLexa"), which rights were originally granted to Chelexa pursuant to an exclusive license agreement with the University of Cincinnati. In addition, Chelexa granted us the right to issue exclusive and nonexclusive sublicenses (with the right to further sublicense to third parties) to make, use, have made, import, offer for sale, and sell products based upon the BioLexa Platform.

The license enables us to develop the platform for any indications in humans. Our initial focus will be on the treatment of eczema through the application of a topical cream. Although our initial focus will be on the treatment of eczema, we intend to develop a second topical cream which, upon application, is intended to reduce post-procedure infections, accelerate healing and improve clinical outcomes for patients undergoing aesthetic dermatology procedures. In addition, we conducted an initial pilot study on the efficacy of BioLexa to accelerate diabetic wound healing and intend to conduct additional studies with respect to the regenerative effects of the BioLexa Platform in the context of chronic diabetic ulcers, with and without substantial bacterial burden. The BioLexa Platform combines a U.S. Food and Drug Administration ("FDA") approved zinc chelator with one or more approved antibiotics in a topical dosage form to address unchecked eczema flare-ups by preventing the formation of infectious biofilms and the resulting clogging of sweat ducts which trigger symptoms. To our knowledge, it is the first product candidate intended to prevent the symptom triggering flare-ups rather than simply treating symptoms when they occur.

We intend to initially use the BioLexa Platform to develop two different topical cream products: (i) a product to treat eczema and (ii) a product that reduces post-procedure infections, accelerates healing and improves clinical outcomes for patients undergoing aesthetic dermatology procedures.

BioLexa Biofilm Platform

The BioLexa Platform is a proprietary, patented, drug compound platform for the treatment of eczema. It combines an FDA-approved zinc chelator with one or more approved antibiotics in a topical dosage form to address unchecked eczema flare-ups by preventing the formation of infectious biofilms and the resulting clogging of sweat ducts.



BIOFILMS IN INFECTIONS, DR TV RAO, MD https://www.slideshare.net/doctorrao/biofilms-2172226

The technology is based on scientific research into the pathogenesis of bacterial biofilm formation conducted by Andrew B. Herr, PhD at the University of Cincinnati. Dr. Herr's work indicated that *staph*-biofilm formation requires the presence of zinc in the cellular environment. If the zinc is removed, the biofilms' formation is inhibited, rendering the bacteria susceptible to immune defenses and antibiotic therapy.

Dr. Herr conducted multiple in-vitro experiments, or experiments conducted in a controlled environment outside of a living organism, in his laboratory demonstrating that chelation of zinc can prevent *staph* bacteria from forming colonies which in turn enables the creation of staph-biofilm. Prevention of the formation of colonies leaves the bacteria in their planktonic, or single cell state and susceptible to host immune defenses, as well as antibiotic therapy.

Dr. Herr's in-vitro work demonstrating that zinc is an enabler for *staph*-biofilm formation led to the design and implementation of a series of in-vivo experiments, or experiments conducted using living organisms, specially, pigs, which experiments were conducted at the University of Miami and intended to demonstrate that the combination of zinc removal, or chelation, and broad spectrum antibiotic therapy was far more effective than either approach on its own.

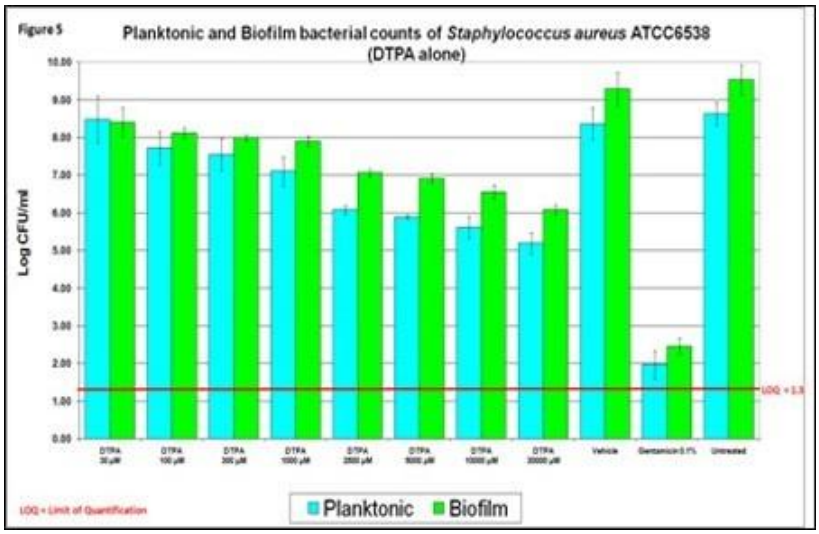
The *in-vivo* porcine deep partial thickness wound study was undertaken to determine the effects of an antimicrobial agent on the proliferation of 10^6 *Staphylococcus aureus* (MRSA USA 300).

Swine were chosen for the *in-vivo* study due to the morphological and biochemical similarity between porcine and human skin. Two young female white Yorkshire/landrace specific pathogen-free pigs weighing 35-40 kg were kept in-house for at least one week prior to initiating the study, and were studied under the same protocol with approximately two weeks separating the two studies. Skin was prepared by washing with a non-antibiotic soap (Neutrogena) and sterile water. The area was blotted dry with sterile gauze. Forty-four rectangular wounds per animal (88 total wounds) measuring 10mm x 7mm x 0.5mm deep were made in the paravertebral and thoracic area with a specialized electrokeratome. The wounds were separated from one another by approximately 15mm of unwounded skin. Four wounds (four per each treatment group) were randomly assigned to each treatment group (n=11), inoculated with 10^6 *Staphylococcus aureus* (MRSA USA 300) and then treated once per day for two days.

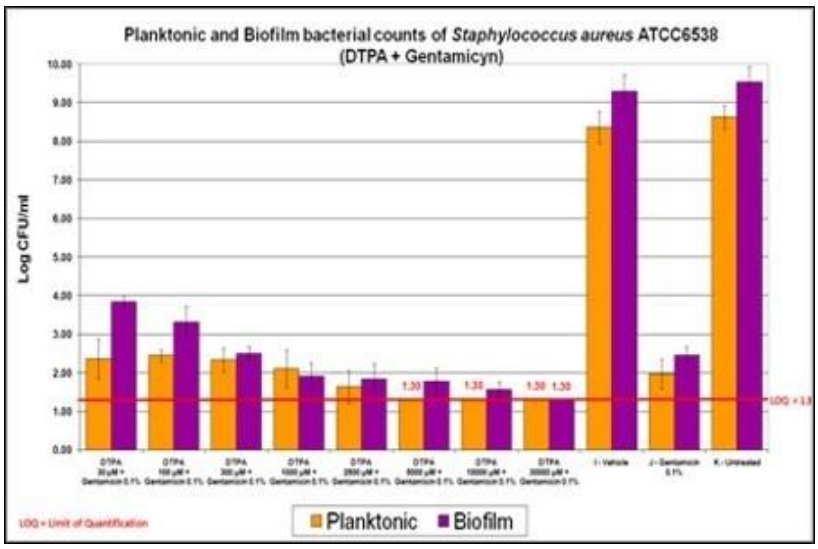
The BioLexa Platform was formulated as a topical cream made up of Glyceryl Stearate/PEG-100 Stearate, Lanolin Alcohol, Cetyl Alcohol, Mineral Oil, Sorbitol 70% Solution, Purified Water and the active components, Gentamicin and Ca-DTPA. Gentamicin 0.1% cream (1-gram cream contains 1 mg of Gentamicin base), a broad-spectrum antibiotic exhibiting bactericidal activity against both gram-positive and gram-negative bacteria, is FDA cleared for both internal (not oral) and external application and provides a highly effective topical treatment in primary and secondary bacterial infections of the skin. Ca-DTPA, at the concentrations used, is treated as an excipient and has also received FDA clearance to be safe and effective for internal usage to increase the rates of elimination of heavy metals.

The concentration of Gentamicin 0.1% was kept constant in the study, since that is the FDA-cleared topical cream concentration. Ca-DTPA concentration was varied with the goal of achieving an optimal dose-response antimicrobial effect. Results revealed that the combination of both Gentamicin and Ca-DTPA is greater than the results achieved by Gentamicin alone or Ca-DTPA alone. In addition, no new chemical entities were formed within this formulation.

The data tables below highlight these results.



Miller School of Medicine, of the University of Miami and University of Cincinnati - Determination of the effects of a novel antimicrobial agent used in conjunction with Gentamicin on *Staphylococcus aureus* using a porcine model: preliminary evaluations Jose Valdes, Joel Gil, Andrew Herr, Andrew Harding and Stephen Davis



Miller School of Medicine, of the University of Miami and University of Cincinnati - Determination of the effects of a novel antimicrobial agent used in conjunction with Gentamicin on *Staphylococcus aureus* using a porcine model: preliminary evaluations Jose Valdes, Joel Gil, Andrew Herr, Andrew Harding and Stephen Davis

The BioLexa Platform has achieved positive results in its initial pre-clinical studies conducted at the University of Miami. BioLexa's formulation is a new topical dosage form "repurposing" the antibiotic, enabling it to be developed for use in patients following a special regulatory pathway codified in Section 505(b)(2) of the FDA rules. Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FDCA") was enacted to enable sponsors to seek New Drug Application ("NDA") approval for novel repurposed drugs without the need for such sponsors to undertake time consuming and expensive pre-clinical safety studies and Phase 1 safety studies. Proceeding under this regulatory pathway, we will be able to rely upon all of the publicly available safety and toxicology data with respect to gentamicin and zinc chelator in our FDA submissions. We will be required to conduct a Phase 2 study to show the safety of the combination in humans and after such Phase 2 study will be required to proceed to Phase 3 pivotal clinical trials. We believe that this path will dramatically reduce the required clinical development effort, costs and risks as compared to what would be required of us if we were required to conduct pre-clinical safety, toxicology and animal studies together with Phase 1 human safety trials required for new chemical entities which are not eligible to be reviewed pursuant to the Section 505(b)(2) regulatory pathway. We estimate that by using the Section 505(b)(2) regulatory pathway, that the clinical development process may be five to six years shorter than is required for a new chemical entity, and the FDA approval process may be six to nine months shorter than the typical eighteen month period, which we believe may result in lower development costs and shorter development time. As of the date hereof, we have not submitted an NDA to the FDA. Although we intend to submit our NDA for such indication by the end of 2021 with approval of such NDA anticipated to be in 2022.no assurances can be given that we will receive approval of the NDA in a timely manner, if at all. In September 2018, we attended the first of a planned series of meetings with the FDA to review the requirements for submission and activation of an investigational new drug application ("IND") with respect to the BioLexa Platform for use in eczema. In preparation for such pre-IND meeting, we prepared and presented to the FDA our proposed Phase 2 clinical trial plan for the treatment of eczema in patients over the age of one year old. As part of our pre-IND meeting, the FDA provided us with general guidance with respect to specific animal studies, dosing schedules and suggested human safety studies before we commence clinical trials in pediatric or adult patients. We are currently investigating multiple potential venues for conducting such trial both in and outside of the U.S. We have engaged Camargo Pharmaceutical Services, LLC ("Camargo") to assist us with the FDA process required for Section 505(b)(2) applications and with the evaluation of potential clinical trial venues for the proof of concept study should we determine to undertake such study. Specifically, Camargo has provided and will continue to provide advice and guidance relative to the IND preparation phase for the BioLexa Platform. Camargo will assist us with the refinement of our non-clinical, clinical, clinical pharmacology and biopharmaceutics strategy incorporating the preliminary feedback we received from the FDA during our pre-IND meeting.

We believe that the key elements for our market success with respect to BioLexa include:

- the proprietary formulation of two FDA-approved drugs to treat bacterial proliferation reduces development time and costs by giving us the ability to rely on safety and efficacy data from the two approved drugs;

- our proprietary formulation is not a topical corticosteroid, and may not be subject to the same FDA black box warning issues as most commonly prescribed treatments currently in use; and

- a recent peer-reviewed publication titled "*Staphylococcal Bacteria May Cause Eczema, Study Reveals*", published by Dr. Herbert B. Allen, highlights that *staph*-induced biofilms are the root cause of flare-ups in eczema. Our BioLexa product candidate has been demonstrated to prevent the formation of these biofilms with the promise of delaying or completely arresting flare-ups, rather than merely treating symptoms of a flare-up already underway.

Sublicense with Chelexa Biosciences, Inc.

On May 26, 2017, we entered into a sublicense agreement with Chelexa, as amended on August 22, 2018 and August 29, 2018, pursuant to which Chelexa granted us an exclusive worldwide sublicense to make, use, have made, import, offer for sale, and sell products based upon or involving the use of the BioLexa Platform, which rights were originally granted to Chelexa pursuant to an exclusive license agreement with the University of Cincinnati. In addition, Chelexa granted us the right to issue exclusive and nonexclusive sublicenses (with the right to further sublicense to third parties) to make, use, have made, import, offer for sale, and sell the products based upon the BioLexa Platform.

In May 2017, we paid $300,000 to Chelexa pursuant to the sublicense agreement. In addition, we issued Chelexa 250,000 shares of our common stock, which was 10% of our fully-diluted equity at May 26, 2017, and Chelexa had the right to receive such number of additional shares of common stock required to maintain its 10% interest in our fully-diluted equity until such time we raised a minimum of $3,000,000 (the "Preemptive Right"). As of the date hereof, we have issued Chelexa an aggregate of 476,943 additional shares of common stock in accordance with the Preemptive Right. However, the Company has raised more than $3,000,000 and therefore the Preemptive Right has been terminated. Furthermore, pursuant to the sublicense agreement, Chelexa has the right to participate (the "Chelexa Participation Right") in certain equity issuances made by us for purposes of raising capital based upon its pro-rata share to enable Chelexa to retain 10% of our fully-diluted equity until such time as we consummate an initial public offering pursuant to which we receive aggregate gross proceeds of not less than $5,000,000. However, since we consummated an initial public offering pursuant to which we received aggregate gross proceeds of $7,000,000, the Chelexa Participation Right has been terminated.

The Chelexa agreement requires us to use our best commercial efforts to develop, produce and commercialize the BioLexa products on a global basis. It further provides for the payment by us of all development and commercialization expenses along with sales-based royalties at percentages which range from mid to high single digits, with high sales volumes being subject to lower royalty rates, and total milestone payments of $3.5 million. Industry standard performance obligations for us are provided for in the sublicense agreement with remedies for breach of such obligations. The sublicense agreement will continue until the later of April 16, 2034 and the last to expire patent, unless earlier terminated pursuant to the terms of the agreement. We, in our sole discretion, have the first right of refusal to renew the term. In addition, at any time after one year from the effective date of the sublicense agreement, Chelexa may, at its sole option, terminate or render the license granted to us nonexclusive if, in Chelexa's judgment, our progress reports do not demonstrate that we have used our best commercial efforts to develop and seek regulatory approval of BioLexa and/or we are engaged in manufacturing, marketing or sublicensing activity which is reasonably expected to ensure that BioLexa is available to the public.

Other License Agreements

License with the University of Cincinnati

On May 18, 2018, we entered into an exclusive license agreement with the University of Cincinnati for a patented, novel genetic marker for food allergies. The genetic marker licensed by us from the University of Cincinnati may be use to (i) identify at risk infants in predicting food allergies, including peanut and milk allergies, (ii) identify a person's predisposition to an allergic reaction, thereby avoiding such reaction and (iii) determine an individual's propensity to develop atopic dermatitis ("AD"), such as eczema. We intend to utilize the genetic marker for purposes of determining an individual's propensity to develop eczema as well as to identify and treat allergies in at-risk infants.

Pursuant to the terms of the license agreement, we agreed to pay the University of Cincinnati a one-time initial fee within 30 days of the date of the agreement in addition to an annual license fee. In addition, we agreed to pay the University of Cincinnati a yearly minimum annual royalty and certain milestone payments upon successful proof of concept of determining an individual's propensity to food allergy and within 30 days of a marketing approval in the U.S. The license agreement will continue until the later of the date upon which a valid claim pursuant to the terms of the license agreement expires or 10 years after the first commercial sale or until earlier terminated pursuant to the terms of the license agreement.

Sublicense Agreement with Zylö Therapeutics, Inc.

On August 19, 2019 (the "Zylö Effective Date"), we entered into the Sublicense Agreement with Zylö Therapeutics, Inc. pursuant to which Zylö granted us an exclusive sublicense to the Licensed Patent Rights (as defined in the Sublicense Agreement) and the Licensed Technology (as defined in the Sublicense Agreement) to, among other things, develop, make and sell the Licensed Products (as defined in the Sublicense Agreement) and to practice the Licensed Technology in the United States and Canada for any and all uses within the Field. "Field" means all therapeutic uses related to lupus in human beings, subject to the Field Expansion Rights (as defined in the Sublicense Agreement). The term of the Sublicense Agreement shall commence on the Zylö Effective Date and shall continue until the latest of (i) ten years from the date of First Commercial Sale (as defined in the Sublicense Agreement) of the Licensed Product in such country and (ii) expiration of the last to expire Valid Claim (as defined in the Sublicense Agreement) of the Licensed Patent Rights that would be infringed by the composition, use or sale of such Licensed Product in such country unless terminated earlier pursuant to the terms of the agreement. Pursuant to the terms of the Sublicense Agreement, we shall establish, with Zylö, a joint development committee to plan, review, coordinate and oversee our development activities with respect to the Licensed Products in the Field. Pursuant to the Sublicense Agreement, we shall pay Zylö (i) an upfront license fee of $50,000 (less the $10,000 we previously paid); (ii) sales-based royalties at percentages which range from mid to high single digits, with low sales volumes being subject to lower royalty rates; and total milestone payments of up to $13.5 million. In addition, within 45 days of our next equity financing pursuant to which we receive gross proceeds of at least $1 million, we shall purchase equity securities of Zylö in an amount equal to $60,000.

North Carolina State University License Agreement

On November 20, 2019 (the "NCSU Effective Date"), we entered into a license agreement with NCSU pursuant to which NCSU granted us an exclusive license to, among other things, develop, make, use, offer and sell certain licensed products throughout the world with respect to NCSU's exon skipping approach for treating allergic diseases. The term of the license agreement shall commence on the NCSU Effective Date and shall continue until the date of the expiration of the last to expire patent right granted pursuant to the license agreement unless terminated earlier pursuant to the terms of the agreement. Pursuant to the terms of the license agreement, we paid NCSU a one-time license fee of $25,000 and are required to pay: (i) sales based royalties at a low single digit percentage, (ii) minimum royalties ranging from $0 to $50,000 and (iii) milestone payments of up to $585,000.

George Washington University Patent License Agreement

On February 1, 2020 (the "GW Effective Date"), we entered into a patent license agreement with GW pursuant to which GW granted us a license to certain patent rights to, among other things, make, use, offer and sell certain licensed products throughout the world with respect to aprepitant as used in treating side effects from drugs used for the treatment of cancer. The term of the patent license agreement shall commence on the GW Effective Date and shall continue until the later of (i) the date upon which the last patent granted pursuant to such license expires or is abandoned and (ii) 10 years after the first sale of the first licensed product if no patent has been issued from the patent rights as set forth in the agreement unless terminated earlier pursuant to the terms of the agreement. Pursuant to the Sublicense Agreement, we paid a $10,000 license initiation fee and shall pay (i) license maintenance fees on each anniversary of the GW Effective Date until the first sale of the first licensed product pursuant to the agreement which shall amount to $2,000 in the first year and $5,000 thereafter, (ii) milestone payments ranging in the low to mid five figures, (iii) sale based royalties at a low single digit percentage, (iv) minimum royalties ranging from $5,000 to $20,000 payable in quarterly period after the first four quarters after the first sale pursuant to the agreement and (v) diligence minimums of $75,000 per year. In addition, we shall issue GW warrants to purchase shares of our common stock.

Product Development and Pipeline

We intend to conduct our first Phase 1 study in healthy adults with an immediate transition to a randomized, vehicle controlled Phase 1b trial in adolescent eczema patients comparing BioLexa to the base vehicle. This Phase 1b trial is intended to examine both safety and efficacy. We will assess the formulation of Ca-DTPA and Gentamicin 0.1% in our proprietary topical lotion delivered by a metered pump system. We will also assess the ability of BioLexa to clear harmful staph aureus bacterial from the skin of atopic dermatitis patients.

Following our Phase 1b trial, we intend to conduct up to two Phase 2 trials in atopic dermatitis patients comparing BioLexa to the base vehicle. Subject numbers and allocation will be informed by the results of the Phase 1b trial. We expect the clinical program to be completed, subject to receipt of funding by us, by the end of 2020 or early 2021 with an NDA submission targeted for mid to late 2021. There is currently no active IND for our product candidate in the United States.

The following table summarizes the BioLexa expected product development pipeline.

Although our initial focus will be on the treatment of eczema, we intend to develop a second topical cream which, upon application, is intended to reduce post-procedure infections, accelerate healing and improve clinical outcomes for patients undergoing aesthetic dermatology procedures. In addition, we conducted an initial pilot study on the efficacy of BioLexa to accelerate diabetic wound healing and intend to conduct additional studies with respect to the regenerative effects of the BioLexa Platform in the context of chronic diabetic ulcers, with and without substantial bacterial burden.

Eczema and Atopic Dermatitis

Eczema is also referred to as atopic dermatitis. According to the National Eczema Association, eczema affects over 32 million Americans alone. Eczema affects 10-20% of children with 60% of cases occurring within a child’s first year and 85% before the age of five.

There is no cure for eczema, but, in most cases, it is manageable. The word eczema comes from a Greek word that means to effervesce or bubble or boil over.

http://www.easeeczema.org/erc/symptoms_of_eczema.htm

Symptoms

The main symptom of eczema is an inflamed, itchy red rash. It can appear all over the body. Many people have it on their elbows or behind their knees. Babies often have eczema on the face, especially the cheeks and chin. They can also have it on the scalp, trunk (chest and back), and outer arms and legs. Children and adults tend to have eczema on the neck, wrists, and ankles, and in areas that bend, like the inner elbow and knee. People with eczema are usually diagnosed with it when they are babies or young children. Eczema symptoms often become less severe as children grow into adults. For some people, eczema continues into adulthood. Less often, it can start in adulthood. The rash of eczema is different for each person. It may even look different or affect different parts of the body from time to time. It can be mild, moderate or severe. Generally, people with eczema suffer from dry, sensitive skin. Eczema is also known for its intense itch. The itch may be so bad that patients scratch their skin until it bleeds, which can make the rash even worse, leading to increased inflammation and itching. This is called the itch-scratch cycle.

Signs and Symptoms of Eczema

- Dry, sensitive skin
- Intense itching
- Red, inflamed skin
- Recurring rash
- Scaly areas
- Rough, leathery patches
- Oozing or crusting
- Areas of swelling
- Dark colored patches of skin

Current Treatments

According to the National Eczema Association, people utilize many treatments for eczema to relieve the itch, including over-the-counter remedies and prescription medications. In addition, some people utilize alternative eczema treatments, such as herbal remedies. However, a study referenced by the National Eczema Association found that the majority of people with eczema are likely not satisfied with the effectiveness of their medications. The most common complaints in the study included that the subjects' medications:

- Do not work;
- Are messy to use;

- Are too expensive; and
- Cause side effects.

There can be no assurances that, if approved, the BioLexa Platform will not be subject to the similar complaints set forth above about its use. Until clinical data is available, there can be no assurances that the BioLexa Platform will not have side effects.

In addition to over-the-counter moisturizers, topical steroids are an important part of the treatment plan for most people with eczema. When eczema flares up, applying cream, lotion or ointment containing a steroid will reduce inflammation, ease soreness and irritation, reduce itching and relieve the need to scratch, allowing the skin to heal and recover.

Steroids are naturally-occurring substances that are produced in our bodies to regulate growth and immune function. There are many kinds of steroids, including “anabolic steroids” such as testosterone, “female hormones” such as estrogen (both produced in the gonads) and corticosteroids such as cortisol, which is produced by the adrenal glands. Corticosteroids are the type of steroid used for the treatment of eczema. Corticosteroids have many functions in the body, including effective control of inflammation. Corticosteroids reduce inflammation by temporarily altering the function of several types of cells and chemicals in the skin.

According to the National Eczema Association, there are many serious risks associated with the chronic use of topical steroids. Thinning of the skin (skin atrophy) is a well-recognized, possible side effect. This is especially true when potent topical corticosteroids are applied too frequently and for a prolonged period of time without a break. Early skin thinning can disappear if the topical corticosteroid use is discontinued, and, while uncommon, prolonged use can cause permanent stretch marks (striae), usually on the upper inner thighs, under the arms and in the elbow and knee creases.

Many patients with undertreated eczema have the opposite of skin thinning, and develop thickening, and sometimes darkening of the skin (changes known as lichenification). This is the skin’s response to rubbing and scratching.

Frequent and prolonged application of a topical corticosteroid to the eyelids can cause glaucoma and even cataracts. Topical corticosteroids can occasionally cause tiny pink bumps and acne, especially when used on the face and around the mouth. On the body, greasy corticosteroid ointments sometimes cause redness around hair follicles, sometimes with a pus bump centered in the follicle (folliculitis). When corticosteroids are applied to large body surface areas, enough may be absorbed to inhibit the body’s own production of cortisol, a condition known as “adrenal suppression.” The risk of adrenal suppression is highest with high potency (Class 1-2) corticosteroids. Infants and young children have a higher ratio of body surface area compared to their weight, so they are more susceptible to topical corticosteroid absorption. Moreover, if a child is given oral corticosteroids in large doses or over a long term, prolonged adrenal suppression can be associated with growth suppression and weakened immune responses.

Alternatives Today

The risks and side effects of prolonged steroid use are driving patients, physicians and the pharmaceutical industry to find safe and effective alternatives. Based upon data from the National Eczema Association our competitors include, but are not limited to, the following:

Competitor Drug	**Types of Therapies in the Market**
Eucrisa	Topical - non steroid
Vanos Cream	Topical - Corticosteroid
Aristocort A Cream	Topical - Corticosteroid
Topicort Cream	Topical - Corticosteroid
Temorate E* Emollient	Emollient
Theraplex	Emollient
Mustela	Emollient
Dupixant	Shot

What is common to all of the above candidates is that they are focused on treating or suppressing symptoms rather than causally preventing or delaying flare-ups.

The graphic below shows the numerous causes of flare-ups in eczema.

https://infodiseases.com/the-causes-symptoms-and-treatments-of-eczema.html

Our product development pipeline is focused on preventing flare-ups caused by *staph* biofilms. The fundamental difference between the product candidate we intend to develop and those in the table above is that ours are intended to prevent eczema flare-ups rather than merely treat symptoms of a flare-up already underway.

Preventing Eczema Flare-Ups By Stopping Biofilms

It is well known that the skin of eczema patients is colonized with *Staphylococcus aureus* (*S. Aureus*) and this organism has been shown to exist in both dry skin as well as areas of severe dermatitis. It is well known that *S. Aureus* bacteria are programmed by nature to form micro-colonies as a means of self-preservation. Once formed, these colonies secrete a polysaccharide matrix "shield" enabling the bacteria to grow unfettered by the host immune system or external antibiotic therapy. These shielded bacteria are referred to as "biofilm." In eczema, biofilms are known to clog sweat ducts, triggering flare-ups. Eczema severity has been directly correlated to the degree of *S. Aureus* colonization and therapy generally fails to improve symptoms in the presence of high *S. Aureus* counts.

Biofilms are implicated in 80% of all human infections. Once formed, bacterial biofilms resist the host immune system and antibiotics. Biofilms may require 1,000 times the antibiotic dose required to kill single bacteria, rendering biofilms virtually nontreatable once formed. Despite these realities, existing technology focuses on treatment rather than prevention.

Competition

The current competition in the eczema therapeutics market consists of conventional forms of therapy such as topical corticosteroids, topical immunomodulators and emollients as the most prominent therapies. Among all the available treatment options, topical corticosteroids hold a majority share and dominate the market. Topical corticosteroids, such as Vanos Cream, Aristorcort A Cream and Topicort Cream are available in various strengths (mild, moderate, potent and very potent) and formulations (ointment, cream, lotion and others), so that they can be used according to the severity of eczema. Calceurin inhibitors (Protopic (tacrolimus) and Elidel (pimecrolimus)) showed higher efficacy in comparison to corticosteroids and these products were widely used after their respective launches. However, in 2005, the FDA issued black box warnings for the calceurin inhibitors (Protopic and Elidel), and this resulted in declining sales of these products. Emollients, such as Theraplex, Mustela and Temorate E* Emollient, have good efficacy as well as good safety. They hydrate, moisturize and repair the skin. These products do not offer first line treatment, but they are useful as maintenance therapy in eczema patients.

Market Opportunity

We believe we have a two-fold competitive advantage over our competition. First, currently available eczema treatment options focus on treating or suppressing symptoms rather than causally preventing or delaying flare-ups. Recent peer-reviewed publications highlight that *staph*-induced biofilms are the root cause of flare-ups in eczema. Our BioLexa product candidate has been demonstrated to prevent the formation of these biofilms with the promise of delaying or completely arresting flare-ups, rather than merely treating symptoms of a flare-up already underway. Second, long-term use of corticosteroids, can have harmful side effects. Because the BioLexa Platform does not use steroids, our treatment avoids these harmful side effects and gives us another advantage over our competition.

Commercialization

Our business success with BioLexa depends not only on the successful development and approval of the product but also on its commercialization. At present, our plan anticipates us making the investments necessary to build an in-house marketing and sales capability for the U.S. market for BioLexa. As BioLexa makes its way through clinical development in the U.S., we intend to approach pharmaceutical and biotechnology companies outside the U.S. to negotiate and enter into strategic partnerships that will enable development and commercialization of BioLexa outside the U.S., where we believe the market opportunity is larger than that of the U.S. albeit far more complex to reach. We have no operations outside the U.S., nor are we planning to have any non-U.S. operations.

Manufacturing and Supply

We do not have any manufacturing capability and therefore have engaged Particle Sciences, Inc. ("Particle Sciences"), a company with over 20 years of experience formulating and producing topical therapeutics under current good manufacturing practice requirements ("cGMP") regulations, to formulate and manufacture the BioLexa product candidate in accordance with cGMP requirements. Although we have not entered into a master service agreement with Particle Sciences, Particle Sciences is charged with, among other things, the following pursuant to the terms of a quote provided to us by Particle Sciences:

- Optimizing the formulation of the BioLexa product candidate for ease of production and analysis;
- Producing and packaging the required doses of the BioLexa product candidate for all clinical testing under cGMP conditions; and
- Evaluating the shelf life of the BioLexa product candidate employing industry standard stability testing techniques and protocol.

In addition to the foregoing, Particle Sciences is required to identify and source the two raw materials, Ca-DTPA and Gentamicin, used to produce the BioLexa product candidate. Both DTPA and Gentamicin are available from multiple suppliers in the U.S., Europe and Asia, and the Company anticipates that such raw materials will be readily available to the Company. Particle Sciences is required to vet and engage potential suppliers of the raw materials. Although the Company is engaged in negotiations with suppliers of the raw materials, the Company has not yet entered into any agreements for the supply of such raw materials. The additional components in the BioLexa formulation are all listed in the United States Pharmacopeia and are readily available from multiple U.S. sources who routinely supply similar materials to the pharmaceutical and cosmetic industries.

Intellectual Property Portfolio

We believe that market exclusivity derived from our licensed intellectual property, the Hatch-Waxman provisions applicable to products approved under 505(b)(2) and possible data protection rights will present barriers to entry and are keys to our success.

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the U.S. and in other countries. Our policy is to actively seek the broadest intellectual property protection possible for our products, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world. In addition, we intend to actively pursue product life-cycle management initiatives to extend our market exclusivity.

We intend to cement our market exclusivity in conjunction with our formulation-development partners through additional patents based on the pharmaceutical and clinical characteristics of our drug in the proprietary formulation and through the introduction of line extensions such as combination drugs and new formulations.

In addition to any granted patents, our products will be eligible for market exclusivity to run concurrently with the term of the patent for three and a half years in the U.S. per the Hatch-Waxman Act and pediatric exclusivity guideline and up to ten years of market exclusivity in the E.U. which includes eight years of data exclusivity and two years of market exclusivity from the date of the NDA or the European equivalent referred to as Marketing Authorization Application, or MAA.

BioLexa, our biofilm-prevention technology, is covered by U.S. Patent No. 9,821,063, which was issued on November 21, 2017 and expires in 2033, and has issued patents in the E.U. and Spain expiring in 2028. Patent applications covering multiple formulations and methods of use for the BioLexa Platform are presently pending in the U.S., Europe and Canada which, if issued, will expire in 2033.

Government Regulation

Governmental authorities in the U.S. and other countries extensively regulate the research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing of pharmaceutical products such as those being developed by us. In the U.S., the FDA regulates such products under the FDCA and implements related regulations. Failure to comply with applicable FDA requirements, both before and after approval, may subject us to administrative and judicial sanctions, such as a delay in approving or refusal by the FDA to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

U.S. Food and Drug Administration Regulation

United States Drug Development

In the United States, the FDA regulates drugs, medical devices and combinations of drugs and devices, or combination products, under the FDCA and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, requests for voluntary product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive pre-clinical laboratory tests, animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in accordance with an applicable IND and other clinical study related regulations, sometimes referred to as good clinical practices, or GCPs, to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with the FDA's cGMP requirements;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA prior to any commercial marketing or sale.

Once a pharmaceutical product candidate is identified for development, it enters the pre-clinical testing stage. Pre-clinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. An IND sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some pre-clinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions related to a proposed clinical trial and places the trial on a clinical hold within that 30-day period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns or non-compliance, and may be imposed on all drug products within a certain class of drugs. The FDA also can impose partial clinical holds, for example, prohibiting the initiation of clinical trials of a certain duration or for a certain dose.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an Institutional Review Board ("IRB") must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. An IRB considers, among other things, whether the risks to individuals participating in the clinical trial are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The product is initially introduced into a small number of healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product is suspected or known to be unavoidably toxic, the initial human testing may be conducted in patients.

- Phase 2. Involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.

- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit relationship of the product and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 trials. Companies that conduct certain clinical trials also are required to register them and post the results of completed clinical trials on a government-sponsored database, such as ClinicalTrials.gov in the United States, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events, findings from other studies that suggest a significant risk to humans exposed to the product, findings from animal or in vitro testing that suggest a significant risk to human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA 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 or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to patients. 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. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the study. The clinical trial sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

NDA and FDA Review Process

The results of product development, pre-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug, requesting approval to market the product. The submission of an NDA is subject to the payment of a substantial user fee, and the sponsor of an approved NDA is also subject to an annual program user fee; although a waiver of such fee may be obtained under certain limited circumstances. For example, the agency will waive the application fee for the first human drug application that a small business or its affiliate submits for review.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA typically makes a decision on accepting an NDA for filing within 60 days of receipt. The decision to accept the NDA for filing means that the FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA's goal to complete its substantive review of a standard NDA and respond to the applicant is ten months from the receipt of the NDA. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification and may go through multiple review cycles.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMPs to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of an NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States, and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 clinical trials to further assess drug safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals, including the requirement for a risk evaluation and mitigation strategy ("REMS"), to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

Section 505(b)(2) Regulatory Approval Pathway

Section 505(b)(2) of the FDCA provides an alternate regulatory pathway for approval of a new drug by allowing the FDA to rely on data not developed by the applicant. Specifically, Section 505(b)(2) permits the submission of an NDA where one or more of the investigations relied upon by the applicant for approval was not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and/or the FDA's findings of safety and effectiveness for an approved drug already on the market. Approval or submission of a 505(b)(2) application, like those for abbreviated new drugs ("ANDAs"), may be delayed because of patent and/or exclusivity rights that apply to the previously approved drug.

A 505(b)(2) application may be submitted for a new chemical entity, or NCE, when some part of the data necessary for approval is derived from studies not conducted by or for the applicant and when the applicant has not obtained a right of reference. Such data are typically derived from published studies, rather than FDA's previous findings of safety and effectiveness of a previously approved drug. For changes to a previously approved drug however, an applicant may rely on the FDA's finding of safety and effectiveness of the approved drug, coupled with information needed to support the change from the approved drug, such as new studies conducted by the applicant or published data. When based on an approved drug, the 505(b)(2) drug may be approved for all of the indications permitted for the approved drug, as well as any other indication supported by additional data.

Section 505(b)(2) applications also may be entitled to marketing exclusivity if supported by appropriate data and information. As discussed in more detail below, three-year new data exclusivity may be granted to the 505(b)(2) application if one or more clinical investigations conducted in support of the application, other than bioavailability/bioequivalence studies, were essential to the approval and conducted or sponsored by the applicant. Five years of marketing exclusivity may be granted if the application is for an NCE, and pediatric exclusivity is likewise available.

Orange Book Listing and Paragraph IV Certification

For NDA submissions, including those under Section 505(b)(2), applicants are required to list with the FDA certain patents with claims that cover the applicant's product. Upon approval, each of the patents listed in the application is published in *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the Orange Book. Any applicant who subsequently files an ANDA or 505(b)(2) NDA that references a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a Paragraph IV Certification.

If an applicant has provided a Paragraph IV Certification to the FDA, the applicant must also send notice of the Paragraph IV Certification to the holder of the NDA for the approved drug and the patent owner once the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to notice of the Paragraph IV Certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV Certification prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of 30 months from the date of the lawsuit, the applicant's successful defense of the suit, or expiration of the patent.

Reimbursement

Potential sales of any of our product candidates, if approved, will depend, at least in part, on the extent to which such products will be covered by third-party payors, such as government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage and/or reducing reimbursements for medical products and services. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our future revenues and results of operations. Decreases in third-party reimbursement or a decision by a third-party payor to not cover a product candidate, if approved, or any future approved products could reduce physician usage of our products, and have a material adverse effect on our sales, results of operations and financial condition.

In the United States, the Medicare Part D program provides a voluntary outpatient drug benefit to Medicare beneficiaries for certain products. We do not know whether our product candidates, if approved, will be eligible for coverage under Medicare Part D, but individual Medicare Part D plans offer coverage subject to various factors such as those described above. Furthermore, private payors often follow Medicare coverage policies and payment limitations in setting their own coverage policies.

Pediatric Exclusivity and Pediatric Use

The Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric studies for most drugs and biologics, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs, biologics license applications and supplements thereto, must contain a pediatric assessment unless the sponsor has received a deferral or waiver. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which an orphan drug designation has been granted. The required assessment must assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data needs to be collected before the pediatric studies begin.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data does not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months.

Healthcare Laws and Regulations

Sales of our product candidates, if approved, or any other future product candidate will be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we might conduct our business. The healthcare laws and regulations that may affect our ability to operate include the following:

- The federal Anti-Kickback Statute makes it illegal for any person or entity to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is in exchange for or to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value.

- Federal false claims and false statement laws, including the federal civil False Claims Act, prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent.

- Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors or making any false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their implementing regulations, impose obligations on certain types of individuals and entities regarding the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information.

- The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Also, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the federal government's and/or pharmaceutical industry's voluntary compliance guidelines, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, as well as state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA.

Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

Employees

As of February 28, 2020, we employed a total of 2 full-time employees, 1 employee consultant, and no part-time employees. We are not a party to any collective bargaining agreements. We believe that we maintain good relations with our employees.

Our Corporate Information

We were incorporated as a Nevada corporation on May 16, 2017. Our principal executive offices are located at 1 Rockefeller Plaza, Suite 1039, New York, New York 10020 and our telephone number is (646) 756-2997.

Available Information

Our website address is *www.hoththerapeutics.com*. The contents of, or information accessible through, our website are not part of this Annual Report on Form 10-K, and our website address is included in this document as an inactive textual reference only. We make our filings with the U.S. Securities and Exchange Commission ("SEC"), including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the SEC. The public may read and copy the materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Additionally, the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is *www.sec.gov*. The information contained in the SEC's website is not intended to be a part of this filing.

ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the following risk factors and the other information in this Annual Report on Form 10-K before investing in our common stock. Our business and results of operations could be seriously harmed by any of the following risks. The risks set out below are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. If any of the following events occur, our business, financial condition and results of operations could be materially adversely affected. In such case, the value and trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Financial Position and Need for Capital

We have generated no revenue from commercial sales to date and our future profitability is uncertain.

We were incorporated in May 2017 and have a limited operating history and our business is subject to all of the risks inherent in the establishment of a new business enterprise. Our likelihood of success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with development and expansion of a new business enterprise. Since inception, we have incurred losses and expect to continue to operate at a net loss for at least the next several years as we commence our research and development efforts, conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. Our net losses for the year ended December 31, 2019 and 2018 were $7,704,636 and $2,495,525, respectively, and our accumulated deficit as of December 31, 2019 and 2018 was $12,215,642 and $4,511,006, respectively. There can be no assurance that the products under development by us will be approved for sale in the U.S. or elsewhere. Furthermore, there can be no assurance that if such products are approved they will be successfully commercialized, and the extent of our future losses and the timing of our profitability are highly uncertain. If we are unable to achieve profitability, we may be unable to continue our operations.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.

Our financial statements as of December 31, 2019 have been prepared under the assumption that we will continue as a going concern for the next twelve months. Our independent registered public accounting firm included in its opinion for the year ended December 31, 2019 an explanatory paragraph referring to our recurring losses from operations and expressing substantial doubt in our ability to continue as a going concern without additional capital becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity or debt financing, reduce expenditures and to generate significant revenue. Our financial statements as of December 31, 2019 did not include any adjustments that might result from the outcome of this uncertainty. The reaction of investors to the inclusion of a going concern statement by our auditors, and our potential inability to continue as a going concern, in future years could materially adversely affect our share price and our ability to raise new capital or enter into strategic alliances. Furthermore, we also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us.

If we fail to obtain the capital necessary to fund our operations, we will be unable to continue or complete our product development and you will likely lose your entire investment.

We will need to continue to seek capital from time to time to continue development of our lead drug candidate beyond the initial Phase 2 clinical trial and to acquire and develop other product candidates. Our first product is not expected to be commercialized until at least 2022 and we cannot provide any assurances that any revenues it may generate in the future will be sufficient to fund our ongoing operations. We believe that we will need to raise substantial additional capital to fund our continuing operations and the development and commercialization of our product candidate.

Our business or operations may change in a manner that would consume available funds more rapidly than anticipated and substantial additional funding may be required to maintain operations, fund expansion, develop new or enhanced products, acquire complementary products, business or technologies or otherwise respond to competitive pressures and opportunities, such as a change in the regulatory environment or a change in preferred eczema treatment modalities. In addition, we may need to accelerate the growth of our sales capabilities and distribution beyond what is currently envisioned, and this would require additional capital. However, we may not be able to secure funding when we need it or on favorable terms. We may not be able to raise sufficient funds to commercialize the product candidates we intend to develop.

If we cannot raise adequate funds to satisfy our capital requirements, we will have to delay, scale back or eliminate our research and development activities, clinical studies or future operations. We may also be required to obtain funds through arrangements with collaborators, which arrangements may require us to relinquish rights to certain technologies or products that we otherwise would not consider relinquishing, including rights to future product candidates or certain major geographic markets. This could result in sharing revenues which we might otherwise retain for ourselves. Any of these actions may harm our business, financial condition and results of operations.

The amount of capital we may need depends on many factors, including the progress, timing and scope of our product development programs; the progress, timing and scope of our pre-clinical studies and clinical trials; the time and cost necessary to obtain regulatory approvals; the time and cost necessary to further develop manufacturing processes and arrange for contract manufacturing; our ability to enter into and maintain collaborative, licensing and other commercial relationships; and our partners' commitment of time and resources to the development and commercialization of our products.

Even if we can raise additional funding, we may be required to do so on terms that are dilutive to you.

The capital markets have been unpredictable in the recent past for unprofitable companies such as ours. In addition, it is generally difficult for early stage companies to raise capital under current market conditions. The amount of capital that a company such as ours is able to raise often depends on variables that are beyond our control. As a result, we may not be able to secure financing on terms attractive to us, or at all. If we are able to consummate a financing arrangement, the amount raised may not be sufficient to meet our future needs. If adequate funds are not available on acceptable terms, or at all, our business, including our results of operations, financial condition and our continued viability will be materially adversely affected.

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

We depend upon the success of the BioLexa Platform, which has not yet demonstrated efficacy in Phase 2 clinical trials, as well as our other licensed products and technologies. If we are unable to generate revenues from the BioLexa Platform or our other licensed products and technologies, our ability to create stockholder value will be limited.

We intend to conduct our first Phase 1 study in healthy adults with an immediate transition to a randomized, vehicle controlled Phase 1b trial in adolescent eczema patients comparing BioLexa to the base vehicle. Following our Phase 1b trial, we intend to conduct up to two Phase 2 trials in atopic dermatitis patients comparing BioLexa to the base vehicle. We expect the clinical program to be completed, subject to receipt of funding by us, by the end of 2020 or early 2021 with an NDA submission targeted for mid to late 2021.

In addition, we have licensed a genetic marker for food allergies, products and technology for therapeutic uses related to lupus in human beings, patents related to an exon skipping approach for treating allergic diseases and patents related to aprepitant which is used to treat side effects from drugs used for the treatment of cancer. We do not generate revenues from any drug products. We may not be successful in obtaining acceptance from the regulatory authorities to start our clinical trials. If we do not obtain such acceptance, the time in which we expect to commence clinical programs for any product candidate will be extended and such extension will increase our expenses and increase our need for additional capital. Moreover, there is no guarantee that our clinical trials will be successful or that we will continue clinical development in support of an approval from the regulatory authorities for any indication. We note that most drug candidates never reach the clinical stage and even those that do commence clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Therefore, our business currently depends entirely on the successful development, regulatory approval and commercialization of our product candidates, which may never occur.

Members of our management team lack experience in the pharmaceutical field.

Members of our management team lack experience in the pharmaceutical field. This lack of experience may impair our ability to commercialize our pharmaceutical products and attain profitability. We will need to hire or engage managerial personnel with relevant experience in the pharmaceutical field; however, there can be no assurance that such personnel will be available to us or, that once engaged, will be retained by us. Failure to establish and maintain an effective management team with experience in the pharmaceutical field and commercialization of pharmaceuticals products would have a material adverse effect on our business and results of operations.

The marketing approval process of the FDA is lengthy, time consuming and inherently unpredictable, and if we are ultimately are unable to obtain marketing approval for the product candidates we intend to develop, our business will be substantially harmed.

None of the product candidates we intend to develop have gained marketing approval in the U.S. and we cannot guarantee that we will ever have marketable products. Our business is substantially dependent on our ability to complete the development of, obtain marketing approval for, and successfully commercialize our product candidates in a timely manner. We cannot commercialize our product candidates in the United States without first obtaining approval from the FDA to market each product candidate. Our product candidates could fail to receive marketing approval for many reasons, including among others:

- the FDA may disagree with the design or implementation of our clinical trials;
- the FDA could determine that we cannot rely on Section 505(b)(2) for any or all of our product candidates; and
- the FDA may determine that we have identified the wrong reference listed drug or drugs or that approval of our Section 505(b)(2) application for any of our product candidates is blocked by patent or non-patent exclusivity of the reference listed drug or drugs.

In addition, the process of seeking regulatory clearance or approval to market the product candidates we intend to develop is expensive and time consuming and, notwithstanding the effort and expense incurred, clearance or approval is never guaranteed. If we are not successful in obtaining timely clearance or approval of our product candidates from the FDA, we may never be able to generate significant revenue and may be forced to cease operations. The NDA process is costly, lengthy and uncertain. Any NDA application filed by the Company will have to be supported by extensive data, including, but not limited to, technical, pre-clinical, clinical, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the product for its intended use.

Obtaining clearances or approvals from the FDA and from the regulatory agencies in other countries is an expensive and time consuming process and is uncertain as to outcome. The FDA and other agencies could ask us to supplement our submissions, collect non-clinical data, conduct additional clinical trials or engage in other time-consuming actions, or it could simply deny our applications. In addition, even if we obtain an NDA approval or pre-market approvals in other countries, the approval could be revoked or other restrictions imposed if post-market data demonstrates safety issues or lack of effectiveness. We cannot predict with certainty how, or when, the FDA will act. If we are unable to obtain the necessary regulatory approvals, our financial condition and cash flow may be adversely affected, and our ability to grow domestically and internationally may be limited. Additionally, even if cleared or approved, the Company's products may not be approved for the specific indications that are most necessary or desirable for successful commercialization or profitability.

We may encounter substantial delays in completing our clinical studies which in turn will require additional costs, or we may fail to demonstrate adequate safety and efficacy to the satisfaction of applicable regulatory authorities.

It is impossible to predict if or when any of our product candidates, will prove safe or effective in humans or will receive regulatory approval. 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. A failure of one or more clinical studies can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching, or failing to reach, a consensus with regulatory agencies on study design;
- delays in reaching, or failing to reach, agreement on acceptable terms with a sufficient number of 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 trial sites;
- delays in obtaining required IRB or Ethics Committee ("EC") approval at each clinical study site;

- delays in recruiting a sufficient number of suitable patients to participate in our clinical studies;
- imposition of a clinical hold by regulatory agencies, after an inspection of our clinical study operations or study sites;
- failure by our CROs, other third parties or us to adhere to clinical study, regulatory or legal requirements;
- failure to perform in accordance with the FDA's GCPs or applicable regulatory guidelines in other countries;
- delays in the testing, validation, manufacturing and delivery of sufficient quantities of our product candidates to the clinical sites;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- clinical study sites or patients dropping out of a study;
- delay or failure to address any patient safety concerns that arise during the course of a trial;
- unanticipated costs or increases in costs of clinical trials of our product candidates;
- occurrence of serious adverse events associated with the product candidate that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ECs of the institutions in which such trials are being conducted, by an independent Safety Review Board ("SRB") for such trial or by the FDA, EMA, or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA, or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Any inability to successfully complete pre-clinical and clinical development could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions.

Clinical study delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The outcome of pre-clinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Further, pre-clinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval. If the results of our clinical studies are inconclusive or if there are safety concerns or adverse events associated with our other product candidates, we may:

- be delayed in obtaining marketing approval for our product candidates, if approved at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be required to change the way the product is administered;
- be required to perform additional clinical studies to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of a product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- be sued; or
- experience damage to our reputation.

Additionally, our product candidates could potentially cause other adverse events that have not yet been predicted. The inclusion of ill patients in our clinical studies may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using. As described above, any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and impair our ability to commercialize our products.

If we are not able to obtain any required regulatory approvals for our product candidates, we will not be able to commercialize our product candidates and our ability to generate revenue will be limited.

We must successfully complete clinical trials for our product candidates before we can apply for marketing approval. Even if we complete our clinical trials, it does not assure marketing approval. Our pre-clinical trials may be unsuccessful, which would materially harm our business. Even if our initial pre-clinical trials are successful, we are required to conduct clinical trials to establish our product candidates' safety and efficacy, before a marketing application (NDA or Biologics License Application, or BLA, or their foreign equivalents) can be filed with the FDA, the European Medicines Agency ("EMA"), or comparable foreign regulatory authorities for marketing approval of our product candidates.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA, EMA, and other regulatory authorities in the United States, European Union, and other countries, where regulations differ from country to country. We are not permitted to market our product candidates as prescription pharmaceutical products in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. In the United States, the FDA generally requires the completion of clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA or other regulatory authorities and even fewer are eventually approved for commercialization. We have not submitted an NDA to the FDA or comparable applications to other regulatory authorities. If our development efforts for our product candidates, including regulatory approval, are not successful for their planned indications, or if adequate demand for our product candidates is not generated, our business will be materially adversely affected.

Our success depends on the receipt of regulatory approval and the issuance of such regulatory approvals is uncertain and subject to a number of risks, including the following:

- the results of nonclinical or toxicology studies may not support the filing of an IND or foreign equivalent for our product candidates;
- the FDA, EMA, or comparable foreign regulatory authorities or IRBs or ECs may disagree with the design or implementation of our clinical trials;
- we may not be able to provide acceptable evidence of our product candidates' safety and efficacy;
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, EMA, or other regulatory agencies for marketing approval;
- the dosing of our product candidates in a particular clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our product candidates;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA, BLA or other marketing application or to obtain regulatory approval in the United States or elsewhere;
- the requirement for additional studies;
- the FDA, EMA, or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the approval policies or regulations of the FDA, EMA, or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval;
- the FDA, EMA, or comparable foreign regulatory authorities may disagree on the design or implementation of our clinical trials, including the methodology used in our studies, our chosen endpoints, our statistical analysis, or our proposed product indication;
- our failure to demonstrate to the satisfaction of the FDA, EMA, or comparable regulatory authorities that a product candidate is safe and effective for its proposed indication;

- we may fail to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- immunogenicity might affect a product candidate efficacy and/or safety;
- the FDA, EMA, or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- data collected from clinical trials of our product candidates may be insufficient to support the submission and filing of a marketing application or to obtain marketing approval. For example, the FDA may require additional studies to show that our product candidates are safe or effective;
- we may fail to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies;
- there may be changes in the approval policies or regulations that render our nonclinical and clinical data insufficient for approval; or
- the FDA, EMA or comparable foreign regulatory authority may require more information, including additional nonclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program.

Failure to obtain regulatory approval for our product candidates for the foregoing, or any other reasons, will prevent us from commercializing our product candidates, and our ability to generate revenue will be materially impaired. We cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we intend to conduct in the future or that such trials will be successful. The FDA, EMA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or pre-clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of our product candidates.

We have not submitted an IND or received regulatory approval to commence clinical trials for our product candidates in any jurisdiction. We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third party CROs with expertise in this area to assist us in this process. Securing regulatory approvals to market a product requires the submission of pre-clinical, clinical, and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities and supporting information to the appropriate regulatory authorities for each therapeutic indication to establish a product candidate's safety and efficacy for each indication. Our product candidates may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory marketing approval for our product candidates in any indication will prevent us from commercializing the product candidate, and our ability to generate revenue will be materially impaired.

If we are unable to submit an application for approval of BioLexa under Section 505(b)(2) of the FDCA or if we are required to generate additional data related to the safety and efficacy of BioLexa in order to obtain approval under Section 505(b)(2), we may be unable to meet our anticipated development and commercialization timelines.

Our current strategy for seeking marketing authorization in the United States of BioLexa relies primarily on Section 505(b)(2) of the FDCA which permits use of a marketing application, referred to as a 505(b)(2) application, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. The FDA interprets this to mean that an applicant may rely for approval on such data as that found in published literature or the FDA's finding of safety or effectiveness, or both, of a previously approved drug product owned by a third party. There is no assurance that the FDA would find third-party data relied upon by us in a 505(b)(2) application with respect to BioLexa sufficient or adequate to support approval and may require us to generate additional data to support the safety and efficacy of BioLexa. Consequently, we may need to conduct substantial new research and development activities beyond those we currently plan to conduct. Such additional new research and development activities would be costly and time consuming and there is no assurance that such data generated from such additional activities would be sufficient to obtain approval.

If the data to be relied upon in a 505(b)(2) application is related to drug products previously approved by the FDA and covered by patents that are listed in the FDA's Orange Book, we would be required to submit with our 505(b)(2) application a Paragraph IV Certification in which we must certify that we do not infringe the listed patents or that such patents are invalid or unenforceable, and provide notice to the patent owner or the holder of the approved NDA. The patent owner or NDA holder would have 45 days from receipt of the notification of our Paragraph IV Certification to initiate a patent infringement action against us. If an infringement action is initiated, the approval of our NDA would be subject to a stay of up to 30 months or more while we defend against such a suit. Approval of our product candidates under Section 505(b)(2) may therefore be delayed until patent exclusivity expires or until we successfully challenge the applicability of those patents to our product candidates. Alternatively, we may elect to generate sufficient clinical data so that we would no longer need to rely on third-party data, which would be costly and time consuming and there would be no assurance that such data generated from such additional activities would be sufficient to obtain approval.

We may not be able to obtain shortened review of our applications, and the FDA may not agree that BioLexa qualifies for marketing approval. If we are required to generate additional data to support approval, we may be unable to meet anticipated or reasonable development and commercialization timelines, may be unable to generate the additional data at a reasonable cost, or at all, and may be unable to obtain marketing approval of BioLexa. If the FDA changes its interpretation of Section 505(b)(2) allowing reliance on data in a previously approved drug application owned by a third party, or there is a change in the law affecting Section 505(b)(2), this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit.

Modifications to our products may require new NDA approvals.

Once a particular product receives FDA approval or clearance, expanded uses or uses in new indications of our products may require additional human clinical trials and new regulatory approvals or clearances, including additional IND and NDA submissions and premarket approvals before we can begin clinical development, and/or prior to marketing and sales. If the FDA requires new clearances or approvals for a particular use or indication, we may be required to conduct additional clinical studies, which would require additional expenditures and harm our operating results. If the products are already being used for these new indications, we may also be subject to significant enforcement actions. Conducting clinical trials and obtaining clearances and approvals can be a time consuming process, and delays in obtaining required future clearances or approvals could adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.

Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population; the nature of the trial protocol; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical trial investigators; support staff; and proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products.

Additional delays to the completion of clinical studies may result from modifications being made to the protocol during the clinical trial, if such modifications are warranted and/or required by the occurrences in the given trial.

Each modification to the protocol during a clinical trial has to be submitted to the FDA. This could result in the delay or halt of a clinical trial while the modification is evaluated. In addition, depending on the quantity and nature of the changes made, the FDA could take the position that the data generated by the clinical trial is not poolable because the same protocol was not used throughout the trial. This might require the enrollment of additional subjects, which could result in the extension of the clinical trial and the FDA delaying clearance or approval of a product. Any such delay could have a material adverse effect on our business and results of operations.

There can be no assurance that the data generated from our clinical trials using modified protocols will be acceptable to FDA.

There can be no assurance that the data generated using modified protocols will be acceptable to the FDA or that if future modifications during the trial are necessary, that any such modifications will be acceptable to the FDA. If the FDA believes that its prior approval is required for a particular modification, it can delay or halt a clinical trial while it evaluates additional information regarding the change.

Serious injury or death resulting from a failure of one of our drug candidates during current or future clinical trials could also result in the FDA delaying our clinical trials or denying or delaying clearance or approval of a product.

Even though an adverse event may not be the result of the failure of our drug candidate, the FDA or an IRB could delay or halt a clinical trial for an indefinite period of time while an adverse event is reviewed, and likely would do so in the event of multiple such events.

Any delay or termination of our current or future clinical trials as a result of the risks summarized above, including delays in obtaining or maintaining required approvals from IRBs, delays in patient enrollment, the failure of patients to continue to participate in a clinical trial, and delays or termination of clinical trials as a result of protocol modifications or adverse events during the trials, may cause an increase in costs and delays in the filing of any product submissions with the FDA, delay the approval and commercialization of our products or result in the failure of the clinical trial, which could adversely affect our business, operating results and prospects.

If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products.

We do not have the ability to independently conduct our pre-clinical and clinical trials for our products and we must rely on third parties, such as CROs, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations, meet expected deadlines or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control. The occurrence of any of the foregoing may adversely affect our business, operating results and prospects.

The future results of our current or future clinical trials may not support our product candidate claims or may result in the discovery of unexpected adverse side effects.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our drug candidate claims or that the FDA or foreign authorities will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our drug candidates are safe and effective for the proposed indicated uses. If the FDA concludes that the clinical trials for any product for which we might seek clearance, has failed to demonstrate safety and effectiveness, we would not receive FDA clearance to market that product in the United States for the indications sought.

In addition, such an outcome could cause us to abandon the product candidate and might delay development of others. Any delay or termination of our clinical trials will delay the filing of any product submissions with the FDA and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile. In addition, our clinical trials for BioLexa involve a relatively small patient population. Because of the small sample size, our results may not be indicative of future results.

Our current and future products may never achieve market acceptance.

Our current and future products that we may develop may never gain market acceptance among physicians, patients and the medical community. The degree of market acceptance of any of our products will depend on a number of factors, including the actual and perceived effectiveness and reliability of our products; the results of any long-term clinical trials relating to use of our products; the availability, relative cost and perceived advantages and disadvantages of alternative technologies; the degree to which treatments using our products are approved for reimbursement by public and private insurers; the willingness of patients to pay out of pocket in the absence of government or third-party coverage; the strength of our marketing and distribution infrastructure; the level of education and awareness among physicians and hospitals concerning our products; and prevalence and severity of any side effects. Failure of our products to significantly penetrate current or new markets would negatively impact our business, financial condition and results of operations.

To be commercially successful, physicians must be persuaded that using our products are effective alternatives to existing therapies and treatments.

We believe that physicians will not widely adopt our products unless they determine, based on experience, clinical data, and published peer-reviewed journal articles, that the use of our products provides an effective alternative to other means of treating dermatological disorders/ailments, lupus or food allergies. Patient studies or clinical experience may indicate that treatment with our products does not provide patients with sufficient benefits in quality of life. We believe that recommendations and support for the use of our products from influential physicians will be essential for widespread market acceptance. Our products are still in development and it is premature to attempt to gain support from physicians at this time. We can provide no assurance that such support will ever be obtained. If our products do not receive such support from these physicians and from long-term data, physicians may not use or continue to use, and hospitals may not purchase or continue to purchase, our products.

Even if our products are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing FDA regulation or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA. In particular, we and our suppliers are required to comply with FDA's Quality System Regulations, or QSR, and International Standards Organization, or ISO, regulations for the manufacture of our products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval. Regulatory bodies, such as the FDA, enforce these regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, enforcement actions by the FDA.

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

Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce the potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that the product promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we or our commercialization partners cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider such training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with adverse event and pharmacovigilance reporting requirements, including the reporting of adverse events which occur in connection with, and whether or not directly related to, our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to recall, replace or refund the cost of any product we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

Our revenue stream will depend upon third-party reimbursement.

The commercial success of our products in both domestic and international markets will be substantially dependent on whether third-party coverage and reimbursement is available for patients that use our products. However, the availability of insurance coverage and reimbursement for newly approved therapies is uncertain, and therefore, third-party coverage may be particularly difficult to obtain even if our products are approved by the FDA as safe and efficacious. Patients using existing approved therapies are generally reimbursed all or part of the product cost by Medicare or other third-party payors. Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs, and, as a result, they may not cover or provide adequate payment for these products. Submission of applications for reimbursement approval generally does not occur prior to the filing of an NDA for that product and may not be granted for as long as many months after NDA approval. In order to obtain reimbursement arrangements for these products, we or our commercialization partners may have to agree to a net sales price lower than the net sales price we might charge in other sales channels. The continuing efforts of government and third-party payors to contain or reduce the costs of healthcare may limit our revenue. Initial dependence on the commercial success of our products may make our revenues particularly susceptible to any cost containment or reduction efforts.

We will need to make additions to senior management in order to successfully execute our business plan.

The Company will need to identify and recruit prospective executives with proven experience in the biopharmaceutical industry, specifically candidates who have managed and completed FDA-required submissions and clinical trials concerning new products. Robb Knie, the acting Chief Executive Officer, is one of the founders and has agreed to serve in that capacity in the interim. Although his primary background involves electronics and technology, he has experience in venture-level investments and early stage capital formation for emerging growth companies. The Company has entered into an employment agreement with Mr. Knie which includes various provisions that may result in significant financial and severance obligations to the Company. Our inability to recruit and retain executives with proven experience in the biopharmaceutical industry could delay or negatively affect our ability to execute on our business plan, which would have a material adverse effect on our financial condition and results of operation.

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain for such product candidates.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know 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, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the Medicare Modernization Act ("MMA") changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our product candidates and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the "Health Care Reform Law") is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Health Care Reform Law revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the law imposed a significant annual fee on companies that manufacture or import branded prescription drug products.

The Health Care Reform Law remains subject to legislative efforts to repeal, modify or delay the implementation of the law. However, if the Health Care Reform Law is repealed or modified, or if implementation of certain aspects of the Health Care Reform Law are delayed, such repeal, modification or delay may materially adversely impact our business, strategies, prospects, operating results or financial condition. We are unable to predict the full impact of any repeal, modification or delay in the implementation of the Health Care Reform Law on us at this time. Due to the substantial regulatory changes that will need to be implemented by the Centers for Medicare & Medicaid Services and others, and the numerous processes required to implement these reforms, we cannot predict which healthcare initiatives will be implemented at the federal or state level, the timing of any such reforms, or the effect such reforms or any other future legislation or regulation will have on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce or eliminate our profitability.

We are dependent on third parties for manufacturing and marketing of our proposed product candidates. If we are not able to secure favorable arrangements with such third parties, our business and financial condition could be harmed.

We will not manufacture any of our proposed product candidates for commercial sale nor do we have the resources necessary to do so. In addition, we currently do not have the capability to market our drug products ourselves. In addition to our internal sales force efforts, we intend to contract with specialized manufacturing companies to manufacture our proposed product candidates and partner with larger pharmaceutical companies for commercialization of our products. In connection with our efforts to commercialize our proposed product candidates, we will seek to secure favorable arrangements with third parties to distribute, promote, market and sell our proposed product candidates. If our internal sales force is unable to successfully distribute, market and promote our product candidates and we are not able to secure favorable commercial terms or arrangements with third parties for the distribution, marketing, promotion and sales of our proposed product candidates, we may have to retain promotional and marketing rights and seek to develop the commercial resources necessary to promote or co-promote or co-market certain or all of our proposed drug candidates to the appropriate channels of distribution in order to reach the specific medical market that we are targeting. We may not be able to enter into any partnering arrangements on this or any other basis. If we are not able to secure favorable partnering arrangements, or are unable to develop the appropriate resources necessary for the commercialization of our proposed product candidates, our business and financial condition could be harmed. In addition, we will have to hire additional employees or consultants, since our current employees have limited experience in these areas. Sufficient employees with relevant skills may not be available to us. Any increase in the number of our employees would increase our expense level, and could have an adverse effect on our financial position.

In addition, we, or our potential commercial partners, may not successfully introduce our proposed product candidates or such candidates may not achieve acceptance by patients, health care providers and insurance companies. Further, it is possible that we may not be able to secure arrangements to manufacture, market, distribute, promote and sell our proposed product candidates at favorable commercial terms that would permit us to make a profit. To the extent that corporate partners conduct clinical trials, we may not be able to control the design and conduct of these clinical trials.

We may have conflicts with our partners that could delay or prevent the development or commercialization of our product candidates.

We may have conflicts with our partners, such as conflicts concerning the interpretation of pre-clinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our partners, such partner may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenues: unwillingness on the part of a partner to pay us milestone payments or royalties we believe are due to us under a collaboration; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the partner to cooperate in the development or manufacture of the product, including providing us with product data or materials; unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

Even if we receive regulatory approval for any of our product candidates, we may not be able to successfully commercialize the product and the revenue that we generate from its sales, if any, may be limited.

If approved for marketing, the commercial success of our product candidates will depend upon each product's acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance for any of our product candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience, dosing burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our product candidates, and the target patient population to try new therapies;
- efficacy of our product candidates compared to competing products;
- the introduction of any new products that may in the future become available targeting indications for which our product candidates may be approved;

- new procedures or therapies that may reduce the incidences of any of the indications in which our product candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our product candidates in applicable therapeutic and vaccine guidelines;
- the effectiveness of our own or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in approved labeling from regulatory authorities;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement or government pricing approvals.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our product candidates not commercially viable. For example, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve any of our product candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization for that indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals or require risk management plans or a REMS to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require a REMS for an approved product when new safety information emerges. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our product candidates. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our product candidates.

Upon commercialization of our products, we may be dependent on third parties to market, distribute and sell our products.

Our ability to receive revenues may be dependent upon the sales and marketing efforts of any future co-marketing partners and third-party distributors. At this time, we have not entered into an agreement with any commercialization partner and only plan to do so prior to commercialization. If we fail to reach an agreement with any commercialization partner, or upon reaching such an agreement that partner fails to sell a large volume of our products, it may have a negative impact on our business, financial condition and results of operations.

Our products will face significant competition in the markets for such products, and if they are unable to compete successfully, our business will suffer.

Our product candidates face, and will continue to face, intense competition from large pharmaceutical companies, as well as academic and research institutions. We compete in an industry that is characterized by: (i) rapid technological change, (ii) evolving industry standards, (iii) emerging competition and (iv) new product introductions. Our competitors have existing products and technologies that will compete with our products and technologies and may develop and commercialize additional products and technologies that will compete with our products and technologies. Because several competing companies and institutions have greater financial resources than us, they may be able to: (i) provide broader services and product lines, (ii) make greater investments in research and development and (iii) carry on larger research and development initiatives. Our competitors also have greater development capabilities than we do and have substantially greater experience in undertaking pre-clinical and clinical testing of products, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. They also have greater name recognition and better access to customers than us. Our chief competitors include companies such as Pfizer Inc. and Sanofi S.A.

Adverse events involving our products may lead the FDA to delay or deny clearance for our products or result in product recalls that could harm our reputation, business and financial results.

Once a product receives FDA clearance or approval, the agency has the authority to require the recall of commercialized products in the event of adverse side effects, material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is a reasonable probability that the product would cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of adverse side effects, impurities or other product contamination, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within ten working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

If we fail to comply with healthcare regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected.

We could be subject to healthcare fraud and abuse laws and patient privacy laws of both the federal government and the states in which we conduct our business. The laws include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims 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 payers that are false or fraudulent, and which may apply to entities like us which provide coding and billing information to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the FDCA which among other things, strictly regulates drug manufacturing and product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, 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 often are not preempted by federal laws, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

If third-party contract manufacturers upon whom we rely to formulate and manufacture our product candidates do not perform, fail to manufacture according to our specifications or fail to comply with strict regulations, our pre-clinical studies or clinical trials could be adversely affected and the development of our product candidates could be delayed or terminated or we could incur significant additional expenses.

We do not own or operate any manufacturing facilities. We intend to rely on third-party contractors, at least for the foreseeable future, to formulate and manufacture these pre-clinical and clinical materials. Our reliance on third-party contract manufacturers exposes us to a number of risks, any of which could delay or prevent the completion of our pre-clinical studies or clinical trials, or the regulatory approval or commercialization of our product candidates, result in higher costs, or deprive us of potential product revenues. Some of these risks include:

- our third-party contractors failing to develop an acceptable formulation to support later-stage clinical trials for, or the commercialization of, our product candidates;
- our contract manufacturers failing to manufacture our product candidate according to their own standards, our specifications, the FDA's cGMP requirements, or otherwise manufacturing material that we or the FDA may deem to be unsuitable in our clinical trials;
- our contract manufacturers being unable to increase the scale of, increase the capacity for, or reformulate the form of our product candidates. We may experience a shortage in supply, or the cost to manufacture our products may increase to the point where it adversely affects the cost of our product candidates. We cannot assure you that our contract manufacturers will be able to manufacture our product candidates at a suitable scale, or we will be able to find alternative manufacturers acceptable to us that can do so;
- our contract manufacturers placing a priority on the manufacture of their own products, or other customers' products;
- our contract manufacturers failing to perform as agreed or not remain in the contract manufacturing business; and
- our contract manufacturers' plants being closed as a result of regulatory sanctions or a natural disaster.

Manufacturers of pharmaceutical products are subject to ongoing periodic inspections by the FDA, the U.S. Drug Enforcement Administration and corresponding state and foreign agencies to ensure strict compliance with FDA-mandated cGMPs, other government regulations and corresponding foreign standards. While we are obligated to audit their performance, we do not have control over our third-party contract manufacturers' compliance with these regulations and standards. Failure by our third-party manufacturers, or us, to comply with applicable regulations could result in sanctions being imposed on us or the drug manufacturer from the production of other third-party products. These sanctions may include fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

In the event that we need to change our third-party contract manufacturers, our pre-clinical studies, clinical trials or the commercialization of our product candidate could be delayed, adversely affected or terminated, or such a change may result in significantly higher costs.

Various steps in the manufacture of our product candidate may need to be sole-sourced. In accordance with cGMPs, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further pre-clinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing our current or future contract manufacturers may be difficult for us and could be costly, which could result in our inability to manufacture our product candidates for an extended period of time and therefore a delay in the development of our product candidates. Further, in order to maintain our development time lines in the event of a change in our third-party contract manufacturer, we may incur significantly higher costs to manufacture our product candidates.

Healthcare Reform in the United States.

In the United States, there have been, and continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect the future results of pharmaceutical manufactures' operations. In particular, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. Most recently, the Patient Protection and Affordable Care Act ("PPACA") was enacted in March 2010, which includes measures to significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the PPACA of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- implementation of the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act";
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and
- expansion of the entities eligible for discounts under the Public Health program.

Some of the provisions of the PPACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the PPACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Congress may consider other legislation to repeal or replace elements of the PPACA.

Many of the details regarding the implementation of the PPACA are yet to be determined, and at this time, the full effect that the PPACA would have on a pharmaceutical manufacturer remains unclear. In particular, there is uncertainty surrounding the applicability of the biosimilars provisions under the PPACA. The FDA has issued several guidance documents, but no implementing regulations, on biosimilars. A number of biosimilar applications have been approved over the past few years. The regulations that are ultimately promulgated and their implementation are likely to have considerable impact on the way pharmaceutical manufacturers conduct their business and may require changes to current strategies. A biosimilar is a biological product that is highly similar to an approved drug notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the approved drug in terms of the safety, purity, and potency of the product.

Individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm a pharmaceutical manufacturer's business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for certain products or put pressure product pricing, which could negatively affect a pharmaceutical manufacturer's business, results of operations, financial condition and prospects.

In addition, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. While no one cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm a pharmaceutical manufacturer's ability to generate revenue. Increases in importation or re-importation of pharmaceutical products from foreign countries into the United States could put competitive pressure on a pharmaceutical manufacturer's ability to profitably price products, which, in turn, could adversely affect business, results of operations, financial condition and prospects. A pharmaceutical manufacturer might elect not to seek approval for or market products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue generated from product sales. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, affect whether government agencies promptly pay amounts awarded under grants from such agencies, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new drugs and medical devices can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and medical devices to be reviewed and/or approved by necessary government agencies as well as affect whether we receive timely payment of amounts awarded to us under grants and contracts with government agencies which would adversely affect our business. For example, over the last several years, including from December 22, 2018 until January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Security threats to our information technology infrastructure and/or our physical buildings could expose us to liability and damage our reputation and business.

It is essential to our business strategy that our technology and network infrastructure and our physical buildings remain secure and are perceived by our customers and corporate partners to be secure. Despite security measures, however, any network infrastructure may be vulnerable to cyber-attacks by hackers and other security threats. We may face cyber-attacks that attempt to penetrate our network security, sabotage or otherwise disable our research, products and services, misappropriate our or our customers' and partners' proprietary information, which may include personally identifiable information, or cause interruptions of our internal systems and services. Despite security measures, we also cannot guarantee security of our physical buildings. Physical building penetration or any cyber-attacks could negatively affect our reputation, damage our network infrastructure and our ability to deploy our products and services, harm our relationship with customers and partners that are affected, and expose us to financial liability.

Additionally, there are a number of state, federal and international laws protecting the privacy and security of health information and personal data. For example, the HIPAA imposes limitations on the use and disclosure of an individual's healthcare information by healthcare providers, healthcare clearinghouses, and health insurance plans, or, collectively, covered entities, and also grants individuals rights with respect to their health information. HIPAA also imposes compliance obligations and corresponding penalties for non-compliance on individuals and entities that provide services to healthcare providers and other covered entities. As part of the American Recovery and Reinvestment Act of 2009 ("ARRA") the privacy and security provisions of HIPAA were amended. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. As amended by ARRA and subsequently by the final omnibus rule adopted in 2013, HIPAA also imposes notification requirements on covered entities in the event that certain health information has been inappropriately accessed or disclosed, notification requirements to individuals, federal regulators, and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by the U.S. Department of Health and Human Services. Most states have laws requiring notification of affected individuals and/or state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms, to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

Risks Relating to Our Intellectual Property Rights

We rely on licenses granted to us by Chelexa, the University of Cincinnati, Zylö, North Carolina State University and George Washington University, and if such licensors do not adequately defend such licenses, our business may be harmed.

Our primary asset is a sublicense agreement with Chelexa pursuant to which Chelexa has granted us an exclusive sublicense to use its BioLexa Platform, a proprietary, patented, drug compound platform developed at the University of Cincinnati. The license enables us to develop the platform for any indications in humans. In addition, we entered into an exclusive license agreement with the University of Cincinnati with respect to a patented, novel genetic marker for food allergies. We also entered into the Sublicense Agreement with Zylö in connection with the development of a treatment for patients suffering from CLE including patents with respect thereto developed by Albert Einstein College of Medicine. We have also entered into a license agreement with NCSU with respect to NCSU's exon skipping approach for treating allergic diseases, and a license agreement with GW with respect to aprepitant as used in treating side effects from drugs used for the treatment of cancer. We rely on the Chelexa, the University of Cincinnati, Zylö, Albert Einstein College of Medicine, NCSU and GW to and otherwise protect the intellectual property, including the patents, covered by our licenses. We have limited control over the activities of Chelexa, the University of Cincinnati, Zylö, Albert Einstein College of Medicine, NCSU, GW or over any other intellectual property that may be related to the BioLexa Platform, the genetic marker, CLE, exon skipping approach for treating allergic diseases or aprepitant. For example, we cannot be certain that activities by Chelexa, the University of Cincinnati, Zylö, Albert Einstein College of Medicine, NCSU or GW have been or will be conducted in compliance with applicable laws and regulations. We may have no control or input over whether, and in what manner, the University of Cincinnati, Albert Einstein College of Medicine, NCSU and/or GW may enforce or defend the patents against a third-party. The University of Cincinnati, Albert Einstein College of Medicine, NCSU and/or GW may enforce or defend the patent less vigorously than if we had enforced or defended the patents ourselves. Further, the University of Cincinnati, Albert Einstein College of Medicine, NCSU and/or GW may not necessarily seek enforcement in scenarios in which we would feel that enforcement was in our best interests. For example, the University of Cincinnati, Albert Einstein College of Medicine, NCSU and/or GW may not enforce the patents against a competitor of ours who is not a direct competitor of the University of Cincinnati, Albert Einstein College of Medicine, NCSU or GW, as applicable. If our in-licensed intellectual property is found to be invalid or unenforceable, then the University of Cincinnati, Albert Einstein College of Medicine, NCSU and/or GW may not be able to enforce the patents against a competitor of ours. If we fail to meet our obligations under the sublicense agreement with Chelexa or Chelexa fails to meet its obligations under its license agreement with the University of Cincinnati, then the University of Cincinnati may terminate the license agreement with Chelexa thereby terminating our sublicense agreement with Chelexa, and we will be unable to conduct our business. Similarly, if we fail to meet our obligations under the sublicense agreement with Zylö or Zylö fails to meet its obligations under its license agreement with Albert Einstein College of Medicine, then Albert Einstein College of Medicine may terminate the license agreement with Zylö thereby terminating our sublicense agreement with Zylö, and we will be unable to conduct our business with respect to the development of treatment for patients suffering from CLE. In addition, if we fail to meet our obligations under the license agreement with the University of Cincinnati, NCSU or GW then the University of Cincinnati, NCSU or GW, as applicable, may terminate our license agreement, and we will be unable to continue to use their products in our business. Although we may choose to terminate our license agreements, doing so would allow a third party to seek and obtain an exclusive license to the BioLexa Platform, the genetic marker and the patents relating to CLE NCSU's exon skipping approach for treating allergic diseases and aprepitant, If a third party obtains an exclusive license to intellectual property with respect to the foregoing products and technologies formerly licensed to us, then the third party may seek to enforce the intellectual property against us which may have a material adverse effect on our business.

We are dependent upon our sublicense agreement with Chelexa with respect to the BioLexa Platform and Zylö with respect the development of a treatment for patients suffering from CLE; however, we have no control over the license agreement between Chelexa and the University of Cincinnati or the license agreement between Zylö and Albert Einstein College of Medicine.

Our sublicense agreements with Chelexa and Zylö are subject to many risks and uncertainties. Although we are dependent upon our sublicense agreement with Chelexa with respect to the BioLexa Platform and Zylö with respect the development of a treatment for patients suffering from CLE, we have no control over the license agreement between Chelexa and the University of Cincinnati pursuant to which the University of Cincinnati licensed the BioLexa Platform to Chelexa or the license agreement between Zylö and Albert Einstein College of Medicine pursuant to which Albert Einstein College of Medicine licensed certain patent rights relating to CLE to Zylö. In the event that Chelexa is unable to fulfill its obligations to the University of Cincinnati pursuant to the terms of its license agreement, the University of Cincinnati may terminate the license thereby voiding our sublicense. Similarly, in the event that Zylö is unable to fulfill its obligations to Albert Einstein College of Medicine pursuant to the terms of its license agreement, Albert Einstein College of Medicine may terminate the license thereby voiding our sublicense. In the event that either the license agreement between Chelexa and the University of Cincinnati or the license agreement between Zylö and Albert Einstein College of Medicine is terminated, there may be a material adverse effect upon our business.

Our business depends upon securing and protecting critical intellectual property.

Although we do not own and only license intellectual property, to the extent we develop intellectual property, our commercial success will depend in part on obtaining and maintaining patent, trade secret, copyright and trademark protection of our technologies in the United States and other jurisdictions as well as successfully enforcing and defending such intellectual property rights against third-party challenges. We will only be able to protect our intellectual property from unauthorized use by third parties to the extent that valid and enforceable intellectual property protection, such as patents or trade secrets, cover them. In particular, we place considerable emphasis on obtaining patent and trade secret protection for significant new technologies, products and processes. Furthermore, the degree of future protection of our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Moreover, the degree of future protection of our proprietary rights is uncertain for products that are currently in the early stages of development because we cannot predict which of these products will ultimately reach the commercial market or whether the commercial versions of these products will incorporate proprietary technologies.

Patent positions in our industry are highly uncertain and involve complex legal and factual questions.

Patent positions in our industry are highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. For example, we or our licensors might not have been the first to make the inventions covered by our pending patent applications and issued patents, as applicable; we or our licensors might not have been the first to file patent applications for these inventions; others may independently develop similar or alternative technologies or duplicate any of our technologies; it is possible that none of our pending patent applications or the pending patent applications of our licensors will result in issued patents; our issued patents and issued patents of our licensors may not provide a basis for commercially viable technologies, or may not provide us with any competitive advantages, or may be challenged and invalidated by third parties; and, we may not develop additional proprietary technologies that are patentable.

As a result, our owned and licensed patents may not be valid and we may not be able to obtain and enforce patents and to maintain trade secret protection for the full commercial extent of our technology. The extent to which we are unable to do so could materially harm our business.

We or our licensors have applied for and will continue to apply for patents for certain products. Such applications may not result in the issuance of any patents, and any patents now held or that may be issued may not provide us with adequate protection from competition. Furthermore, it is possible that patents issued or licensed to us may be challenged successfully. In that event, if we have a preferred competitive position because of such patents, any preferred position held by us would be lost. If we are unable to secure or to continue to maintain a preferred position, we could become subject to competition from the sale of generic products. Failure to receive, inability to protect, or expiration of our patents for medical use, manufacture, conjugation and labeling of BioLexa, the product platform that we license from Chelexa, or subsequent related filings, would adversely affect our business and operations.

Patents issued or licensed to us may be infringed by the products or processes of others. The cost of enforcing our patent rights against infringers, if such enforcement is required, could be significant, and we do not currently have the financial resources to fund such litigation. Further, such litigation can go on for years and the time demands could interfere with our normal operations. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. We may become a party to patent litigation and other proceedings. The cost to us of any patent litigation, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation more effectively than we can because of their substantially greater financial resources. Litigation may also absorb significant management time.

Unpatented trade secrets, improvements, confidential know-how and continuing technological innovation are important to our scientific and commercial success. Although we attempt to and will continue to attempt to protect our proprietary information through reliance on trade secret laws and the use of confidentiality agreements with our corporate partners, collaborators, employees and consultants and other appropriate means, these measures may not effectively prevent disclosure of our proprietary information, and, in any event, others may develop independently, or obtain access to, the same or similar information.

The patent rights for our primary product are licensed to us by third parties. If we fail to comply with the terms of these license agreements, our rights to those patents may be terminated, and we will be unable to conduct our business.

If we are found to be infringing on patents or trade secrets owned by others, we may be forced to cease or alter our product development efforts, obtain a license to continue the development or sale of our products, and/or pay damages.

Our manufacturing processes and potential products may violate proprietary rights of patents that have been or may be granted to competitors, universities or others, or the trade secrets of those persons and entities. As the pharmaceutical industry expands and more patents are issued, the risk increases that our processes and potential products may give rise to claims that they infringe the patents or trade secrets of others. These other persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the affected product or process. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to conduct clinical tests, manufacture or market the affected product or use the affected process. Required licenses may not be available on acceptable terms, if at all, and the results of litigation are uncertain. If we become involved in litigation or other proceedings, it could consume a substantial portion of our financial resources and the efforts of our personnel.

Our ability to protect and enforce any patents we may obtain does not guaranty that we will secure the right to commercialize such patents.

A patent is a limited monopoly right conferred upon an inventor, and his successors in title, in return for the making and disclosing of a new and non-obvious invention. This monopoly is of limited duration but, while in force, allows the patent holder to prevent others from making and/or using his invention. While a patent gives the holder this right to exclude others, it is not a license to commercialize the invention, where other permissions may be required for permissible commercialization to occur. For example, a drug cannot be marketed without the appropriate authorization from the FDA, regardless of the existence of a patent covering the product. Further, the invention, even if patented itself, cannot be commercialized if it infringes the valid patent rights of another party.

We rely on confidentiality agreements to protect our trade secrets. If these agreements are breached by our employees or other parties, our trade secrets may become known to our competitors.

We rely on trade secrets which we seek to protect through confidentiality agreements with our employees and other parties. If these agreements are breached, our competitors may obtain and use our trade secrets to gain a competitive advantage over us. We may not have any remedies against our competitors and any remedies that may be available to us may not be adequate to protect our business or compensate us for the damaging disclosure. In addition, we may have to expend resources to protect our interests from possible infringement by others.

Related Risks to the Company

We have expanded and may continue to expand, our business through the acquisition of rights to new drug candidates that could disrupt our business, harm our financial condition and may also dilute current shareholders' ownership interests in our Company.

Our business strategy includes expanding our products and capabilities, and we may seek acquisitions of additional drug candidates or technologies to do so. Acquisitions involve numerous risks, including substantial cash expenditures; potentially dilutive issuance of equity securities; incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition; difficulties in assimilating the acquired technologies or the operations of the acquired companies; diverting our management's attention away from other business concerns; risks of entering markets in which we have limited or no direct experience; and the potential loss of our key employees or key employees of the acquired companies.

We cannot assure you that any acquisition will result in short-term or long-term benefits to us. We may misjudge the value or worth of an acquired product, company or business. In addition, our future success would depend in part on our ability to manage the rapid growth associated with acquisitions. We cannot assure you that we will be able to make the combination of our business with that of acquired products, businesses or companies work or be successful. Furthermore, the development or expansion of our business or any acquired products, business or companies may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our preferred or common stock, which could dilute each current shareholder's ownership interest in the Company.

We may undertake international operations, which will subject us to risks inherent with operations outside of the United States.

Although we do not have any foreign operations at this time, we intend to seek to obtain market clearances in foreign markets that we deem to generate significant opportunities. However, even with the cooperation of a commercialization partner, conducting drug development in foreign countries involves inherent risks, including, but not limited to: difficulties in staffing, funding and managing foreign operations; unexpected changes in regulatory requirements; export restrictions; tariffs and other trade barriers; difficulties in protecting, acquiring, enforcing and litigating intellectual property rights; fluctuations in currency exchange rates; and potentially adverse tax consequences.

If we were to experience any of the difficulties listed above, or any other difficulties, any international development activities and our overall financial condition may suffer and cause us to reduce or discontinue our international development and registration efforts.

We may not be successful in hiring and retaining key employees, including executive officers.

Our future operations and successes depend in large part upon the strength of our management team. We rely heavily on the continued service of Robb Knie, our President and Chief Executive Officer. Accordingly, if Mr. Knie terminates his employment with us, such a departure may have a material adverse effect on our business, and our future success depends on our ability to identify, attract, hire or engage, retain and motivate other well-qualified financial, managerial, technical, clinical and regulatory personnel. There can be no assurance that these professionals will be available in the market, or that we will be able to retain existing professionals or to meet or to continue to meet their compensation requirements. Furthermore, the cost base in relation to such compensation, which may include equity compensation, may increase significantly, which could have a material adverse effect on us. Failure to establish and maintain an effective management team and work force could adversely affect our ability to operate, grow and manage our business.

Managing our growth as we expand operations may strain our resources.

We expect to grow rapidly in order to support additional, larger, and potentially international, pivotal clinical trials of our drug candidates, which will place a significant strain on our financial, managerial and operational resources. In order to achieve and manage growth effectively, we must continue to improve and expand our operational and financial management capabilities. Moreover, we will need to increase staffing and to train, motivate and manage our employees. All of these activities will increase our expenses and may require us to raise additional capital sooner than expected. Failure to manage growth effectively could harm our business, financial condition or results of operations.

If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business.

The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We currently do not have product liability insurance coverage but we intend to obtain such insurance. Such insurance coverage may not protect us against any or all of the product liability claims that may be brought against us in the future. We may not be able to acquire or maintain adequate product liability insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. In the event our product candidate is approved for sale by the FDA and commercialized, we may need to substantially increase the amount of our product liability coverage. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business.

Risks Related to Our Common Stock

The price of our common stock may fluctuate substantially.

You should consider an investment in our common stock to be risky, and you should invest in our common stock only if you can withstand a significant loss and wide fluctuations in the market value of your investment. Some factors that may cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, are:

- sale of our common stock by our shareholders, executives, and directors;
- volatility and limitations in trading volumes of our shares of common stock;
- our ability to obtain financings to conduct and complete research and development activities including, but not limited to, our clinical trials, and other business activities;
- the timing and success of introductions of new products by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors;
- our ability to attract new customers;
- our ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;
- commencement, enrollment or results of our clinical trials for our product candidates or any future clinical trials we may conduct;
- changes in the development status of our product candidates;
- any delays or adverse developments or perceived adverse developments with respect to the FDA's review of our planned pre-clinical and clinical trials;
- any delay in our submission for studies or product approvals or adverse regulatory decisions, including failure to receive regulatory approval for our product candidates;
- unanticipated safety concerns related to the use of our product candidates;
- changes in our capital structure or dividend policy, future issuances of securities, sales of large blocks of common stock by our shareholders;

- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new products;
- reputational issues;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new products, capital commitments, or other events by us or our competitors;
- changes in general economic, political and market conditions in or any of the regions in which we conduct our business;
- changes in industry conditions or perceptions;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigations related to intellectual properties, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

We may acquire other companies or technologies, which could divert our management's attention, result in dilution to our stockholders and otherwise disrupt our operations and adversely affect our operating results.

We may in the future seek to acquire or invest in businesses, applications and services or technologies that we believe could complement or expand our services, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated.

In addition, we do not have any experience in acquiring other businesses. If we acquire additional businesses, we may not be able to integrate the acquired personnel, operations and technologies successfully, or effectively manage the combined business following the acquisition. We also may not achieve the anticipated benefits from the acquired business due to a number of factors, including:

- inability to integrate or benefit from acquired technologies or services in a profitable manner;

- unanticipated costs or liabilities associated with the acquisition;
- difficulty integrating the accounting systems, operations and personnel of the acquired business;
- difficulties and additional expenses associated with supporting legacy products and hosting infrastructure of the acquired business;
- difficulty converting the customers of the acquired business onto our platform and contract terms, including disparities in the revenue, licensing, support or professional services model of the acquired company;
- diversion of management's attention from other business concerns;
- adverse effects to our existing business relationships with business partners and customers as a result of the acquisition;
- the potential loss of key employees;
- use of resources that are needed in other parts of our business; and
- use of substantial portions of our available cash to consummate the acquisition.

In addition, a significant portion of the purchase price of companies we acquire may be allocated to acquired goodwill and other intangible assets, which must be assessed for impairment at least annually. In the future, if our acquisitions do not yield expected returns, we may be required to take charges to our operating results based on this impairment assessment process, which could adversely affect our results of operations.

Acquisitions could also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial position may suffer.

Market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over inflation, energy costs, geopolitical issues, the U.S. mortgage market and a declining real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

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

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our common stock, the lack of research coverage may adversely affect the market price of our common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

Because certain of our shareholders control a significant number of shares of our common stock, they may have effective control over actions requiring shareholder approval.

As of February 28, 2020, our directors and executive officers and their respective affiliates, beneficially own approximately 20.93% of our outstanding shares of common stock on a fully diluted basis. As a result, these shareholders acting together, would have the ability to control the outcome of matters submitted to our shareholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these shareholders, acting together, would have the ability to control the management and affairs of our Company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Future sales and issuances of our securities could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, including research and development, increased marketing, hiring new personnel, commercializing our products, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our shareholders may experience substantial dilution. 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 may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing shareholders, and new investors could gain rights superior to our existing shareholders.

We do not intend to pay cash dividends on our shares of common stock so any returns will be limited to the value of our shares.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to shareholders will therefore be limited to the increase, if any, of our share price.

We are an "emerging growth company" and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended ("Sarbanes-Oxley"), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. In addition, pursuant to Section 107 of the JOBS Act, as an "emerging growth company" we intend to take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We cannot predict if investors will find our common stock less attractive because we may 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. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of our initial public offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. 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 and results in a decline in the market price of our common stock.

We are currently listed on The Nasdaq Capital Market. If we are unable to maintain listing of our securities on Nasdaq or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our stockholders to sell their securities.

Although our common stock is currently listed on The Nasdaq Capital Market, we may not be able to continue to meet the exchange's minimum listing requirements or those of any other national exchange. If we are unable to maintain listing on Nasdaq or if a liquid market for our common stock does not develop or is sustained, our common stock may remain thinly traded.

The Listing Rules of Nasdaq require listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, we should fail to maintain compliance with these listing standards and Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another national securities exchange, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our stockholders:

- the liquidity of our common stock;
- the market price of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of institutional and general investors that will consider investing in our common stock;
- the number of investors in general that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock.

Financial reporting obligations of being a public company in the United States are expensive and time-consuming, and our management will be required to devote substantial time to compliance matters.

As a publicly traded company we incur significant legal, accounting and other expenses. The obligations of being a public company in the United States require significant expenditures and places significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the listing requirements of The Nasdaq Capital Market. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company." In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

If we fail to comply with the rules under Sarbanes-Oxley related to internal controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal controls over financial reporting, our stock price could decline significantly and raising capital could be more difficult.

Section 404 of Sarbanes-Oxley requires annual management assessments of the effectiveness of our internal controls over financial reporting. If we fail to comply with the rules under Sarbanes-Oxley related to disclosure controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal controls over financial reporting, our stock price could decline significantly and raising capital could be more difficult. If material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal controls, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of Sarbanes-Oxley. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly.

The 2017 Comprehensive tax reform could adversely affect our business and financial condition.

The Tax Cuts and Jobs Act of 2017 (the "Tax Cut Act") among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a single rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses carried forward from taxable years beginning after December 31, 2017 to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), providing immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reduction of tax credits under the Orphan Drug Act). Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if, and to what extent, various states will conform to the Tax Act. We urge our shareholders to consult with their legal and tax advisors with respect to any such legislation and the potential tax consequences of investing in our securities.

Our Articles of Incorporation, as amended ("Articles of Incorporation") our Amended and Restated Bylaws, and Nevada law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our Articles of Incorporation, Amended and Restated Bylaws, and Nevada law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. We are authorized to issue up to 10,000,000 shares of preferred stock, none of which are outstanding as of February25, 2020. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by shareholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. As of February 28, 2020, 5,000,000 shares of our preferred stock have been designated as Series A Preferred Stock of which 3,102,480 shares of Series A Preferred Stock which were previously issued were converted into common stock at the time of our initial public offering and 1,897,520 shares of Series A Preferred Stock remain authorized. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our Articles of Incorporation, our Amended and Restated Bylaws and Nevada law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a shareholder might consider favorable. Such provisions may also prevent or frustrate attempts by our shareholders to replace or remove our management. In particular, the Articles of Incorporation, our Amended and Restated Bylaws and Nevada law, as applicable, among other things:

- provide the board of directors with the ability to alter the Amended and Restated Bylaws without shareholder approval;
- place limitations on the removal of directors;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at shareholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

Our Amended and Restated Bylaws provide that the Eighth Judicial District Court of Clark County, Nevada will be the sole and exclusive forum for certain disputes which could limit stockholders' ability to obtain a favorable judicial forum for disputes with the Company or its directors, officers, employees or agents.

Our Amended and Restated Bylaws provide that unless the Company consents in writing to the selection of an alternative forum, the Eighth Judicial District Court of Clark County, Nevada shall be the sole and exclusive forum for state law claims with respect to: (i) any derivative action or proceeding brought in the name or right of the Company or on its behalf, (ii) any action asserting a claim for breach of any fiduciary duty owed by any director, officer, employee or agent of the Company to the Company or the Company's stockholders, (iii) any action arising or asserting a claim arising pursuant to any provision of Nevada Revised Statutes Chapters 78 or 92A or any provision of the Company's Articles of Incorporation or Amended and Restated Bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine, including, without limitation, any action to interpret, apply, enforce or determine the validity of the Company's Articles of Incorporation or Amended and Restated Bylaws. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with the Company or its directors, officers, other employees or agents, which may discourage such lawsuits against the Company and its directors, officers, other employees and agents. Alternatively, if a court were to find the choice of forum provision contained in our Amended and Restated Bylaws to be inapplicable or unenforceable in an action, the Company may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on the Company's business, results of operations, and financial condition.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our executive office is located at 1 Rockefeller Plaza, Suite 1039, New York, NY 10020. We lease our office for approximately $2,500 per month pursuant to a lease which terminates on July 31, 2020. We believe that our existing facilities are suitable and adequate to meet our current needs. We intend to add new facilities or expand existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

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

On February 15, 2019, our common stock began trading on The Nasdaq Capital Market under the symbol "HOTH." Prior to that time, there was no public market for our common stock.

Stockholders

As of February 28, 2020, there were 156 stockholders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors that our board of directors deems relevant.

Recent Sales of Unregistered Securities

From January 2019 until December 2019, the Company issued an aggregate of 8,328 shares of the Company's common stock, which shares are subject to a vesting schedule, to a member of the Company's Board for services rendered.

On February 20, 2019, the Company issued Laidlaw & Company (UK) Ltd. a warrant to purchase up to 50,000 shares of common stock for services rendered in connection with the Company's initial public offering.

On April 17, 2019, the Company entered into a Master Service Agreement with a consultant. In consideration for services provided by the consultant, the Company issued the consultant a two year warrant to purchase up to 50,000 shares of the Company's common stock at an exercise price of $0.01 per share. On May 22, 2019, the Company and consultant agreed to terminate the Master Service Agreement and number of shares of the Company's common stock issuable upon exercise of the consultant's warrant was reduced to 16,333. In June 2019, the Company issued 16,333 shares of common stock upon exercise of the consultant's warrant.

On September 26, 2019, the Company issued 10,000 and 30,000 shares of common stock to the Benchmark Company, LLC and FON Consulting, LLC, respectively, for services rendered.

On December 24, 2019, the Company issued its officers, directors and an advisor options to purchase an aggregate of 475,000 shares of common stock at an exercise price of $5.26 per share for services rendered.

The foregoing offers, sales and issuances were exempt from registration under Section 4(a)(2) of the Securities Act and/or Rule 506 of Regulation D thereunder.

ITEM 6. SELECTED FINANCIAL DATA

As a smaller reporting company, we are not required to provide the information required by this item.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITIONS AND RESULT OF OPERATIONS

You should read the following discussion and analysis of our financial condition and plan of operations together with and our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Annual Report on Form 10-K. All amounts in this report are in U.S. dollars, unless otherwise noted.

Overview

We are a clinical-stage biopharmaceutical company incorporated in May 2017 focused on developing new generation therapies for dermatological disorders. We believe that our pipeline has the potential to improve the quality of life for patients suffering from indications including atopic dermatitis (also known as eczema), chronic wounds, psoriasis, asthma and acne.

Our primary asset is a sublicense agreement with Chelexa which we entered into on May 26, 2017, as amended on August 22, 2018 and August 29, 2018, pursuant to which Chelexa has granted us an exclusive sublicense to make, use, have made, import, offer for sale, and sell products based upon or involving the BioLexa Platform, which rights were originally granted to Chelexa pursuant to an exclusive license agreement with the University of Cincinnati. The license enables us to develop the platform for any indications in humans. Our initial focus will be on the treatment of eczema through the application of a topical cream. Although our initial focus will be on the treatment of eczema, we intend to develop a second topical cream which, upon application, is intended to reduce post-procedure infections, accelerate healing and improve clinical outcomes for patients undergoing aesthetic dermatology procedures. In addition, we conducted an initial pilot study on the efficacy of BioLexa to accelerate diabetic wound healing and intend to conduct additional studies with respect to the regenerative effects of the BioLexa Platform in the context of chronic diabetic ulcers, with and without substantial bacterial burden. The BioLexa Platform combines an FDA approved zinc chelator with one or more approved antibiotics in a topical dosage form to address unchecked eczema flare-ups by preventing the formation of infectious biofilms and the resulting clogging of sweat ducts which trigger symptoms. It is the first product candidate intended to prevent the symptom triggering flare-ups rather than simply treating symptoms when they occur.

We intend to initially use the BioLexa Platform to develop two different topical cream products: (i) a product to treat eczema and (ii) a product that reduces post-procedure infections, accelerates healing and improves clinical outcomes for patients undergoing aesthetic dermatology procedures. Eczema is a disease that results in inflammation of the skin and is characterized by rash, red skin, and itchiness. Eczema is also referred to as atopic dermatitis. We are concentrating our effort and resources to develop the BioLexa Platform, utilizing our novel formulation and approach for these two markets.

The BioLexa Platform has achieved positive results in its initial pre-clinical studies conducted at the University of Miami. BioLexa's formulation is a new topical dosage form "repurposing" the antibiotic, enabling it to be developed for use in patients following a special regulatory pathway codified in Section 505(b)(2) of the FDA rules. Section 505(b)(2) of the FDCA was enacted to enable sponsors to seek NDA approval for novel repurposed drugs without the need for such sponsors to undertake time consuming and expensive pre-clinical safety studies and Phase 1 safety studies. Proceeding under this regulatory pathway, we will be able to rely upon all of the publicly available safety and toxicology data with respect to gentamicin and zinc chelator in our FDA submissions. We will be required to conduct a Phase 2 study to show the safety of the combination in humans and after such Phase 2 study will be required to proceed to Phase 3 pivotal clinical trials. We believe that this path will dramatically reduce the required clinical development effort, costs and risks as compared to what would be required of us if we were required to conduct pre-clinical safety, toxicology and animal studies together with Phase 1 human safety trials required for new chemical entities which are not eligible to be reviewed pursuant to the Section 505(b)(2) regulatory pathway. We estimate that by using the Section 505(b)(2) regulatory pathway, that the clinical development process may be five to six years shorter than is required for a new chemical entity, and the FDA approval process may be six to nine months shorter than the typical eighteen month period, which we believe may result in lower development costs and shorter development time. As of the date hereof, we have not submitted an NDA to the FDA. In September 2018, we attended the first of a planned series of meetings with the FDA to review the requirements for submission and activation of an IND with respect to the BioLexa Platform for use in eczema. In preparation for such pre-IND meeting, we prepared and presented to the FDA our proposed Phase 2 clinical trial plan for the treatment of eczema in patients over the age of one year old. As part of our pre-IND meeting, the FDA provided us with general guidance with respect to specific animal studies, dosing schedules and suggested human safety studies before we commence clinical trials in pediatric or adult patients. We are currently investigating multiple potential venues for conducting such trial both in and outside of the U.S. We have engaged Camargo to assist us with the FDA process required for Section 505(b)(2) applications and with the evaluation of potential clinical trial venues for the proof of concept study should we determine to undertake such study. Specifically, Camargo has provided and will continue to provide advice and guidance relative to the IND preparation phase for the BioLexa Platform. Camargo will assist us with the refinement of our non-clinical, clinical, clinical pharmacology and biopharmaceutics strategy incorporating the preliminary feedback we received from the FDA during our pre-IND meeting.

We believe that the key elements for our market success with respect to BioLexa include:

- the proprietary formulation of two FDA-approved drugs to treat bacterial proliferation reduces development time and costs by giving us the ability to rely on safety and efficacy data from the two approved drugs;

- our proprietary formulation is not a topical corticosteroid, and may not be subject to the same FDA black box warning issues as most commonly prescribed treatments currently in use; and

- a recent peer-reviewed publication titled "*Staphylococcal Bacteria May Cause Eczema, Study Reveals*", published by Dr. Herbert B. Allen, highlights that *staph*-induced biofilms are the root cause of flare-ups in eczema. Our BioLexa product candidate has been demonstrated to prevent the formation of these biofilms with the promise of delaying or completely arresting flare-ups, rather than merely treating symptoms of a flare-up already underway.

In addition to our sublicense agreement with Chelexa, we entered into the following agreements:

- an exclusive license agreement with the University of Cincinnati for a patented, novel genetic marker for food allergies. The genetic marker licensed by us from the University of Cincinnati may be used to (i) identify at risk infants in predicting food allergies, including peanut and milk allergies, (ii) identify a person's predisposition to an allergic reaction, thereby avoiding such reaction and (iii) determine an individual's propensity to develop AD, such as eczema. We intend to utilize the genetic marker for purposes of determining an individual's propensity to develop eczema as well as to identify and treat allergies in at-risk infants.

- the Sublicense Agreement with Zylö pursuant to which Zylö granted us an exclusive sublicense to the Licensed Patent Rights (as defined in the Sublicense Agreement) and the Licensed Technology (as defined in the Sublicense Agreement) to, among other things, develop, make and sell the Licensed Products (as defined in the Sublicense Agreement) and to practice the Licensed Technology in the United States and Canada for any and all therapeutic uses related to lupus in human beings, subject to the Field Expansion Rights (as defined in the Sublicense Agreement).

- a license agreement with NCSU pursuant to which NCSU granted us an exclusive license to, among other things, develop, make, use, offer and sell certain licensed products throughout the world with respect to NCSU's exon skipping approach for treating allergic diseases.

- a patent license agreement with GW pursuant to which GW granted us a license to certain patent rights to, among other things, make, use, offer and sell certain licensed products throughout the world with respect to aprepitant as used in treating side effects from drugs used for the treatment of cancer.

In order to generate revenue from our product candidates, we will need to sell our product candidates either through distribution partnerships or through our own sales efforts. Prior to selling our product candidates, we will need to receive FDA approval of our NDA for each indication that we intend to treat. The first indication we are seeking approval for is the BioLexa Platform for treating eczema. We intend to submit our NDA for such indication by the end of 2021 with approval of such NDA anticipated to be in 2022; however, no assurances can be given that we will receive approval of the NDA in a timely manner, if at all.

Results of Operations

Comparison of Our Results of Operations for the Years Ended December 31, 2019 and 2018

Operating Costs and Expenses

Research and Development Expenses

For the year ended December 31, 2019, research and development expenses were approximately $2.1 million which primarily consisted of $50,000 related to the Zylö Sublicense Agreement, $10,000 related to a license acquired from the University of Maryland and Isoprene Pharmaceuticals Inc., $25,000 related to a license acquired from the North Carolina State University, and approximately $2.0 million related to other research and development expenses.

For the year ended December 31, 2018, research and development expenses were approximately $1.0 million, of which approximately $0.1 million was related to license acquired, $0.1 million was related to the issuance of 213,166 shares of our common stock pursuant to the sublicense agreement with Chelexa and $0.8 million was related to other research and development expenses.

We expect our research and development activities to increase as we develop our existing product candidate and potentially acquire new product candidates, reflecting increasing costs associated with the following:

- employee-related expenses, which include salaries and benefits, and rent expenses;

- license fees and milestone payments related to in-licensed products and technology;

- expenses incurred under agreements with CROs, investigative sites and consultants that conduct our clinical trials and a substantial portion of our pre-clinical activities;

- the cost of acquiring and manufacturing clinical trial materials; and

- costs associated with non-clinical activities, and regulatory approvals.

General and Administrative Expenses

For the year ended December 31, 2019, general and administrative expenses were approximately $5.6 million, which primarily consisted of approximately $2.9 million related to payroll expenses and stock-based compensation, approximately $2.1 million for professional fees and $0.6 million for other expenses.

For the year ended December 31, 2018, general and administrative expenses were approximately $1.5 million, which primarily consisted of approximately $0.4 million related to payroll expenses, approximately $0.1 million related to the issuance of 145,970 shares of our common stock to two employees and two directors and approximately $0.7 million for professional fees.

We anticipate that our general and administrative expenses will increase in future periods, reflecting continued and increasing costs associated with:

- support of our research and development activities;
- stock compensation granted to key employees and non-employees;
- support of business development activities; and
- increased professional fees and other costs associated with the regulatory requirements and increased compliance associated with being a public reporting company.

Liquidity and Capital Resources

We have incurred substantial operating losses since inception and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2019, we had approximately $1.7 million in cash, marketable securities of $0.8 million, current liabilities of $0.4 million and an accumulated deficit of approximately $12.2 million.

Cash Flows from Operating Activities

For the year ended December 31, 2019, net cash used in operations was approximately $4.9 million, which primarily resulted from a net loss of approximately $7.7 million, partially offset by approximately $2.5 million stock-based compensation and changes in operating assets and liabilities of approximately $0.2 million.

For the year ended December 31, 2018, net cash used in operations was $2.1 million, which primarily resulted from a net loss of $2.5 million, partially offset by $0.1 million stock-based compensation expense and $0.1 million non-cash research and development expense related with license acquisition.

Cash Flows from Investing Activities

For the year ended December 31, 2019, net cash used in investing activities was approximately $0.9 million, which was related to the purchase of marketable securities of $0.8 million and the purchase of research and development licenses of $0.9 million.

For the year ended December 31, 2018, there was no investing activities.

Cash Flows from Financing Activities

For the year ended December 31, 2019, net cash provided by financing activities was approximately $7.5 million, including approximately $0.2 million restricted cash. The cash provided by financing activities primarily resulted from approximately $5.8 million in net proceeds from the Company's initial public offering (the "IPO") and approximately $1.6 million in net proceeds from a private offering of an aggregate of 407,474 units with each unit consisting of one share of the Company's common stock and a warrant to purchase one-half share of the Company's common stock. On February 20, 2019, we closed the IPO pursuant to which we issued 1,250,000 shares of our common stock for net proceeds of approximately $5.8 million, after deducting underwriting discounts and commissions and offering expenses. The $0.2 million restricted cash has been deposited into a third-party escrow account in order to provide a source of funding for certain indemnification obligations the Company has pursuant to its Qualified Independent Underwriter Engagement Agreement.

For the year ended December 31, 2018, net cash provided by financing activities was $1.2 million, which is the net proceeds raised from investors in consideration for the issuance of 13.77 units (the "Units"). Each Unit consisted of 100,000 shares of Series A Preferred Stock and a warrant to purchase 25% of the shares of common stock issuable upon conversion of the Series A Preferred Stock.

Our ultimate success is dependent on our ability to obtain additional financing and generate sufficient cash flow to meet our obligations on a timely basis. We will require significant amounts of capital to sustain operations, and we will need to make the investments we need to execute our longer-term business plan to support new technologies and help advance innovation. Absent generation of sufficient revenue from the execution of our long-term business plan, we will need to obtain debt or equity financing, especially if we experience downturns in our business that are more severe or longer than anticipated, or if we experience significant increases in expense levels resulting from being a publicly-traded company or from operations. Such additional debt or equity financing may not be available to us on favorable terms, if at all.

We plan to pursue our plans with respect to the research and development of our pre-clinical products which will require resources beyond those that we currently have, ultimately requiring additional capital from third party sources. We currently do not expect to generate any revenue and our independent registered public accounting firm has included in its opinion for the year ended December 31, 2019 an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern within one year from the date of this filing. The consolidated financial statements have been prepared assuming that we will continue as a going concern, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Off-Balance Sheet Arrangements

As of December 31, 2019 and 2018, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K or any commitments or contractual obligations.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the balance sheet and the reported amounts of expenses during the reporting period. In accordance with U.S. GAAP, we evaluate our estimates and judgments on an ongoing basis. The most significant estimates relate to the valuation of preferred and common stock, the valuation of stock options and the valuation allowance of deferred tax assets resulting from net operating losses. We base our estimates and assumptions on current facts, our limited historical experience and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those accounting principles that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in Annual Report on Form 10-K, we believe the following are the critical accounting policies used in the preparation of our consolidated financial statements that require significant estimates and judgments:

Stock-based compensation

We expense stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. We record the expense for stock-based compensation awards subject to performance-based milestone vesting over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the expected satisfaction of the performance conditions at each reporting date. All stock-based compensation costs are recorded in general and administrative or research and development costs in the statements of operations based upon the underlying employees' or non-employees' roles.

Income taxes

Income taxes are recorded in accordance with Accounting Standards Codification ("ASC") 740, Income Taxes, or ASC 740, which provides for deferred taxes using an asset and liability approach. We recognize deferred tax assets and liabilities for the expected future tax consequences of events that have been included in our consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between our financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We account for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

Recent Accounting Pronouncements

See Note 2 to the consolidated financial statements for a discussion of recent accounting standards and pronouncements.

JOBS Act

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have chosen to take advantage of the extended transition periods available to emerging growth companies under the JOBS Act for complying with new or revised accounting standards until those standards would otherwise apply to private companies provided under the JOBS Act. As a result, our consolidated financial statements may not be comparable to those of companies that comply with public company effective dates for complying with new or revised accounting standards.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including, without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board ("PCAOB") regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the consolidated financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the IPO; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

As a smaller reporting company, we are not required to provide the information required by this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Hoth Therapeutics, Inc.
Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of
Hoth Therapeutics, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Hoth Therapeutics, Inc. (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, changes in stockholders' equity and cash flows, for each of the two years in the period ended December 31, 2019, 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 consolidated financial position of the Company as of December 31, 2019 and 2018, and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and does not expect to generate revenue and as such, there is substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 audits to obtain reasonable assurance about whether the consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ WithumSmith+Brown, PC

We have served as the Company's auditor since 2018.

New York, New York
March 2, 2020

Hoth Therapeutics, Inc.
Consolidated Balance Sheets

	December 31, 2019	December 31, 2018
ASSETS		
Current assets		
Cash	$ 1,690,866	$ 282,621
Marketable securities	803,664	-
Prepaid expenses	110,072	12,356
Deferred offering cost	30,484	206,671
Total current assets	2,635,086	501,648
Property and equipment, net	1,043	2,268
Restricted cash	200,000	-
Total assets	**$ 2,836,129**	**$ 503,916**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 403,885	$ 142,280
Accrued expenses	36,236	206,671
Total current liabilities	440,121	348,951
Total liabilities	**440,121**	**348,951**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized, 0 shares issued and outstanding at December 31, 2019 and 2018, respectively	-	-
Series A Convertible Preferred Stock, $0.0001 par value, 1,897,250 and 5,000,000 shares authorized, 0 and 3,102,480 shares issued and outstanding at December 31, 2019 and 2018, respectively	-	310
Common stock, $0.0001 par value, 75,000,000 shares authorized, 10,119,844 and 5,071,400 shares issued and outstanding at December 31, 2019 and 2018, respectively	1,012	507
Additional paid-in-capital	14,610,638	4,665,154
Accumulated deficit	(12,215,642)	(4,511,006)
Total stockholders' equity	2,396,008	154,965
Total liabilities and stockholders' equity	**$ 2,836,129**	**$ 503,916**

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

Hoth Therapeutics, Inc.
Consolidated Statements of Operations

	Years Ended December 31,	
	2019	**2018**
Operating costs and expenses		
Research and development	$ 2,025,120	$ 785,274
Research and development - licenses acquired	95,000	230,693
Compensation and related expenses (including stock-based compensation)	2,932,933	509,667
Professional fees (including stock-based compensation)	2,091,745	682,929
Rent	31,622	28,252
Other expenses	538,577	258,710
Total operating expenses	7,714,997	2,495,525
Loss from operations	(7,714,997)	(2,495,525)
Other income (expenses)		
Other income, net	10,636	-
Loss on foreign currency exchange	(275)	-
Total other income	10,361	-
Net loss	**$ (7,704,636)**	**$ (2,495,525)**
Weighted average number of common shares outstanding, basic and diluted	9,164,577	5,031,062
Net loss per share, basic and diluted	$ (0.84)	$ (0.50)

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

Hoth Therapeutics, Inc.
Consolidated Statements of Changes in Stockholders' Equity

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2017	**1,725,980**	**$ 173**	**4,706,277**	**$ 470**	**$ 3,199,304**	**$ (2,015,481)**	**$ 1,184,466**
Issuance of Series A Convertible Preferred Stock and warrants for cash in an offering (net of offering costs of $190,180)	1,376,500	137	-	-	1,021,417	-	1,021,554
Warrant value related to Issuance of Series A Convertible Preferred Stock	-	-	-	-	164,766	-	164,766
Stock-based compensation	-	-	145,970	15	143,038	-	143,053
Stock issued for research and development	-	-	37,500	4	35,996	-	36,000
Stock issued for acquired license	-	-	213,166	21	132,143	-	132,164
Repurchase of restricted stock to pay for employee withholding taxes	-	-	(31,513)	(3)	(31,510)	-	(31,513)
Net loss	-	-	-	-	-	(2,495,525)	(2,495,525)
Balance at December 31, 2018	**3,102,480**	**$ 310**	**5,071,400**	**$ 507**	**$ 4,665,154**	**$ (4,511,006)**	**$ 154,965**
Conversion of preferred stock to common stock upon completion of the IPO	(3,102,480)	(310)	3,102,480	310	-	-	-
Issuance of common stock in the IPO (net of offering costs of $1,159,833)	-	-	1,250,000	125	5,840,042	-	5,840,167
Issuance of common stock and warrants (net of offering costs of $426,990)			407,424	41	1,610,089	-	1,610,130
Cashless warrant exercise	-	-	223,877	22	(22)	-	-
Warrant exercise			16,333	2	161	-	163
Stock-based compensation	-	-	48,330	5	2,495,214	-	2,495,219
Net loss	-	-	-	-	-	(7,704,636)	(7,704,636)
Balance at December 31, 2019	**-**	**$ -**	**10,119,844**	**$ 1,012**	**$ 14,610,638**	**$ (12,215,642)**	**$ 2,396,008**

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

Hoth Therapeutics, Inc.
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$(7,704,636)	$(2,495,525)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	1,225	1,224
Research and development-acquired license, expensed	95,000	132,164
Stock issued for research and development	-	36,000
Stock-based compensation	2,495,219	143,053
Unrealized gain on marketable securities	(3,664)	-
Changes in assets and liabilities:		
Prepaid expenses	(97,716)	(12,356)
Accrued salaries and benefits	-	(1,542)
Accounts payable	267,357	94,356
Net cash used in operating activities	(4,947,215)	(2,102,626)
Cash flows from investing activities		
Purchase of marketable securities	(800,000)	-
Purchase of research and development licenses	(95,000)	-
Net cash used in investing activities	(895,000)	-
Cash flows from financing activities		
Proceeds from issuance of Series A Convertible Preferred Stock and warrants for cash in an offering, net	-	1,186,320
Proceeds from issuance of common stock in the IPO, net of offering cost	5,840,167	-
Proceeds from issuance common stock and warrants, net of offering cost	1,610,130	-
Proceeds from exercise of warrants	163	-
Payment of employee withholdings for vested restricted stock	-	(31,513)
Net cash provided by financing activities	7,450,460	1,154,807
Net increase (decrease) in cash	1,608,245	(947,819)
Cash and restricted cash, beginning of year	282,621	1,230,440
Cash and restricted cash, end of year	$ 1,890,866	$ 282,621
Non-cash investing and financing activities		
Conversion of preferred stock to common stock upon completion of the IPO	$ 310	$ -
Common stock issued for acquired license		$ 132,164
Cashless warrant exercise	$ 22	$ -
Offering cost included in accrued expenses	$ 30,484	$ 206,671

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

Note 1—Organization and description of business operations

Hoth Therapeutics, Inc. (together with its wholly-owned subsidiary, Hoth Therapeutics Australia Pty Ltd., the "Company") was incorporated under the laws of the State of Nevada on May 16, 2017. The Company's primary asset is a sublicense agreement with Chelexa Biosciences, Inc. ("Chelexa") pursuant to which Chelexa has granted the Company an exclusive sublicense to use its BioLexa Platform (as defined herein), a proprietary, patented, drug compound platform developed at the University of Cincinnati. The license enables the Company to develop the platform for all indications in humans. The Company's initial focus will be on the treatment of eczema. The BioLexa Platform combines a U.S. Food and Drug Administration ("FDA") approved zinc chelator with one or more approved antibiotics in a topical dosage form to address unchecked eczema flare-ups by preventing the formation of infectious biofilms and the resulting clogging of sweat ducts which trigger symptoms. To the Company's knowledge, it is the first product candidate intended to prevent the symptom triggering flare-ups rather than simply treating symptoms when they occur.

During the year ended December 31, 2019, the Company also entered into agreements with the George Washington University, the University of Maryland Baltimore and Isoprene Pharmaceuticals, Inc., North Carolina State University and Zylö Therapeutics, Inc.. These agreements are further described in Note 3 of these financial statements.

Amendment to Articles of Incorporation

In December 2018, the Company's board of directors and stockholders approved a 1-for-4 reverse stock split of the Company's issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's convertible preferred stock (see Note 6). Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the convertible preferred stock conversion ratios.

Initial Public Offering

On February 15, 2019, the Company announced the pricing of its initial public offering (the "IPO") of 1,250,000 shares of its common stock at an initial offering price to the public of $5.60 per share. In addition, the Company granted the underwriters a 45-day option to purchase up to an additional 187,500 shares of common stock at the initial public offering price, less the underwriting discount, to cover over-allotments (the "Green-shoe"), if any. The underwriters did not exercise any portion of the Green-shoe. Therefore, the Company issued 1,250,000 shares of common stock and received net proceeds of $5.8 million from the IPO.

The Company's common stock commenced trading on The Nasdaq Capital Market, on February 15, 2019 under the ticker symbol "HOTH." The IPO closed on February 20, 2019.

On February 14, 2019, the Company entered into an underwriting agreement with Laidlaw & Co. (UK) Ltd. ("Laidlaw") pursuant to which the Company paid Laidlaw a fee in the amount of 7% of the gross proceeds of the IPO, or $490,000. These costs were reflected net of the $5.8 million of proceeds from the IPO. The Company also reimbursed Laidlaw for certain out-of-pocket expenses, including the fees and disbursements of their counsel, up to an aggregate of $0.2 million. In addition, Laidlaw received five-year warrants to purchase 50,000 shares of common stock of the Company at an exercise price of $7.00 per share.

Liquidity and capital resources

Accounting Standards Update, or ("ASU"), No. 2014-15, Presentation of Financial Statements - Going Concern, requires management to evaluate the Company's ability to continue as a going concern one year beyond the filing date of the given financial statements. This evaluation requires management to perform two steps. First, management must evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern. Second, if management concludes that substantial doubt is raised, management is required to consider whether it has plans in place to alleviate that doubt. Disclosures in the notes to the consolidated financial statements are required if management concludes that substantial doubt exists or that its plans alleviate the substantial doubt that was raised.

The Company's ultimate success is dependent on its ability to obtain additional financing and generate sufficient cash flow to meet its obligations on a timely basis. The Company's business will require significant amounts of capital to sustain operations and the Company will need to make the investments it needs to execute its longer-term business plan to support new technologies and help advance innovation. Absent generation of sufficient revenue from the execution of the Company's long-term business plan, the Company will need to obtain debt or equity financing, especially if the Company experiences downturns in its business that are more severe or longer than anticipated, or if the Company experiences significant increases in expense levels resulting from being a publicly-traded company or operations. Such additional debt or equity financing may not be available to the Company on favorable terms, if at all.

The Company plans to pursue its plans regarding research and development which will require resources beyond those currently available, including third party capital. During this time, the Company does not expect to generate revenue as such there is substantial doubt about the Company's ability to continue as a going concern within one year from the date of this filing. The consolidated financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Note 2—Significant accounting policies

Basis of Presentation and Principles of Consolidation

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP").

The accompanying consolidated financial statements include the accounts of the Company's wholly-owned subsidiary, Hoth Therapeutics Australia Pty Ltd, which was incorporated under the laws of the State of Victoria in Australia on June 5, 2019. All intercompany balances and transactions have been eliminated.

Use of estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. The most significant estimates in the Company's consolidated financial statements relate to the valuation of preferred and common stock, stock-based compensation and the valuation allowance of deferred tax assets resulting from net operating losses. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Segments

The Company operates in one operating segment and, accordingly, no segment disclosures have been presented herein.

Cash and cash equivalents

The Company considers all highly liquid investments purchased with original maturities of 90 days or less at acquisition to be cash equivalents. There were no cash equivalents as of December 31, 2019 and 2018.

Restricted Cash

In November 2016, the Financial Accounting Standards Board ("FASB") issued *ASU No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash* ("ASU 2016-18"), which clarifies the presentation of restricted cash in the statements of cash flows. Under ASU 2016-18, restricted cash is included with cash when reconciling the beginning-of-period and end-of-period total amounts shown on the statements of cash flows. The Company adopted ASU 2016-18 during the year ended December 31, 2019 on a retrospective basis. The following is a summary of the Company's cash and restricted cash total as presented in the consolidated statements of cash flows for the year ended December 31, 2019:

Cash	$ 1,690,866
Restricted cash	200,000
Total cash and restricted cash	**$ 1,890,866**

The $0.2 million restricted cash has been deposited into a third-party escrow account in order to provide a source of funding for certain indemnification obligations the Company has pursuant to its Qualified Independent Underwriter Engagement Agreement.

Marketable Securities

Marketable securities are classified as trading and are carried at fair value. The Company's marketable securities consist of a mutual fund which is valued at a quoted market price.

Concentrations of credit risk and off-balance sheet risk

Cash is a financial instrument that is potentially subject to concentrations of credit risk. The Company's cash is deposited in accounts at large financial institutions, and amounts may exceed federally insured limits. The Company believes it is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash is held. The Company has no financial instruments with off-balance sheet risk of loss.

Deferred Offering Costs

Deferred offering costs, which primarily consist of direct, incremental professional fees incurred in connection with the Company's IPO as well as other private equity offerings are capitalized as current assets on the consolidated balance sheet. Upon the closing of the offerings, the deferred offering costs are offset against the offering proceeds. Approximately $30,000 and $200,000 of such offering costs were accrued but unpaid at December 31, 2019 and 2018, respectively.

Research and development costs

Research and development costs, including acquired in-process research and development expenses for which there is no alternative future use, are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Fair value measurement

FASB Accounting Standards Codification ("ASC") 820, *Fair Value Measurements*, provides guidance on the development and disclosure of fair value measurements. Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance classifies fair value measurements in one of the following three categories for disclosure purposes:

Level 1: Quoted prices in active markets for identical assets or liabilities.
Level 2: Inputs other than Level 1 prices for similar assets or liabilities that are directly or indirectly observable in the marketplace.
Level 3: Unobservable inputs which are supported by little or no market activity and values determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

In some circumstances, the inputs used to measure fair value might be categorized within different levels of the fair value hierarchy. In those instances, the fair value measurement is categorized in its entirety in the fair value hierarchy based on the lowest level input that is significant to the fair value measurement.

The following table presents the Company's assets and liabilities that are measured at fair value at December 31, 2019:

	Fair value measured at December 31, 2019			
	Total at December 31, 2019	**Quoted prices in active markets (Level 1)**	**Significant other observable inputs (Level 2)**	**Significant unobservable inputs (Level 3)**
Assets				
Marketable securities - mutual funds	$ 803,664	$ 803,664	$ -	$ -

Convertible Preferred Stock

The Company applies the accounting standards for distinguishing liabilities from equity when determining the classification and measurement of its convertible preferred stock. Convertible preferred stock subject to mandatory redemption are classified as liability instruments and are measured at fair value. Conditionally redeemable convertible preferred stock (including preferred stock that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control) are classified as temporary equity. At all other times, convertible preferred stock are classified as stockholders' equity.

The Company accounts for convertible preferred stock with detachable warrants in accordance with ASC 470: *Debt* and allocated proceeds received to the convertible preferred stock and detachable warrants based on relative fair values. The Company evaluated the classification of its convertible preferred stock and warrants and determined that such instruments meet the criteria for equity classification. The Company recorded the related issuance costs and value ascribed to the warrants as a reduction of the convertible preferred stock as a component of additional paid in capital.

The Company has also evaluated its convertible preferred stock and warrants in accordance with the provisions of ASC 815, *Derivatives and Hedging*, including consideration of embedded derivatives requiring bifurcation. The issuance of the convertible preferred stock could generate a beneficial conversion feature, which arises when a debt or equity security is issued with an embedded conversion option that is beneficial to the investor or in the money at inception because the conversion option has an effective strike price that is less than the market price of the underlying stock at the commitment date.

Stock-based compensation

The Company accounts for share-based payment awards exchanged for services at the estimated grant date fair value of the award. Stock options issued under the Company's long-term incentive plans are granted with an exercise price equal to no less than the market price of the Company's stock at the date of grant and expire up to ten years from the date of grant. These options generally vest over a one to five year period.

The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Expected Term - The expected term of options represents the period that the Company's stock-based awards are expected to be outstanding based on the simplified method, which is the half-life from vesting to the end of its contractual term.

Expected Volatility - The Company computes stock price volatility over expected terms based on its historical common stock trading prices.

Risk-Free Interest Rate - The Company bases the risk-free interest rate on the implied yield available on U. S. Treasury zero-coupon issues with an equivalent remaining term.

Expected Dividend - The Company has never declared or paid any cash dividends on its common shares and does not plan to pay cash dividends in the foreseeable future, and, therefore, uses an expected dividend yield of zero in its valuation models.

Effective January 1, 2017, the Company elected to account for forfeited awards as they occur, as permitted by Accounting Standards Update ("ASU") 2016-09. Ultimately, the actual expenses recognized over the vesting period will be for those shares that vested. Prior to making this election, the Company estimated a forfeiture rate for awards at 0%, as the Company did not have a significant history of forfeitures.

Income taxes

Income taxes are recorded in accordance with ASC 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

Net loss per share

Net loss per share is computed by dividing net loss by the weighted average number of common stock outstanding during the period. Since the Company had a net loss in the periods presented, basic and diluted net loss per common share are the same. The following were excluded from the computation of diluted shares outstanding due to the losses for each period presented, as they would have had an anti-dilutive impact on the Company's net loss:

	As of December 31,	
Potentially dilutive securities	**2019**	**2018**
Series A Convertible Preferred Stock (Common Stock Equivalent)	-	3,102,480
Warrants	1,032,692	991,367
Options	525,000	-
Non-vested restricted stock units	13,200	21,530
Total	1,570,892	4,115,377

Recent accounting pronouncements

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which supersedes FASB ASC Topic 840, Leases (Topic 840) and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying virtually all leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. The standard is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. On January 1, 2019, the Company adopted ASU No. 2016-02, and the adoption did not have a material impact on its consolidated financial statements and related disclosures due to the short-term nature of its operating leases.

In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*, ("ASU 2017-09"), which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. It is effective prospectively for the annual period ending December 31, 2018 and interim periods within that annual period. The Company adopted ASU 2017-09 on January 1, 2018, and the adoption did not have a material impact on its consolidated financial statements and disclosures.

In June 2018, the FASB issued ASU 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 simplifies several aspects of the accounting for nonemployee share-based payment transactions resulting from expanding the scope of Topic 718, Compensation—Stock Compensation, to include share-based payment transactions for acquiring goods and services from non-employees. ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. On January 1, 2019, the Company adopted ASU 2018-07, and the adoption did not have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, "*Fair Value Measurement (Topic 820), - Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*," which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the update. The Company does not expect the adoption of this guidance to have a material impact on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, "*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements and related disclosures.

Note 3—License agreements

The following summarizes the Company's research and development expenses for licenses acquired during the years ended December 31, 2019 and 2018:

	For the Years Ended December 31,	
	2019	**2018**
Chelexa BioSciences, Inc.	$ -	$ 132,164
The George Washington University	2,500	-
University of Maryland and Isoprene Pharmaceuticals, Inc.	10,000	-
North Carolina State University	25,000	-
University of Cincinnati	7,500	7,500
Zylö Therapeutics Inc.	50,000	-
Other	-	91,029
	$ 95,000	**$ 230,693**

Chelexa BioSciences, Inc.

On May 26, 2017, the Company entered into a sublicense agreement with Chelexa, as amended on August 22, 2018 and August 29, 2018, pursuant to which Chelexa granted the Company an exclusive sublicense to make, use, have made, import, offer for sale, and sell products based upon or involving the use of (i) topical compositions comprising a zinc chelator and gentamicin and (ii) zinc chelators to inhibit biofilm formation (the "BioLexa Platform" or "BioLexa"), which rights were originally granted to Chelexa pursuant to an exclusive license agreement with the University of Cincinnati. In addition, Chelexa granted the Company the right to issue exclusive and nonexclusive sublicenses (with the right to further sublicense to third parties) to make, use, have made, import, offer for sale, and sell products based upon the BioLexa Platform. The term of such agreement will expire on the later of April 16, 2034 and the last to expire patent in the patent rights granted to the Company (the "Term"). The Company shall, in its sole discretion, have the first right of refusal to renew the Term. The Company is subject to total milestone payments of $3.5 million royalty payments and has agreed to fund all development and commercialization costs related to the licensed products.

During the year ended December 31, 2018, the Company recorded an expense of approximately $0.1 million related to the issuance of 213,166 shares of its common stock pursuant to the sublicense agreement with Chelexa. There were no expenses incurred for the year ended December 31, 2019.

The George Washington University

Effective as of June 1, 2019, the Company and The George Washington University ("GWU") entered into a sponsored research agreement (the "Sponsored Research Agreement"), as amended on July 29, 2019, with respect to the exploration of the potential use of Aprepitant for topical and/or systemic therapy to counter the dermatological related side-effects of Erlotinib therapy in cancer patients. Pursuant to the terms of the Sponsored Research Agreement, GWU granted the Company a non-exclusive, license to certain of GWU's intellectual property. The Company has agreed to pay GWU for all costs incurred in connection with the research; provided, however, such costs shall not exceed approximately $0.3 million. The Sponsored Research Agreement shall terminate on June 30, 2020 unless extended by the parties. The Sponsored Research Agreement may be terminated by either party upon 30 days written notice.

On June 28, 2019 (the "Effective Date"), the Company and GWU entered into a research option agreement (the "Research Option Agreement") pursuant to which GWU granted the Company an option (the "Option") until April 30, 2020 to acquire an exclusive license to certain products made or used by the Company (the "GWU Licensed Product") that involve certain patents owned by GWU (the "Licensed Patents"). On February 1, 2020, the Company exercised the Option and entered into a patent license agreement with GWU. On the Effective Date, the Company paid GWU $2,500, and on February 27, 2020, the Company paid GWU $10,000 as a license initiation fee. Until the first commercial sale of the GWU Licensed Product, the Company shall pay (i) $75,000 per year for the development and commercialization of the GWU Licensed Product, (ii) $2,000 for license maintenance fees on the first anniversary of the Effective Date and (iii) $5,000 for license maintenance fees commencing on the second anniversary of the Effective Date and thereafter. Furthermore, the Company shall be required to pay GWU a sublicense fee equal to a certain percentage of the sum of payments plus the fair market value of all other consideration of any kind received by the Company from sublicensees during each quarter as follows: a 40% sublicense fee until the first anniversary of the Effective Date, a 30% sublicense fee until the third anniversary of the Effective Date and a 20% sublicense fee after the third anniversary of the Effective Date; provided, however, such sublicense fee shall exclude certain fees paid to the Company such as certain royalties, equity investments, loan proceeds and sponsored research funding. Subject to the execution of a definitive license agreement with GWU, the Company shall also pay GWU milestone payments of up to an aggregate of $90,000 and sales based royalties at a low single digit percentage, subject to certain minimum royalty requirements. In addition, during each Option Exercise Period and Renewal Period (as defined in the Research Option Agreement) the Company shall pay GWU, on a quarterly basis, for all costs and expenses related to the GWU Licensed Patents (the "Patent Costs").

In July 2019, after the signing of the Research Option Agreement, the Company recorded an expense of $2,500 for the option fee.

University of Maryland and Isoprene Pharmaceuticals, Inc.

On March 8, 2019, the Company entered into a commercial evaluation sublicense and option agreement with the University of Maryland, Baltimore ("UMD") and Isoprene Pharmaceuticals, Inc. ("Isoprene"). Pursuant to the agreement, the Company paid an initial option and material access fee of $5,000 to UMD and $5,000 to Isoprene. In the event that Isoprene enters into a master license agreement with UMD (the "MLA"), UMD shall permit Isoprene to grant an exclusive option to the Company to negotiate and obtain an exclusive sublicensable, worldwide royalty-bearing license to the subject technology (the "Isoprene-Hoth Option"); provided, however, in the event Isoprene does not enter into the MLA, UMD may grant the Company an option to negotiate and obtain an exclusive sublicensable, worldwide royalty-bearing license to the subject technology (the "UMD-Hoth Option"). If the Company exercises the Isoprene-Hoth Option, it shall pay Isoprene an option exercise fee of $20,000. If the Company exercises the UMD-Hoth Option, it shall pay UMD an option exercise fee of $20,000.

In March 2019, the Company recorded an expense of an aggregate of $10,000 for the initial option and materials access fee.

North Carolina State University

On November 20, 2019 (the "NCSU Effective Date"), the Company entered into a license agreement with North Carolina State University ("NCSU") pursuant to which NCSU granted the Company an exclusive license to, among other things, develop, make, use, offer and sell certain licensed products throughout the world with respect to NCSU's exon skipping approach for treating allergic diseases. The term of the license agreement shall commence on the NCSU Effective Date and shall continue until the date of the expiration of the last to expire patent right granted pursuant to the license agreement unless terminated earlier pursuant to the terms of the agreement. Pursuant to the terms of the license agreement, the Company paid NCSU a one-time license fee $25,000 and is also required to pay (i) sales based royalties at a low single digit percentage, (ii) minimum royalties ranging from $0 to $50,000 and (iii) milestone payments of up to $585,000.

In December 2019, the Company recorded an expense of $25,000 for the license fee.

University of Cincinnati

On May 18, 2018, the Company entered into an exclusive license agreement with the University of Cincinnati for a patented, novel genetic marker for food allergies. The genetic marker licensed by the Company from the University of Cincinnati may be used to (i) identify at risk infants in predicting food allergies, including peanut and milk allergies, (ii) identify a person's predisposition to an allergic reaction, thereby avoiding such reaction and (iii) determine an individual's propensity to develop atopic dermatitis, such as eczema. The Company intends to utilize the genetic marker for purposes of determining an individual's propensity to develop eczema as well as to identify and treat allergies in at-risk infants.

Pursuant to the terms of the exclusive license agreement, the Company agreed to pay the University of Cincinnati a one-time initial fee of $5,000 within 30 days of the date of the exclusive license agreement in addition to an annual license fee of $5,000 initially due and payable within 30 days of the one year anniversary of the exclusive license agreement and every year thereafter. In addition, the Company agreed to pay the University of Cincinnati a yearly annual license maintenance fee of $2,500 and a yearly minimum annual royalty of $5,000 and milestone payments of up to $120,000. The exclusive license agreement will continue until the later of (i) the date upon which a valid claim pursuant to the terms of the exclusive license agreement expires or (ii) 10 years after the first commercial sale or unless earlier terminated pursuant to the terms of the exclusive license agreement.

In August 2018 and July 2019, respectively, the Company recorded an expense of $2,500 for annual license maintenance fee and $5,000 for yearly minimum annual royalty fee, respectively.

Zylö Therapeutics Inc.

On August 19, 2019 (the "Zylö Effective Date"), the Company entered into an exclusive sublicense agreement (the "Sublicense Agreement") with Zylö Therapeutics, Inc. ("Zylö") pursuant to which Zylö granted to the Company an exclusive sublicense to the Licensed Patent Rights (as defined in the Sublicense Agreement) and the Licensed Technology (as defined in the Sublicense Agreement) to, among other things, develop, make and sell the Licensed Products (as defined in the Sublicense Agreement) and to practice the Licensed Technology in the United States and Canada for any and all uses within the Field. "Field" means all therapeutic uses related to lupus in human beings, subject to the Field Expansion Rights (as defined in the Sublicense Agreement). The term of the Sublicense Agreement shall commence on the Zylö Effective Date and shall continue until the latest of (i) ten years from the date of First Commercial Sale (as defined in the Sublicense Agreement) of the Licensed Product in such country and (ii) expiration of the last to expire Valid Claim (as defined in the Sublicense Agreement) of the Licensed Patent Rights that would be infringed by the composition, use or sale of such Licensed Product in such country. Pursuant to the terms of the Sublicense Agreement, the Company and Zylö shall establish a joint development committee to plan, review, coordinate and oversee the Company's development activities with respect to the Licensed Products in the Field. Pursuant to the Sublicense Agreement, the Company paid Zylö (i) an upfront license fee of $50,000; (ii) sales-based royalties at percentages which range from high single digits to low double digits, with low sales volumes being subject to lower royalty rates; and total milestone payments of up to $13.5 million. In addition, within 45 days of the Company's next equity financing pursuant to which the Company receives gross proceeds of at least $1 million, the Company shall purchase equity securities of Zylö in an amount equal to $60,000.

In May 2019 and September 2019, the Company recorded an expense of $10,000 and $40,000, respectively, for upfront license fee.

Note 4—Related Party

A director of the Company, is also the Executive Chairman of Chelexa. During the year ended December 31, 2019, that director received $30,000 in cash compensation for services provided as a board member of the Company and $5,000 cash compensation for his services as a member of the Company's Scientific Advisory Board. The Company also granted him options to purchase up to 35,000 of the Company's common stock pursuant to the Company's 2018 Equity Incentive Plan. During the year ended December 31, 2018, that director received $30,000 in cash compensation for services provided as a board member of the Company and $10,000 cash compensation for his services as a member of the Company's Scientific Advisory Board. He also received a stock grant for 12,500 shares of common stock for his services as a member of the Company's Scientific Advisory Board.

A director of the Company, is also the Chief Executive Officer, Principal Accounting and Financial Officer and a member of the board of directors of Spherix Incorporated. During the year ended December 31, 2019, that director received $30,000 in cash compensation for services provided as a board member of the Company. The Company also granted such director options to purchase up to 35,000 shares of the Company's common stock pursuant to the Company's 2018 Equity Incentive Plan. During the year ended December 31, 2018, that director received $42,000 in cash compensation and the Company issued such director 12,500 shares of common stock for services rendered as a member of the Company's board of directors.

Note 5. Investments in Marketable Securities

The realized gain or loss, unrealized gain or loss, and dividend income related to marketable securities for the year ended December 31, 2019 and 2018, which are recorded as a component of other income (expenses) on the consolidated statements of operations, are as follows:

	For the Years Ended December 31,	
	2019	**2018**
Unrealized gain (loss)	$ 3,664	$ -
Dividend income	6,947	-
Interest income	25	-
	$ 10,636	$ -

Note 6—Stockholders' Equity

Preferred Stock

The Company is authorized to issue up to 10,000,000 shares of preferred stock. This preferred stock may be issued in one or more series, and shall have such designations, preferences and relative, participating, optional or other special rights and qualifications, limitations or restrictions thereof as shall be determined at the time of issuance by the Company's board of directors without further action by the Company's shareholders. As of December 31, 2019, 5,000,000 shares of the Company's preferred stock has been designated as Series A Convertible Preferred Stock of which 3,102,480 shares which were previously issued were converted into common stock at the time of the Company's initial public offering. During the year ended December 31, 2018, the Company raised $1.2 million (net of offering costs) in cash from investors in exchange for the issuance of 13.77 units.

The shares of Series A Convertible Preferred Stock are not mandatorily redeemable and does not embody an unconditional obligation to settle in a variable number of equity shares. As such, the shares of Series A Convertible Preferred Stock are classified as permanent equity on the balance sheets. The holders' contingent redemption right in the event of certain deemed liquidation events does not preclude permanent equity classification. Further, the shares of Series A Convertible Preferred Stock are considered an equity-like host for purposes of assessing embedded derivative features for potential bifurcation. The embedded conversion feature is considered to be clearly and closely related to the associated convertible preferred stock host instrument and therefore was not bifurcated from the equity host.

The Company had 1,897,520 and 5,000,000 shares of Series A Convertible Preferred Stock authorized as of December 31, 2019 and 2018, respectively, 0 and 3,102,480 shares outstanding as of December 31, 2019 and 2018, respectively.

Common Shares

On February 15, 2019, the Company announced the pricing of its initial public offering of 1,250,000 shares of its common stock at an initial offering price to the public of $5.60 per share. The Company issued an aggregate of 1,250,000 shares of common stock and received net proceeds of $5.8 million from the IPO.

Private Placement of Securities

On August 16, 2019 (the "Closing Date"), the Company entered into subscription agreements (the "Subscription Agreements") and unit purchase agreements (the "Purchase Agreements") with certain accredited investors (the "Investors") pursuant to which it sold units (the "Units") for aggregate gross proceeds of $2,037,120, exclusive of placement agent commission and fees and offering and transaction expenses (the "Offering"). Each Unit was sold at an offering price of $5.00 per Unit and consisted of (i) one share of the Company's common stock and (ii) a warrant (the "Warrant") to purchase one-half share of common stock.

Each Warrant is exercisable for a period of two years beginning six months from the Closing Date at an exercise price of $8.00 per whole share, subject to adjustment. The Company is prohibited from effecting an exercise of the Warrant to the extent that, as a result of such exercise, the holder together with the holder's affiliates, would beneficially own more than 4.99% of the number of shares of common stock outstanding immediately after giving effect to the issuance of shares of common stock upon exercise of the Warrant, which beneficial ownership limitation may be increased by the holder up to, but not exceeding, 9.99%.

In addition, pursuant to the terms of the Offering, the Company issued Laidlaw warrants (the "Placement Agent Warrants") to purchase up to 61,113 shares of the Company's common stock. The Placement Agent Warrants are exercisable for a period of five years from the Closing Date (the "Initial Exercise Date") at an exercise price of $5.00 per share, subject to adjustment. The Warrants may be exercised at any time after the Initial Exercise Date on a cashless basis and contain piggy-back registration rights.

Pursuant to the Offering, the Company received $1.6 million in net proceeds from the issuance of 407,424 Units.

The Company has determined that the 2019 warrants should be accounted as a component of stockholders' equity. For the warrants issued on August 16, 2019, the Company estimated the relative fair value of the warrants at $0.8 million using the Black-Scholes option pricing model using the following primary assumptions: fair value of common stock underlying the warrants ranges from $2.55 to $4.33, expected life ranges from 2.0 to 5.0 years, volatility rate ranges from 107.30% to 110.08%, risk-free interest rate ranges from 1.42% to 1.48% and expected dividend rate of 0%.

During the year ended December 31, 2018, the Company raised $1.2 million (net of offering costs) in cash from investors in exchange for the issuance of 13.77 units.

For the warrants issued during the year ended December 31, 2018, the Company has determined that the warrants should be accounted as a component of stockholders' equity. On the issuance date, the Company estimated the relative fair value of the warrants at $0.1 million using the Black-Scholes option pricing model using the following primary assumptions: fair value of common stock underlying the warrants is $0.16, expected life of 7.0 years, volatility rate of 75.0%, risk-free interest rate of 1.83% and expected dividend rate of 0%. Based on the warrant's relative fair value to the fair value of the Series A Preferred Stock, approximately $0.2 million of the $1.2 million of aggregate fair value was allocated to the warrants, creating a corresponding preferred stock discount in the same amount.

2018 Equity Incentive Plan

The Company's 2018 Equity Incentive Plan (the "2018 Plan") was adopted by its board of directors on May 4, 2018 and by its shareholders on May 4, 2018. The Company has reserved 1,000,000 shares of common stock for issuance pursuant to the 2018 Plan.

2018 Activity

In January 2018, the Company granted an employee 25,000 shares of common stock with a $15,000 fair value.

On March 23, 2018, the Company granted 12,500 shares of common stock of the Company to a member of the Company's Scientific Advisory Board. The fair value of the stock award was $11,000.

On May 4, 2018, the Company granted 12,500 shares of common stock of the Company under the 2018 Plan to a member of the Company's Scientific Advisory Board. The fair value of the stock award was $12,500.

On May 4, 2018, the Company granted the same employee 5,000 shares of common stock under the 2018 Plan with a $5,000 fair value. The Company's Chief Executive Officer and co-founder was issued 87,500 shares of common stock for a value of $87,500. On August 15, 2018, the Company bought back 31,513 shares from the employees who were issued common stock as part of the 2018 Plan to pay for payroll taxes. The fair value of the shares was $31,513. Immediately after the buyback of the 31,513 shares such shares were immediately cancelled.

During the year ended December 31, 2018, the Company issued a total of 25,000 shares of common stock under the 2018 Plan to two directors for a value of $25,000.

Restricted Stock Awards

During the year ended December 31, 2019, the Company issued 10,000 and 30,000 shares of restricted common stock with a total fair value of approximately $0.2 million to The Benchmark Company, LLC and FON Consulting, LLC, respectively, consultants to the Company. On January 7, 2020, the Company entered into a termination and general release agreement with FON Consulting, LLC pursuant to which 15,000 shares of restricted common stock originally granted to FON Consulting, LLC were cancelled.

During the year ended December 31, 2018, 37,500 shares of restricted stock awards with a fair value of approximately $38,000 were granted. 12,500 shares of these restricted stock awards were vested immediately and 25,000 shares of these restricted stock awards were vested in 1/36 increments in monthly installments beginning August 3, 2018.

A summary of the Company's restricted stock awards granted under the 2018 Plan during the years ended December 31, 2019 and 2018 is as follows:

	Number of Units	Weighted Average Grant Day Fair Value
Nonvested at December 31, 2017	-	-
Granted	37,500	$ 0.25
Vested	(15,970)	0.25
Nonvested at December 31, 2018	21,530	$ 0.25
Granted	40,000	5.11
Vested	(48,330)	4.28
Nonvested at December 31, 2019	13,200	$ 0.25

As of December 31, 2019, approximately $4,000 of unrecognized stock-based compensation expense related to restricted stock awards. The weighted average remaining contractual terms of unvested restricted stock awards is approximately 0.8 years at December 31, 2019.

Stock Options

On March 6, 2019, the Company granted options to purchase up to 50,000 shares of the Company's common stock to its CFO pursuant to the 2018 Plan. The aggregate grant date fair value of these options was approximately $0.2 million. The stock options vested in full upon grant.

On December 24, 2019, the Company granted a total of options to purchase up to an aggregate of 475,000 shares of the Company's common stock to directors and advisors pursuant to the 2018 Plan. The aggregate grant date fair value of these options was approximately $2.0 million. The stock options vested in full upon grant.

The fair value of options granted in 2019 and 2018 was estimated using the following assumptions:

	For the Years Ended December 31,	
	2019	2018
Exercise price	$ 5.26-$5.88	-
Term (years)	4.18-9.98	-
Expected stock price volatility	111.2%-112.1%	-
Risk-free rate of interest	1.75%-2.52%	-

A summary of option activity under the Company's stock option plan for year ended December 31, 2019 and 2018 is presented below:

	Number of Shares	Weighted Average Exercise Price	Total Intrinsic Value	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2018	-	$ -	$ -	-
Employee options issued	525,000	5.32	457,250	9.4
Outstanding as of December 31, 2019	525,000	$ 5.32	$ 457,250	9.4
Options vested and exercisable	525,000	$ 5.32	$ 457,250	9.4

Stock Based Compensation

Stock-based compensation expense for the years ended December 31, 2019 and 2018 was approximately $2.5 million and $0.1 million, respectively, and comprised of the following:

	For the Years Ended December 31,	
	2019	**2018**
Employee common stock awards	$ -	$ 107,500
Directors common stock awards	-	25,000
Employee stock option awards	2,195,812	-
Employee restricted stock awards	10,252	10,553
Non-employee restricted stock awards	204,550	-
Non-employee warrant awards	84,605	-
	$ 2,495,219	**$ 143,053**

Employee and director related stock-based compensation was included in compensation and related expenses, and non-employee related stock-based compensation was included in professional fees on the consolidated statements of operations.

In addition, the Company recorded $0 and $36,000 of stock issued for research and development services for the year ended December 31, 2019 and 2018, respectively.

Warrants

A summary of warrant activity for the years ended December 31, 2019 and 2018 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Total Intrinsic Value	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2017	647,242	$ 1.00	$ -	4.2
Issued	344,125	1.00	-	6.1
Outstanding as of December 31, 2018	991,367	$ 1.00	$ -	5.9
Issued	331,155	6.90	100,938	4.1
Exercised	(289,830)	0.94	-	-
Outstanding as of December 31, 2019	1,032,692	$ 2.91	$ 3,725,745	4.2
Warrants exercisable as of December 31, 2019	1,032,692	$ 2.91	$ 3,725,745	4.2

2019 Activity

On February 20, 2019, Laidlaw received five-year warrants to purchase 50,000 shares of the Company's common stock at an exercise price of $7.00 per share. These warrants were not exercisable prior to August 13, 2019.

On April 17, 2019, the Company entered into a Master Service Agreement (the "MSA") with a consultant (the "Consultant"). In consideration for services provided by the Consultant, the Company issued the Consultant a two year warrant to purchase up to 50,000 shares of the Company's common stock at an exercise price of $0.01 per share (the "Consultant Warrant"). On May 22, 2019, the Company and Consultant agreed to terminate the MSA and number of shares of the Company's common stock issuable upon exercise of the Consultant Warrant was reduced to 16,333. On June 27, 2019, the Company issued 16,333 shares of common stock upon exercise of the Consultant Warrant which resulted in gross proceeds of approximately $163.

On April 16, 2019, the Company issued 176,272 shares of common stock upon the cashless exercise of warrants to purchase up to 215,747 shares of common stock. Those warrants were issued by the Company to Laidlaw pursuant to the terms of its engagement letter with Laidlaw with respect to the private placement of its securities from October 2017 through December 2017.

On June 6, 2019, the Company issued 47,605 shares of common stock upon the cashless exercise of warrants to purchase up to 57,750 shares of common stock.

On August 16, 2019, in connection with the Offering, the Company issued Warrants to purchase up to 203,709 shares of the Company's common stock at an exercise price of $8.00 per whole share. In addition, pursuant to the terms of the Offering, the Company issued Laidlaw the Placement Agent Warrants to purchase up to 61,113 shares of the Company's common stock. The Placement Agent Warrants are exercisable for a period of five years from the Closing Date at an exercise price of $5.00 per share.

2018 Activity

During the year ended December 31, 2018, the Company issued seven-year warrants to purchase 344,125 shares of the Company's common stock at an exercise price of $1.00 per share to investors.

The Company has determined that the warrants should be accounted as a component of stockholders' equity.

Note 7—Commitments and contingencies

Office lease

Rent expense for the years ended December 31, 2019 and 2018 was approximately $32,000 and $28,000, respectively. The Company is not a party to a lease that is in excess of 12 months.

Litigation

The Company is not a party to any material legal proceedings and is not aware of any pending or threatened claims. From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities.

Note 8—Income taxes

The table below presents the components of the provision for taxes:

	As of December 31,	
	2019	**2018**
Current		
US Federal	$ -	$ -
US State	-	-
Total current provision	-	-
Deferred		
US Federal	1,692,939	414,952
US State	-	2,825
Total deferred benefit	1,692,939	417,777
Change in valuation allowance	(1,692,939)	(417,777)
Total provision for income taxes	$ -	$ -

At December 31, 2019 and 2018, the tax effects of the temporary differences and carryforwards that give rise to deferred tax assets consist of the following:

	As of December 31,	
	2019	**2018**
Deferred tax assets:		
Net operating loss carryforward	$ 1,975,501	$ 701,785
License acquired	133,182	144,265
Stock Compensation	427,558	-
Total deferred income tax assets	2,536,241	846,050
Deferred income tax assets liabilities:		
Prepaids	-	(2,613)
Depreciation fixed assets	(132)	(267)
Total deferred income tax liabilities	(132)	(2,880)
Net deferred income tax assets	2,536,109	843,170
Valuation allowance	(2,536,109)	(843,170)
Deferred tax asset, net of allowance	$ -	$ -

A reconciliation of the statutory income tax rates and the Company's effective tax rate for the year ended December 31, 2019 and 2018 is as follows:

	For the Years ended December 31,	
	2019	**2018**
Statutory federal income tax rate	(21.0)%	(21.0)%
State taxes, net of federal tax benefit	0.0%	(0.1)%
Return to Provision	(1.3)%	-%
Other	0.4%	-%
Change in valuation allowance	22.0%	21.1%
Income taxes provision (benefit)	-%	-%

The Company has determined, based upon available evidence, that it is more likely than not that the net deferred tax assets will not be realized and, accordingly, has provided a full valuation allowance against its net deferred tax assets.

As of December 31, 2019, the Company has net operating loss carryforwards of approximately $9.4 million available to reduce future taxable income, if any, for Federal and state income tax purposes. Approximately $1.5 million of Federal net operating losses can be carried forward to future tax years and expire in 2037. The Federal net operating loss generated during the year ended December 31, 2018 and 2019 of approximately $7.9 million can be carried forward indefinitely. However, the deduction for net operating losses incurred in tax years beginning after January 1, 2018 is limited to 80% of annual taxable income.

At December 31, 2019 and 2018, the Company did not have any significant uncertain tax positions. The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2019 and 2018, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statement of operations. The Company does not anticipate a material change to unrecognized tax benefits in the next twelve months.

All of the Company's tax years will remain open for examination by the Federal and state tax authorities from the date of utilization of the net operating loss.

Note 9—Subsequent Events

The Company evaluates events that have occurred after the balance sheet date but before the consolidated financial statements are issued.

Pursuant to the Patent License Agreement between the Company and GWU, on February 1, 2020, the Company issued GWU warrants to purchase up to 22,988 shares of the Company's common stock at an exercise price of $4.35 per share. The warrants vest as follows: 20% upon the date of issuance and the balance, or 80% of the warrants shall vest in four equal annual installments of 20% on each anniversary of the initial issuance date.

On February 5, 2020, the Company issued 12,500 shares of common stock upon exercise of the warrants originally granted to an investor on January 19, 2018, which resulted in gross proceeds of $12,500.

From January 1, 2020 until February 29, 2020, the Company issued an aggregate of 1,388 shares of the Company's common stock to a member of the Company's Board for services rendered.

Effective as of February 28, 2020, Vadim Mats resigned as a member of the Company's Audit Committee. Effective as of February 28, 2020, the Board appointed Graig Springer as a member of the Company's Board. In addition, effective as of February 28, 2020, the Board appointed Graig Springer as a member of the Company's Audit Committee to fill the vacancy created by the resignation of Vadim Mats.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls

Our principal executive officer and principal financial officer, after evaluating the effectiveness of the Company's "disclosure controls and procedures" (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) as of December 31, 2019, the end of the period covered by this Annual Report, have concluded that our disclosure controls and procedures were effective such that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Management's 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 Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. GAAP. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

As of December 31, 2019, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework - 2013. Based on this assessment, our management concluded that, as of December 31, 2019, our internal control over financial reporting was effective based on such criteria.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to the exemption provided to issuers that are not "large accelerated filers" nor "accelerated filers" under the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Effective as of February 28, 2020, Vadim Mats resigned as a member of the Company's Audit Committee. Effective as of February 28, 2020, the Board appointed Graig Springer as a member of the Company's Board. In addition, effective as of February 28, 2020, the Board appointed Graig Springer as a member of the Company's Audit Committee to fill the vacancy created by the resignation of Vadim Mats. Mr. Springer will serve for a term expiring at the next annual meeting of shareholders in 2020 or until his successor has been duly elected and qualified, or until his earlier resignation, removal or death.

Mr. Springer's biography is set forth below under "Item 10. Directors, Executive Officers and Corporate Governance." Mr. Springer's ongoing annual compensation will be consistent with that provided to the Company's other non-employee directors. Except as set forth in this Annual Report on Form 10-K, there is no arrangement or understanding between Mr. Springer and any other persons pursuant to which Mr. Springer was selected as a director. There are no related party transactions involving Mr. Springer that are reportable under Item 404(a) of Regulation S-K.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth the name, age and positions of our executive officers and directors.

NAME	AGE	POSITION
Robb Knie	51	President, Chief Executive Officer and Director
David Briones	43	Chief Financial Officer
Vadim Mats	35	Director
Kenneth Rice	66	Director
Anthony Hayes	52	Director
David B. Sarnoff	52	Director
Graig Springer	40	Director

The business background and certain other information about our directors and executive officers is set forth below:

Robb Knie

Robb Knie has served as President and Chief Executive Officer and as a director of the Company since May 2017 and served as our principal financial and accounting officer from June 2018 until March 2019. Mr. Knie has served as the President of Equity Research and a corporate advisor of Lifeline Industries Inc. since its inception in 1995. From 2002 to 2010 he was a Semiconductor Analyst for PAW Partners. From 1993 until 1995, Mr. Knie served as Northeast Regional Manager of American Express Financial Advisors. Mr. Knie served as a board member of Inventergy Global, Inc. (NASDAQ: INVT) from December 2013 until October 2014. We believe that Mr. Knie is qualified to serve as a director because of his business and leadership experience and experience as a board member of public companies.

David Briones

David Briones served as Chief Financial Officer of the Company since March 5, 2019 and has over nineteen years of public accounting and executive level experience. He consults with various public companies in financial reporting, internal control development and evaluation, budgeting and forecasting. Since May 2018, Mr. Briones has served as Executive Chair of Zovis Pharmaceuticals, and since October 2010, he has served as the managing member and founder of Brio Financial Group, LLC, a financial reporting consulting firm. In addition, since August 2013, Mr. Briones has served as Chief Financial Officer of Petro River Oil Corp., an independent energy company focused on the exploration and development of conventional oil and gas assets. Mr. Briones has also served as interim Chief Financial Officer of AdiTx Therapeutics, Inc., a pre-clinical stage, life sciences company with a mission to prolong life and enhance life quality of transplanted patients, since January 2018. From October 2017 to May 2018, Mr. Briones served as the Chief Financial Officer of Bitzumi, Inc., a Bitcoin exchange and marketplace. Prior to founding Brio Financial Group, LLC, Mr. Briones was an auditor with Bartolomei Pucciarelli, LLC in Lawrenceville, New Jersey and PricewaterhouseCoopers LLP in New York, New York. Mr. Briones received a BS in accounting from Fairfield University.

Vadim Mats

Vadim Mats has served as a director of the Company since May 2017. Since March 2018, Mr. Mats has served as the Chief Financial Officer and Chief Operating Officer of Grand Private Equity. Mr. Mats consults with multiple companies in a range of industries on all aspects of finance, accounting, tax and operations. From June 2010 to December 2016, Mr. Mats was Chief Financial Officer of Whalehaven Capital. Mr. Mats also served as the Assistant Controller at Eton Park Capital Management, LP, a multi-strategy fund, from July 2007 to December 2009. From June 2006 to July 2007, Mr. Mats was a Senior Fund Accountant at The Bank of New York Mellon (NYSE: BK), where he was responsible for over fifteen funds. From 2011 until March 2017, Mr. Mats served as Director and Chair of the Audit Committee of Wizard World Inc. (OTCQB: WIZD). Mr. Mats holds a Master of Science degree in accounting and finance and a Bachelor's degree in Business Administration specializing in finance and investments from the Zicklin School of Business at Bernard Baruch College. Further, Mr. Mats is a CAIA© Charterholder and a Certified Public Accountant in the State of New York. We believe that Mr. Mats is qualified to serve as a director because of his experience as a board member of a public company and his knowledge with respect to finance, accounting, tax, and operations matters.

Kenneth Rice

Kenneth Rice has served as a director of the Company since May 2017. In addition, since October 2017, Mr. Rice has served as Chief Executive Officer of Alderaan Group LLC, a consulting services company. Mr. Rice served as the Executive Vice President and Chief Financial Officer of LikeMinds, Inc., an affiliate of Alseres Pharmaceuticals, Inc. ("Alseres") from 2015 through March 2019. From 2005 through March 2019, Mr. Rice served as the Executive Vice President, Chief Financial Officer and in-house counsel to Alseres. In addition, since 2012, Mr. Rice has served as Executive Chairman of Chelexa. From August 1999 through March 2001, Mr. Rice served as Vice President and Chief Financial Officer of MacroChem Corporation, a publicly-traded drug delivery company. Mr. Rice received his Bachelor of Science degree from Babson College, his MBA from Babson College, his Juris Doctorate from Suffolk University Law School and his LLM from Boston University Law School. We believe that Mr. Rice is qualified to serve as a director because of his over 25 years of experience in operations, finance, marketing and sales and business development in both private and public life science companies.

Anthony Hayes

Anthony Hayes has served as a director of the Company since June 2017 and as Chief Executive Officer and director of Spherix Incorporated (NASDAQ: SPEX) since September 2013. Since 2017, Mr. Hayes has served as the Principal Accounting and Financial Officer of Spherix Incorporated. In addition, Mr. Hayes has served as the Chief Executive Officer of North South since March 2013. Mr. Hayes was the fund manager of JaNSOME IP Management LLC and JaNSOME Patent Fund LP from August 2012 to August 2013, both of which he co-founded. Mr. Hayes was the founder and Managing Member of Atwater Partners of Texas LLC from March 2010 to August 2012 and a partner at Nelson Mullins Riley & Scarborough LLP from May 1999 to March 2010. Mr. Hayes received his Juris Doctorate from Tulane University School of Law and his B.A. in economics from Mary Washington College. We believe that Mr. Hayes is qualified to serve as a director because of his experience as CEO of Spherix Incorporated and North South.

David B. Sarnoff

David Sarnoff has served as a director of the Company since August 2018. Since June 2015, Mr. Sarnoff has served as the founder and Principal of Sarnoff Group, LLC, and since January 2019, he has served as the Director of Strategic Partnerships and Executive Leadership Coach at Loeb Leadership. From October 2003 until June 2015, Mr. Sarnoff served as the co-founder and Principal of Morandi, Taub & Sarnoff LLC, an executive search firm, and from July 1998 until October 2003 he served as a Legal Recruiter for Schneider Legal Search, Inc. From August 1994 until July 1998, Mr. Sarnoff served as a litigation associate attorney at Wachtel Missry LLP (formerly known as Gold & Wachtel LLP). Since July 2018, Mr. Sarnoff has served as a member of the advisory committee of the New Jersey Association of School Resource Officers. From January 2015 until January 2018, Mr. Sarnoff served as board President of Fort Lee Board of Education and served as a board member from January 2013 through January 2019. Mr. Sarnoff received his Juris Doctor from Rutgers University School of Law and his bachelor of arts from Hofstra University. Mr. Sarnoff is admitted to the New York and New Jersey (retired status) state bars. Mr. Sarnoff is qualified to serve as a director because of his legal experience as well as his extensive experience in executive leadership and business development.

Graig Springer

Graig Springer has served as a director of the Company since February 2020. From May 2019 to August 2019, Mr. Springer assisted with product development and governance at Invesco U.S., an investment management company, and from December 2013 to May 2019, he served in various capacities at OppenheimerFunds, Inc., an investment management company acquired by Invesco U.S., including distribution compliance and product development. In addition, Mr. Springer served on the Sub-Adviser Oversight Committee at OppenheimerFunds, Inc. Mr. Springer received his Bachelor of Arts from Columbia University and his Juris Doctor from Fordham University School of Law. Mr. Springer is qualified to serve as a director because of his fifteen years of experience within the financial services industry overseeing and advising firms' compliance with federal rules and regulations.

Family Relationships

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

Arrangements between Officers and Directors

Except as set forth herein, to our knowledge, there is no arrangement or understanding between any of our officers or directors and any other person pursuant to which the officer or director was selected to serve as an officer or director.

Involvement in Certain Legal Proceedings

We are not aware of any of our directors or officers being involved in any legal proceedings in the past ten years relating to any matters in bankruptcy, insolvency, criminal proceedings (other than traffic and other minor offenses), or being subject to any of the items set forth under Item 401(f) of Regulation S-K.

Committees of Our Board of Directors

Our board of directors directs the management of our business and affairs, as provided by Nevada law, and conducts its business through meetings of the board of directors and its standing committees. We have a standing audit committee, compensation committee and nominating and corporate governance committee. In addition, from time to time, special committees may be established under the direction of the board of directors when necessary to address specific issues.

Our board of directors has determined that all of the members of the audit committee, the compensation committee and the nominating and corporate governance committee are independent as defined under the applicable rules of The Nasdaq Capital Market, including, in the case of all of the members of our audit committee, the independence requirements contemplated by Rule 10A-3 under the Exchange Act. In making such determination, the board of directors considered the relationships that each director has with our Company and all other facts and circumstances that the board of directors deemed relevant in determining director independence, including the beneficial ownership of our capital stock by each director.

Audit Committee

Our audit committee will be responsible for, among other things:

- approving and retaining the independent registered public accounting firm to conduct the annual audit of our consolidated financial statements;
- reviewing the proposed scope and results of the audit;
- reviewing and pre-approval of audit and non-audit fees and services;
- reviewing accounting and financial controls with the independent registered public accounting firm and our financial and accounting staff;
- reviewing and approving transactions between us and our directors, officers and affiliates;

- establishing procedures for complaints received by us regarding accounting matters;
- overseeing internal audit functions, if any; and
- preparing the report of the audit committee that the rules of the Securities and Exchange Commission require to be included in our annual meeting proxy statement.

Our audit committee consists of Anthony Hayes, David Sarnoff and Graig Springer, with Anthony Hayes serving as chair. Each member of our audit committee meets the financial literacy requirements of the Nasdaq rules. In addition, our board of directors has determined that Anthony Hayes qualifies as an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K.

Our board of directors adopted a written charter for the audit committee, which is available on our principal corporate website at *www.hoththerapeutics.com.*

Compensation Committee

Our compensation committee is responsible for, among other things:

- reviewing and recommending the compensation arrangements for management, including the compensation for our president and chief executive officer;
- establishing and reviewing general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals;
- administering our stock incentive plans; and
- preparing the report of the compensation committee that the rules of the Securities and Exchange Commission require to be included in our annual meeting proxy statement.

Our compensation committee consists of Anthony Hayes, Vadim Mats and David Sarnoff, with Anthony Hayes serving as chair.

Our board of directors adopted a written charter for the compensation committee, which is available on our principal corporate website at *www.hoththerapeutics.com*.

Nominating and Governance Committee

Our nominating and governance committee is responsible for, among other things:

- identifying and nominating members of the board of directors;
- developing and recommending to the board of directors a set of corporate governance principles applicable to our Company; and
- overseeing the evaluation of our board of directors.

Our nominating and corporate governance committee consists of Vadim Mats, Anthony Hayes and David Sarnoff, with Vadim Mats serving as chair.

Our board of directors adopted a written charter for the nominating and corporate governance committee, which is available on our principal corporate website at *www.hoththerapeutics.com*.

Scientific Advisory Board

In July 2017, the board of directors formed a Scientific Advisory Board (formerly known as the Technology Advisory Board). The members of such board are as follows: (i) Dr. Richard Granstein, Dr. Gurjit Hershey, Dr. William Weglicki, Dr. Vincent Njar, Dr. Glenn Cruse and Dr. Adam Friedman as Medical Doctor members and (ii) Dr. Andrew Herr, Sergio Traversa and Dr. Stefanie Johns as Non-Medical Doctor members.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than 10% of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities.

To our knowledge, based solely upon a review of Forms 3, 4, and 5 filed with the SEC during the fiscal year ended December 31, 2019, we believe that, except as set forth below, our directors, executive officers, and greater than 10% beneficial owners have complied with all applicable filing requirements during the fiscal year ended December 31, 2019.

- Robb Knie failed to report one transaction on time on a Form 3;
- Anthony Hayes failed to report two transactions on time on a Form 3;
- David Sarnoff failed to report one transaction on time on a Form 3;
- Kenneth Rice failed to report two transactions on time on a Form 3;
- Vadim Mats failed to report one transaction on time on a Form 3;
- James Ahern failed to report one transaction on time on a Form 3;
- Matthew Eitner failed to report three transactions on time on a Form 3 and two transactions on time on a Form 4;
- Kevin Jess Poor failed to report two transactions on time on a Form 3 and two transactions on time on a Form 4; and
- Spherix Incorporated failed to report four transactions on time on a Form 5.

Code of Ethics and Code of Conduct

We adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code is posted on our website at *www.hoththerapeutics.com*. Disclosure regarding any amendments to, or waivers from, provisions of the code of conduct and ethics that apply to our directors, principal executive and financial officers will be posted on the "Investors-Corporate Governance" section of our website at *www.hoththerapeutics.com* or will be included in a Current Report on Form 8-K, which we will file within four business days following the date of the amendment or waiver.

Changes in Nominating Procedures

None.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth the compensation paid or accrued during the fiscal year ended December 31, 2019 and 2018 to our principal executive officer and one additional officer (collectively, the "named executive officers"):

- Robb Knie, Chief Executive Officer; and
- Jane H. Behrmann, Vice President of Operations.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified deferred compensation earnings ($)	All Other Compensation ($)	Total ($)
Robb Knie	2019	350,000	175,000	-	1,050,858	-	-	-	1,575,858
Chief Executive Officer and President	2018	250,000	-	58,170	-	-	-	-	308,170
Jane H. Behrmann	2019	123,780	-	-	210,172	-	-	-	333,952
Vice President of Operations	2018	52,083	-	5,000	-	-	-	-	57,083

Outstanding Equity Awards at December 31, 2019

The following table provides information regarding option awards held by each of our named executive officers that were outstanding as of December 31, 2019. There were no stock awards or other equity awards outstanding as of December 31, 2019.

	Option Awards			
Name	**Number of securities underlying unexercised options (#) exercisable**	**Number of securities underlying unexercised options (#) unexercisable**	**Option Exercise Price ($)**	**Option Expiration Date**
Robb Knie Chief Executive Officer	250,000	—	5.26	12/24/2029
Jane H. Behrmann Vice President of Operations	50,000	—	5.26	12/24/2029

Non-Employee Director Compensation

The following table presents the total compensation for each person who served as a non-employee member of our board of directors and received compensation for such service during the fiscal year ended December 31, 2019. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2019.

Name	**Fees earned or paid in cash ($)**	**Stock Awards ($)**	**Option Awards ($)**	**Non-Equity Incentive Plan Compensation ($)**	**Nonqualified deferred compensation earnings ($)**	**All Other Compensation ($)**	**Total ($)**
Vadim Mats	30,000	-	147,120	-	-	-	177,120
Kenneth Rice	45,000	-	147,120	-	-	-	192,120
Anthony Hayes	30,000	-	147,120	-	-	-	177,120
David Sarnoff	30,000	-	147,120	-	-	-	177,120
Graig Springer (1)	-	-	-	-	-	-	-

(1) Graig Springer was appointed as a member of the Company's board of directors on February 28, 2020.

Non-Employee Director Compensation Policy

Our directors will receive $30,000 cash compensation per year for their service on the board of directors, as well as reimbursement for out-of-pocket expenses with respect to such directors' attendance at meetings of the board of directors of the Company. Committee chairs receive an additional one-time $6,000 cash compensation upon appointment for their added services in such roles. In addition, non-employee directors received options to purchase up to 35,000 shares of the Company's common stock at an exercise price of $5.26 per share.

Employment Agreements

Robb Knie Employment Agreement

On February 20, 2019, the Company entered into an amended and restated employment agreement (the "Employment Agreement") with Robb Knie, the Company's Chief Executive Officer in connection with the IPO. The term of the Employment Agreement will continue for a period of one year from the date of execution and automatically renews for successive one year periods at the end of each term until either party delivers written notice of their intent not to review at least six months prior to the expiration of the then effective term. Mr. Knie's base salary was increased to $350,000 per year upon completion of the IPO. Mr. Knie is eligible to receive an annual bonus of up to $100,000 per year at the discretion of the compensation committee of the Company. Mr. Knie is also entitled to participate in any and all Benefit Plans (as defined in the Employment Agreement), from time to time, in effect for senior executives, along with vacation, sick and holiday pay in accordance with the Company's policies established and in effect from time to time.

The Employment Agreement may be terminated upon (i) Mr. Knie's death, (ii) Mr. Knie's Total Disability (as defined in the Employment Agreement), (iii) expiration of the term if either party has provided a timely non-renewal notice, (iv) at Mr. Knie's option (A) upon 90 days prior written notice; provided, however, Mr. Knie may terminate the Employment Agreement by providing written notice at any time within 40 days of the consummation of a Change in Control Transaction (as defined in the Employment Agreement) or (B) for Good Reason (as defined in the Employment Agreement); or (v) at the Company's option (A) for Cause (as defined in the Employment Agreement) or (B) upon 90 days prior written notice without Cause (as defined in the Employment Agreement).

Upon the termination of Mr. Knie's employment for any reason, whether by Mr. Knie or by the Company, Mr. Knie shall be paid accrued but unpaid compensation and vacation pay through the date of termination and any other benefits accrued to him under any Benefit Plans (as defined in the Employment Agreement) outstanding at the date of termination and the reimbursement of expenses incurred on or prior to such date (the "Severance Package"). In addition to the Severance Package, upon Mr. Knie's termination for death or Total Disability (as defined in the Employment Agreement), Mr. Knie or his estate or beneficiaries, as applicable, shall receive (i) 12 months base salary at the then current rate and (ii) payment on a pro-rated basis of any annual bonus or other payments earned in connection with any bonus plan to which the Mr. Knie was a participant as of the date of death or Total Disability. Upon Mr. Knie's termination for Good Reason (as defined in the Employment Agreement), without Cause (as defined in the Employment Agreement) or Mr. Knie's termination upon 90 days prior written notice to the Company or notice to the Company within 40 days of the consummation of a Change in Control Transaction (as defined in the Employment Agreement), in addition to the Severance Package, Mr. Knie shall receive (i) 12 months base salary at the then current rate, (ii) payment on a pro-rated basis of any annual bonus or other payments earned in connection with any bonus plan to which the Mr. Knie was a participant as of the date of termination and (iii) any equity grants to Mr. Knie shall be immediately vested upon termination. The Employment Agreement also contains covenants prohibiting Mr. Knie from disclosing confidential information with respect to the Company.

Jane Behrmann Employment Agreement

On November 12, 2019, the Company entered into an Amended and Restated Employment Agreement (the "Behrmann Employment Agreement") with Jane Behrmann pursuant to which Ms. Behrmann will continue to serve as Vice President of Operations of the Company. The term of the Behrmann Employment Agreement will continue for a period of one year from the date of execution and automatically renews for successive one year periods at the end of each term until either party delivers written notice of their intent not to review at least 30 days prior to the expiration of the then effective term. Pursuant to the terms of the Behrmann Employment Agreement, Ms. Behrmann's base salary was increased to $175,000, and Ms. Behrmann shall continue be entitled to earn a bonus, subject to the sole discretion of the Company's Board. In addition, Ms. Behrmann shall continue be eligible to receive awards pursuant to the Company's equity incentive plans, subject to the sole discretion of the Company's Compensation Committee. Ms. Behrmann is also entitled to participate in any and all Employee Benefit Plans (as defined in the Behrmann Employment Agreement), from time to time, that are then in effect along with vacation, sick and holiday pay in accordance with the Company's policies established and in effect from time to time.

The Behrmann Employment Agreement may be terminated by either the Company or Ms. Behrmann at any time and for any reason upon 10 days prior written notice. Upon termination of the Behrmann Employment Agreement, Ms. Behrman shall be entitled to (i) any equity award that has vested prior to the termination date, (ii) reimbursement of expenses incurred on or prior to such termination date and (iii) such employee benefits to which Ms. Behrmann may be entitled as of the termination date (collectively, the "Accrued Amounts"). The Behrmann Employment Agreement shall also terminate upon Ms. Behrmann's death or the Company may terminate Ms. Behrmann's employment upon her Disability (as defined in the Behrmann Employment Agreement). Upon the termination of Ms. Behrmann's employment for death or Disability, Ms. Behrmann shall be entitled to receive the Accrued Amounts. The Behrmann Employment Agreement also contains covenants prohibiting Ms. Behrmann from disclosing confidential information with respect to the Company.

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

The following table sets forth certain information regarding beneficial ownership of shares of our common stock as of February 28, 2020 by (i) each person known to beneficially own more than 5% of our outstanding common stock, (ii) each of our directors, (iii) each of our named executive officers and (iv) all of our directors and named executive officers as a group. Except as otherwise indicated, the persons named in the table below have sole voting and investment power with respect to all shares beneficially owned, subject to community property laws, where applicable.

Beneficial Owner[1]	Shares of Common Stock Beneficially Owned	Percentage[2]
Directors and Named Executive Officers:		
Robb Knie	1,058,255(3)	10.21%
Vadim Mats	72,500(4)	*
Kenneth Rice (5)	811,944(6)	8.00%
Anthony Hayes (7)	140,329(8)	1.38%
David Sarnoff	49,575(9)	*
Jane H. Behrmann	77,817(10)	*
Graig Springer	0	0%
All Named Executive Officers and Directors as a Group (7 persons)	2,210,420	20.93%
5% or Greater Stockholders:		
Spherix Incorporated (11) One Rockefeller Plaza New York, NY 10020	1,636,230	16.17%
Chelexa Biosciences, Inc. (5) P.O. Box 7122 Lowell, MA 01852	726,944	7.18%
Matthew Eitner (12) 521 Fifth Avenue, 12th Floor New York, NY 10175	785,020(13)	7.76%
Laidlaw Holdings Ltd.	799,499(14)	7.84%
Kevin Poor 750 Beulahs Lane Idaho Falls, ID 83401	937,500(15)	9.10%

* Represents beneficial ownership of less than 1%.

(1) The address of each person is c/o Hoth Therapeutics, Inc., 1 Rockefeller Plaza, Suite 1039, New York, New York 10020 unless otherwise indicated herein.

(2) The calculation in this column is based upon 10,118,732 shares of common stock outstanding on February 28, 2020. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to the subject securities. Shares of common stock that are currently exercisable or convertible within 60 days of February 28, 2020 are deemed to be beneficially owned by the person holding such securities for the purpose of computing the percentage beneficial ownership of such person, but are not treated as outstanding for the purpose of computing the percentage beneficial ownership of any other person.

(3) Includes an option to purchase up to 250,000 shares of the Company's common stock.

(4) Includes an option to purchase up to 35,000 shares of the Company's common stock.

(5) Kenneth Rice is the Executive Chairman of Chelexa and in such capacity has voting and dispositive power over the securities held by such entity.

(6) Includes (i) 50,000 shares of common stock held by Kenneth Rice, (ii) 726,944 shares of common stock held by Chelexa and (ii) an option to purchase up to 35,000 shares of the Company's common stock held by Kenneth Rice.

(7) Pursuant to the Form 5 filed by Spherix Incorporated ("Spherix") on February 27, 2020, the board of directors of Spherix appointed a committee of 3 members to exercise voting and dispositive power over the securities held by Spherix. Anthony Hayes, the Chief Executive Officer and a member of the board of directors of Spherix, abstained from the vote to appoint the committee and is not part of the committee and does not exercise voting and dispositive power over the securities held by such Spherix.

(8) Includes (i) 105,301 shares of common stock and (ii) an option to purchase up to 35,000 shares of the Company's common stock.

(9) Excludes 10,425 shares of common stock which vest in equal installments over a 15 month period.

(10) Includes an option to purchase up to 50,000 shares of the Company's common stock.

(11) Pursuant to the Form 5 filed by Spherix on February 27, 2020, the board of directors of Spherix appointed a committee of 3 members to exercise voting and dispositive power over the securities held by Spherix.

(12) Matthew Eitner is the Chief Executive Officer of Laidlaw & Company (UK) Ltd. ("Laidlaw"). Matthew Eitner disclaims beneficial ownership of the securities owned by Laidlaw and Laidlaw Holdings Ltd.

(13) Includes (i) 765,000 shares of common stock held by Matthew Eitner, (ii) 1,084 shares of common stock held by Matthew Eitner as UTMA custodian for Brynn E. Eitner, (iii) 2,050 shares of common stock held by Matthew Eitner as UTMA custodian for Luke S. Eitner, (iv) 2,035 shares of common stock held by Matthew Eitner as UTMA custodian for Matthew J. Eitner, (v) 11,101 shares of common stock held by Matthew D. Eitner SEP IRA and (vi) 3,750 shares of common stock underlying warrants to purchase common stock held by Matthew Eitner. Matthew Eitner is the Trustee of the Matthew D. Eitner SEP IRA and in such capacity has voting and dispositive power over the securities held by such IRA.

(14) Includes (i) 726,272 shares of common stock held by Laidlaw, (ii) warrants to purchase 70,138 shares of common stock held by Laidlaw and (iii) warrants to purchase 3,089 shares of common stock held by Laidlaw Holdings Ltd. Laidlaw is a subsidiary of Laidlaw Holdings Ltd. Accordingly, Laidlaw Holdings Ltd. has the right to vote and dispose of the securities held by Laidlaw.

(15) Includes (i) 750,000 shares of common stock and (ii) 187,500 shares of common stock underlying warrants to purchase common stock.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes information about our equity compensation plans as of December 31, 2019.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holder	525,000	$ 5.32	299,013
Equity compensation plans not approved by security holder	-	-	-
Total	525,000		299,013

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

The following includes a summary of transactions during our fiscal years ended December 31, 2019 and December 31, 2018 to which we have been a party, including transactions in which the amount involved in the transaction exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described elsewhere in this Annual Report on Form 10-K. We are not otherwise a party to a current related party transaction, and no transaction is currently proposed, in which the amount of the transaction exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years and in which a related person had or will have a direct or indirect material interest.

Laidlaw & Company (UK) Ltd.

On July 6, 2017, we entered into an engagement agreement with Laidlaw. We agreed to pay Laidlaw a fee in the amount of 10% of the gross proceeds of the private placement of our securities received from investors at the closing of such offering. During the year ended December 31, 2018, we paid Laidlaw an aggregate of $174,180 (including expenses of Laidlaw's legal counsel) pursuant to such agreement, inclusive of a non-accountable expense reimbursement equal to 2% of the gross proceeds received from investors during such period.

On February 14, 2019, we entered into an underwriting agreement with Laidlaw pursuant to which we paid Laidlaw a fee in the amount of 7% of the gross proceeds of the IPO, or $490,000. We also reimbursed Laidlaw for certain out-of-pocket expenses, including the fees and disbursements of their counsel, up to an aggregate of $200,000. In addition, Laidlaw received five-year warrants to purchase 50,000 shares of our common stock at an exercise price of $7.00 per share.

On August 16, 2019, we consummated a private offering of units which each unit consisting of one share of our common stock and a warrant to purchase one-half share of our common stock. In connection with the offering, we paid Laidlaw a fee of $294,454.40. In addition, Laidlaw received five-year warrants to purchase 61,113 shares of our common stock at an exercise price of $5.00 per share.

Chelexa Biosciences, Inc.

On May 26, 2017, we entered into a sublicense agreement with Chelexa, as amended on August 22, 2018 and August 29, 2018. Kenneth Rice, a member of our board of directors is the Executive Chairman of Chelexa. Pursuant to the terms of the sublicense agreement, Chelexa granted us an exclusive worldwide sublicense to use the BioLexa Platform, a proprietary, patented, drug compound platform developed at the University of Cincinnati. Furthermore, pursuant to the terms of the sublicense agreement, we will pay Chelexa up to an aggregate of $3.8 million, of which $300,000 has been paid to date. Such amount consists of total milestone payments of $3.5 million in addition to payments by us of certain licensing fees and all development and commercialization expenses. In addition, we will also be required to pay sales-based royalties at percentages which range from mid to high single digits, with high sales volumes being subject to lower royalty rates. We also issued Chelexa 250,000 shares of our common stock, as well as an additional 476,943 shares of our common stock which was 10% of our fully-diluted equity at May 26, 2017, as adjusted, until such time that we had raised a minimum of $3,000,000. As of the date hereof, we have issued Chelexa an aggregate of 476,943 additional shares of common stock pursuant to the Preemptive Right. We have raised more than $3,000,000 and therefore the Preemptive Right has been terminated. The sublicense agreement shall terminate on the later of April 16, 2034 or the last to expire patent in the Patent Rights (as defined in the sublicense agreement) (the "Sublicense Term"). We have the right of first refusal, in our sole discretion, to renew the Sublicense Term. We may terminate the sublicense agreement at any time upon twelve months prior notice. In the event we are in default of any of our material obligations under the sublicense agreement, Chelexa may, at its option upon 90 days prior written notice, terminate the sublicense agreement if we do not cure such default prior to the expiration of such 90 day period. In addition, at any time after May 26, 2018, Chelexa may, at its sole discretion, terminate or render the license non-exclusive if, in Chelexa's judgment the Progress Reports (as defined in the sublicense agreement) furnished by us does not demonstrate that we used our best commercial efforts to develop and seek regulatory approval for the BioLexa Platform in the Territory (as defined in the sublicense agreement) and in the Field (as defined in the sublicense agreement) and /or is engaged in manufacturing, marketing or sublicensing activity which is reasonably expected to keep the BioLexa Platform reasonably available to the public. The sublicense agreement will automatically terminate upon the expiration of the UC License (as defined in the sublicense agreement).

Spherix

In connection with the sale of 1,700,000 the shares of common stock, on June 30, 2017, we entered into a registration rights agreement ("Spherix RRA") with Spherix Incorporated ("Spherix"), a company in which Anthony Hayes, a member of our board of directors, is the Chief Executive Officer and member of the board of directors, pursuant to which we agreed, among other things, to file with the SEC a registration statement on Form S-1 under the Securities Act that covers the resale of 1,700,000 shares of common stock issued to Spherix pursuant to a securities purchase agreement between us and Spherix and any securities issued or issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect to the foregoing (the "Spherix Registrable Securities"). Pursuant to the Spherix RRA, we are obligated to use our best efforts to have the registration statement declared effective by the SEC as soon as practicable after it is filed with the SEC, but in no event later than the applicable Effectiveness Date. "Effectiveness Date" means with respect to the initial registration statement required to be filed pursuant to the Spherix RRA, the 18 month anniversary of the closing date of the transactions contemplated by the securities purchase agreement and, with respect to any additional registration statements which may be required pursuant to the Spherix RRA, the earliest practical date on which we are permitted to go effective on such additional registration statement; provided, however, that, in the event we are notified by the SEC that one or more of the above registration statements will not be reviewed or is no longer subject to further review and comments, the Effectiveness Date as to such registration statement shall be the fifth trading day following the date on which we are so notified if such date precedes the dates otherwise required above. In addition, pursuant to the terms of the Spherix RRA, without the consent of Spherix, neither we nor any of our security holders may include our securities in any registration statements other than the Spherix Registrable Securities. Furthermore, subject to certain exemptions, if at any time during the Effectiveness Period there is not an effective registration statement covering all of the Spherix Registrable Securities and we shall determine to prepare and file with the SEC a registration statement relating to an offering for our own account or the account of others under the Securities Act of any of our equity securities, then we shall deliver to Spherix a written notice of such determination and, if within 15 days after the date of the delivery of such notice, Spherix notifies us in writing, we must include in such registration statement all or any part of such Spherix Registrable Securities requested to be registered by Spherix.

In addition, we entered into a lock-up leak-out agreement with Spherix pursuant to which Spherix and its affiliates have agreed to not take certain actions, including exercising their registration rights, until the 36 month anniversary of the IPO.

Pursuant to such agreement and the Spherix RRA, we have registered 70,000 of the Spherix Registrable Securities for resale on a registration statement on Form S-1. In addition, we registered 100,000 of the Spherix Registrable Securities for distribution to Spherix's stockholders on a registration statement on Form S-1.

Alderaan Group, LLC

On January 1, 2019, we entered into a Project Management Agreement with Alderaan Group, LLC ("Alderaan"), a company in which Kenneth Rice, a member of our board of directors, is the Chief Executive Officer. Pursuant to the terms of the Project Management Agreement, Alderaan provides us with certain services including assistance with certain clinical trials of BioLexa, non-clinical work, material production and stability studies, expansion efforts with respect to intellectual property and providing support with respect to our acquisition efforts. During the year ended December 31, 2019, we paid Alderaan an aggregate of $145,000 pursuant to such agreement.

Related Person Transaction Policy

We have adopted a formal policy regarding approval of transactions with related parties. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds the lesser of $120,000 or 1% of our total assets at the end of our last completed fiscal year. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our code of business conduct and ethics, our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our shareholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

Director Independence

Our board of directors has determined that a majority of the board consists of members who are currently "independent" as that term is defined under NASDAQ Listing Rule 5605(a)(2). The Board considers Anthony Hayes, Vadim Mats, David Sarnoff and Graig Springer to be "independent."

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table sets forth the aggregate fees billed by as described below:

	2019	2018
Audit Fees	152,011	71,400
Audit Related Fees	-	-
Tax Fees	6,232	1,525
All Other Fees	-	-
Total	158,243	72,925

Audit Fees: Audit Fees consist of fees billed for professional services performed by WithumSmith+Brown, PC for the audit of our annual consolidated financial statements, the review of interim consolidated financial statements, and related services that are normally provided in connection with registration statements.

Audit-Related Fees: Audit Related Fees may consist of fees billed by an independent registered public accounting firm for assurance and related services that are reasonably related to the performance of the audit or review of our consolidated financial statements.

Tax Fees: Tax Fees consist of fees for professional services, including tax compliance performed by WithumSmith+Brown, PC.

All Other Fees: There were no such fees incurred by the Company in the fiscal years ended December 31, 2019 and 2018.

Pre-Approval Policies and Procedures

In accordance with the Sarbanes-Oxley Act, our audit committee charter requires the audit committee to pre-approve all audit and permitted non-audit services provided by our independent registered public accounting firm, including the review and approval in advance of our independent registered public accounting firm's annual engagement letter and the proposed fees contained therein. The audit committee has the ability to delegate the authority to pre-approve non-audit services to one or more designated members of the audit committee. If such authority is delegated, such delegated members of the audit committee must report to the full audit committee at the next audit committee meeting all items pre-approved by such delegated members. In the fiscal years ended December 31, 2019 and 2018 all of the services performed by our independent registered public accounting firm were pre-approved by the audit committee.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

(1) Financial Statements:

The consolidated financial statements required by this Item are included beginning at page F-1.

(1) Financial Statement Schedules:

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

(b) Exhibits

EXHIBIT INDEX

Exhibit Number	Exhibit
3.1	Articles of Incorporation (Incorporated by reference to Exhibit 3.1 to the Company's Form S-1/A filed on December 14, 2018)
3.2	Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.2 to the Company's Form S-1/A filed on December 14, 2018)
3.3	Certificate of Designations, Preferences and Rights of the Series A Convertible Preferred Stock (Incorporated by reference to Exhibit 3.3 to the Company's Form S-1/A filed on December 14, 2018)
3.4	Amendment to Articles of Incorporation (Incorporated by reference to Exhibit 3.1 to the Company's Form 8-K filed on February 20, 2019)
3.5	Amended and Restated Bylaws (Incorporated by reference to Exhibit 3.2 to the Company's Form 8-K filed on February 20, 2019)
4.1	Specimen Stock Certificate evidencing the shares of common stock (Incorporated by reference to Exhibit 4.1 to the Company's Form S-1/A filed on December 14, 2018)
4.2	Form of Underwriter Warrant (Incorporated by reference to Exhibit 4.2 to the Company's Form S-1/A filed on January 11, 2019)
10.1+	Amended and Restated Employment Agreement between Hoth Therapeutics, Inc. and Robb Knie (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on February 20, 2019)
10.2#	Sublicense Agreement with Chelexa Biosciences, Inc. dated May 26, 2017 (Incorporated by reference to Exhibit 10.4 to the Company's Form S-1/A filed on December 14, 2018)
10.3#	License Agreement with the University of Cincinnati dated May 18, 2018 (Incorporated by reference to Exhibit 10.5 to the Company's Form S-1/A filed on December 14, 2018)
10.4	Office Service Agreement with Regus dated June 26, 2017 (Incorporated by reference to Exhibit 10.7 to the Company's Form S-1/A filed on December 14, 2018)
10.5	Form of Warrant (Incorporated by reference to Exhibit 10.8 to the Company's Form S-1/A filed on December 14, 2018)
10.6	Form of Unit Purchase Agreement (Incorporated by reference to Exhibit 10.9 to the Company's Form S-1/A filed on December 14, 2018)
10.7	Form of Investor Rights Agreement (Incorporated by reference to Exhibit 10.10 to the Company's Form S-1/A filed on December 14, 2018)
10.8+	2018 Equity Incentive Plan (Incorporated by reference to Exhibit 10.11 to the Company's Form S-1/A filed on December 14, 2018)
10.9*	Renewal Agreement with Regus dated May 2, 2019
10.10	Form of Securities Purchase Agreement (Incorporated by reference to Exhibit 10.13 to the Company's Form S-1/A filed on December 14, 2018)
10.11	Form of Registration Rights Agreement (Incorporated by reference to Exhibit 10.14 to the Company's Form S-1/A filed on December 14, 2018)
10.12	Amendment No. 1 to Sublicense Agreement with Chelexa Biosciences, Inc. dated August 22, 2018 (Incorporated by reference to Exhibit 10.15 to the Company's Form S-1 filed on October 10, 2018)
10.13	Amendment No. 2 to Sublicense Agreement with Chelexa Biosciences, Inc. dated August 29, 2018 (Incorporated by reference to Exhibit 10.16 to the Company's Form S-1 filed on October 10, 2018)

10.14+	Employment Agreement between Hoth Therapeutics, Inc. and David Briones (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on March 7, 2019)
10.15	Form of Subscription Agreement (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on August 21, 2019)
10.16	Form of Unit Purchase Agreement (Incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed on August 21, 2019)
10.17	Form of Warrant (Incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed on August 21, 2019)
10.18	Form of Registration Rights Agreement (Incorporated by reference to Exhibit 10.4 to the Company's Form 8-K filed on August 21, 2019)
10.19	Form of Placement Agent Warrant (Incorporated by reference to Exhibit 10.5 to the Company's Form 8-K filed on August 21, 2019)
10.20##	Exclusive Sublicense Agreement between the Company and Zylö Therapeutics, Inc. (Incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on August 23, 2019)
10.21+	Amended and Restated Employment Agreement between Hoth Therapeutics, Inc. and Jane H. Behrmann (Incorporated by reference to Exhibit 10.7 to the Company's Form 10-Q filed on November 12, 2019)
10.22*	License Agreement with North Carolina State University dated November 20, 2019
21.1*	Subsidiaries of the registrant
23.1*	Consent of WithumSmith+Brown, PC
31.1*	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of the Exchange Act, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase.
101.LAB*	XBRL Taxonomy Extension Labels Linkbase.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase.

* Filed herewith.

\+ Indicates a management contract or any compensatory plan, contract or arrangement.

\# Confidential treatment has been requested to a portion of this exhibit, and such confidential portion has been deleted and filed separately with the SEC.

Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized on this 2nd day of March, 2020.

HOTH THERAPEUTICS, INC.

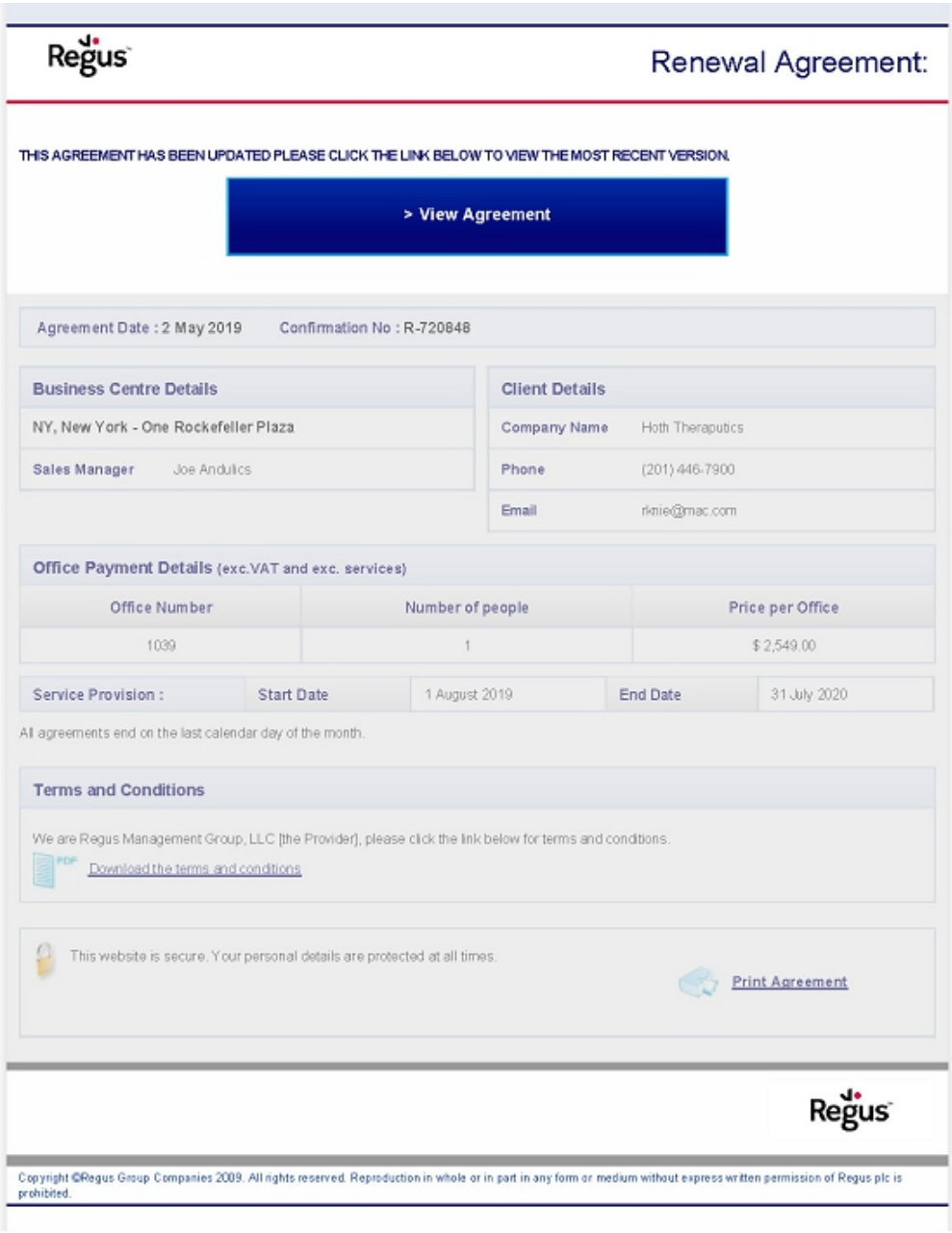
/s/ Robb Knie
Robb Knie
Chief Executive Officer
(Principle Executive Officer)

/s/ David Briones
David Briones
Chief Financial Officer
(Principal Financial and Accounting Officer)

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

Signature	Title	Date
/s/ Robb Knie Robb Knie	Chief Executive Officer, President and Director (Principle Executive Officer)	March 2, 2020
/s/ David Briones David Briones	Chief Financial Officer (Principal Financial and Accounting Officer)	March 2, 2020
/s/ Vadim Mats Vadim Mats	Director	March 2, 2020
/s/ Kenneth Rice Kenneth Rice	Director	March 2, 2020
/s/ Anthony Hayes Anthony Hayes	Director	March 2, 2020
/s/ David B. Sarnoff David B. Sarnoff	Director	March 2, 2020
/s/ Graig Springer Graig Springer	Director	March 2, 2020

Exhibit 10.9



Regus

Renewal Agreement:

THIS AGREEMENT HAS BEEN UPDATED PLEASE CLICK THE LINK BELOW TO VIEW THE MOST RECENT VERSION.

> View Agreement

Agreement Date : 2 May 2019 Confirmation No : R-720848

Business Centre Details

NY, New York - One Rockefeller Plaza

Sales Manager Joe Andulics

Client Details

Company Name Hoth Theraputics

Phone (201) 446-7900

Email rkmie@mac.com

Office Payment Details (exc.VAT and exc. services)

Office Number	Number of people	Price per Office
1039	1	$ 2,549.00

Service Provision :	Start Date	1 August 2019	End Date	31 July 2020

All agreements end on the last calendar day of the month.

Terms and Conditions

We are Regus Management Group, LLC [the Provider], please click the link below for terms and conditions.

Download the terms and conditions

This website is secure. Your personal details are protected at all times.

Print Agreement

Regus

These General Terms and Conditions apply to Office/Co-Working, Virtual Office and Membership agreements for services We supply to You.

1. General Agreement

1.1. Nature of an agreement: At all times, each Centre remains in Our possession and control. YOU ACCEPT THAT AN AGREEMENT CREATES NO TENANCY INTEREST, LEASEHOLD ESTATE OR OTHER REAL PROPERTY INTEREST IN YOUR FAVOUR WITH RESPECT TO THE ACCOMMODATION. Occupation by You is the commercial equivalent of an agreement for accommodation in a hotel. We are giving You the right to share the use of the Centre with Us and other clients.

1.2. House Rules: The House Rules, which are incorporated into these terms and conditions, are primarily in place and enforced to ensure that all clients have a professional environment to work in.

1.3. Availability at the start of an agreement: If for any unfortunate reason We cannot provide the services or accommodation in the Centre stated in an agreement by the start date, We will have no liability to You for any loss or damage but You may either move to one of Our other Centres (subject to availability), delay the start of the agreement or cancel it.

1.4. **AUTOMATIC RENEWAL:** SO THAT WE CAN MANAGE YOUR SERVICES EFFECTIVELY AND TO ENSURE SEAMLESS CONTINUITY OF THOSE SERVICES, ALL AGREEMENTS WILL RENEW AUTOMATICALLY FOR SUCCESSIVE PERIODS EQUAL TO THE CURRENT TERM UNTIL BROUGHT TO AN END BY YOU OR US. ALL PERIODS SHALL RUN TO THE LAST DAY OF THE MONTH IN WHICH THEY WOULD OTHERWISE EXPIRE. THE FEES ON ANY RENEWAL WILL BE AT THE THEN PREVAILING MARKET RATE. IF YOU DO NOT WISH FOR AN AGREEMENT TO RENEW THEN YOU CAN CANCEL IT EASILY WITH EFFECT FROM THE END DATE STATED IN THE AGREEMENT, OR AT THE END OF ANY EXTENSION OR RENEWAL PERIOD, BY GIVING US PRIOR NOTICE. NOTICE MUST BE GIVEN THROUGH YOUR ONLINE ACCOUNT OR THROUGH THE APP. THE NOTICE PERIODS REQUIRED ARE AS FOLLOWS:

Term	Notice Period
Month-to-Month	no less than 1 month's notice from the 1st day of any calendar month
3 months	no less than 2 months' notice prior to the end of the term
More than 3 months	no less than 3 months' notice prior to the end of the term

1.5. We may elect not to renew an agreement. If so, We will inform You by email, through the App or Your online account, following the same notice periods specified above.

1.6. If the Centre is no longer available: In the event that We are permanently unable to provide the services and accommodation at the Centre stated in an agreement, We will offer You accommodation in one of Our other centres. In the unlikely event we unable to find an alternative accommodation that is acceptable to You, Your agreement will end and You will only have to pay monthly fees up to that date and for any additional services You have used.

1.7. Ending an agreement immediately: We may put an end to an agreement immediately by giving You notice if (a) You become insolvent or bankrupt; or (b) You breach one of your obligations which cannot be put right, or which We have given You notice to put right and which You have failed to put right within 14 days of that notice; or (c) Your conduct, or that of someone at the Centre with Your permission or invitation, is incompatible with ordinary office use and, (i) that conduct continues despite You having been given notice, or (ii) that conduct is material enough (in Our reasonable opinion) to warrant immediate termination; or (d) You are in breach of the "Compliance With Law" clause below. If We put an end to an agreement for any of the reasons referred to in this clause it does not put an end to any of Your financial obligations, including, without limitation, for the remainder of the period for which Your agreement would have lasted if We had not terminated it.

1.8. When an Office agreement ends: When an agreement ends You must vacate Your accommodation immediately, leaving it in the same state and condition as it was when You took it. Upon Your departure or if You choose to relocate to a different room within a Centre, We will charge a fixed office restoration service fee to cover normal cleaning and any costs incurred to return the accommodation to its original condition and state. This fee will differ by country and is listed in the House Rules. We reserve the right to charge additional reasonable fees for any repairs needed above and beyond normal wear and tear. If You leave any property in the Centre We may dispose of it at Your cost in any way, We choose without owing You any responsibility for it or any proceeds of sale. If You continue to use the accommodation when an agreement has ended, You are responsible for any loss, claim or liability We may incur as a result of Your failure to vacate on time.

2. Use of the Centres:

2.1. Business Operations: You may not carry on a business that competes with Our business of providing serviced offices and flexible working. You may not use Our name (or that of Our affiliates) in any way in connection with Your business. You are only permitted to use the address of a Centre as Your registered office address if it is permitted by both law and if We have given You prior written consent (given the additional administration there is an additional fee chargeable for this service). You must only use the accommodation for office business purposes. If We decide that a request for any particular service is excessive, We reserve the right to charge an additional fee. In order to ensure that the Centre provides a great working environment for all, We kindly ask you to limit any excessive visits by members of the public.

2.2. Accommodation

2.2.1. Alterations or Damage: You are liable for any damage caused by You or those in the Centre with Your permission, whether express or implied, including but not limited to all employees, contractors and/or agents.

2.2.2. IT Installations: We take great pride in Our IT infrastructure and its upkeep and therefore You must not install any cabling, IT or telecom connections without Our consent, which We may refuse in our absolute discretion. As a condition to Our consent, You must permit Us to oversee any installations (for example IT or electrical systems) and to verify that such installations do not interfere with the use of the accommodation by other clients or Us or any landlord of the building. Fees for installation and de-installation will be at Your cost.

2.2.3. Use of the Accommodation: An agreement will list the accommodation We initially allocate for Your use. You will have a non-exclusive right to the rooms allocated to You. Occasionally to ensure the efficient running of the Centre, We may need to allocate different accommodation to You, but it will be of reasonably equivalent size and We will notify You with respect to such different accommodation in advance.

2.2.4. Access to the Accommodation: In order to maintain a high level of service, We may need to enter Your accommodation and may do so at any time, including without limitation, in an emergency, for cleaning and inspection or in order to resell the space if You have given notice to terminate. We will always endeavour to respect any of Your reasonable security procedures to protect the confidentiality of Your business.

2.3. Membership:

2.3.1. If You have subscribed to a Membership Agreement You will have access to all participating centres worldwide during standard business working hours and subject to availability.

2.3.2. Membership Usage: Usage is measured in whole days and unused days cannot be carried over to the following month. A membership is not intended to be a replacement for a full-time workspace and all workspaces must be cleared at the end of each day. You are solely responsible for Your belongings at the centre at all times. We are not responsible for any property that is left unattended. Should You use more than Your membership entitlement, We will charge You an additional usage fee. You may bring in 1 guest free of charge (subject to fair usage). Any further guests will be required to purchase a day pass.

2.3.3. As a Member, You may not use any Centre as Your business address without an accompanying office or virtual office agreement in place. Any use of the Centre address in such a way will result in an automatic enrolment in the Virtual Office product for the same term as Your membership and You will be invoiced accordingly.

2.4. Compliance with Law: You must comply with all relevant laws and regulations in the conduct of Your business. You must not do anything that may interfere with the use of the Centre by Us or by others (including but not limited to political campaigning or immoral activity), cause any nuisance or annoyance, or cause loss or damage to Us (including damage to reputation) or to the owner of any interest in the building. If We have been advised by any government authority or other legislative body that it has reasonable suspicion that You are conducting criminal activities from the Centre, or You are or become subject to any government sanctions, then We shall be entitled to terminate any and all of Your agreements with immediate effect. You acknowledge that any breach by You of this clause shall constitute a material default, entitling Us to terminate Your agreement without further notice.

2.5. Ethical Trading: Both We and You shall comply at all times with all relevant anti-slavery, anti-bribery and anti-corruption laws.

2.6. Data protection: You acknowledge that We may collect and process personal data from You and Your employees as strictly necessary to ensure compliance with applicable laws and regulations and to enable Us effectively to provide services to You. You acknowledge and accept that such personal data may be transferred or made accessible to other entities in our group, wherever located, for the purposes of providing the services, in each case in accordance with all applicable data protection legislation.

2.7. Employees: We will both have invested a great deal in training Our staff, therefore, neither of us may knowingly solicit or offer employment to the other's staff employed in the Centre (or for 3 months after they have left their employment). To recompense the other for staff training and investment costs, if either of us breaches this clause the breaching party will pay upon demand the other the equivalent of 6 months' salary of any employee concerned.

2.8. Confidentiality: The terms of an agreement are confidential. Neither of us may disclose them without the other's consent unless required to do so by law or an official authority. This obligation continues for a period of 3 years after an agreement ends.

2.9. Assignment: An agreement is personal to You and cannot be transferred to anyone else without prior consent from Us unless such transfer is required by law. However, We will not unreasonably withhold our consent to assignment to an affiliate provided that You execute our standard form of assignment. We may transfer any agreement and any and all amounts payable by You under an agreement to any other member of Our group.

2.10. Applicable law: An agreement is interpreted and enforced in accordance with the law of the place where the Centre is located other than in a few specific jurisdictions which are detailed in the House Rules. We and You both accept the exclusive jurisdiction of the courts of that jurisdiction. If any provision of these terms and conditions is held void or unenforceable under the applicable law, the other provisions shall remain in force.

3. Our liability to You and Insurance

3.1. The extent of Our liability: To the maximum extent permitted by applicable law, We are not liable to You in respect of any loss or damage You suffer in connection with an agreement, including without limitation any loss or damage arising as a result of our failure to provide a service as a result of mechanical breakdown, strike or other event outside of Our reasonable control otherwise unless We have acted deliberately or have been negligent. In no event shall We be liable for any loss or damage until You provide written notice and give Us a reasonable time to put it right. If We are liable for failing to provide You with any service under an agreement then, subject to the exclusions and limits set out immediately below, We will pay any actual and the reasonable additional expense You have incurred in obtaining the same or similar service from elsewhere.

3.2. Your Insurance: It is Your responsibility to arrange insurance for property which You bring in to the Centre, for any post You send or receive and for Your own liability to your employees and to third parties. We strongly recommend that You put such insurance in place.

3.3. IT Services and Obligations: Whilst We have security internet protocols in place and strive to provide seamless internet connectivity, WE DO NOT MAKE ANY REPRESENTATION AND CANNOT GUARANTEE ANY MAINTAINED LEVEL OF CONNECTIVITY TO OUR NETWORK OR TO THE INTERNET, NOR THE LEVEL OF SECURITY OF IT INFORMATION AND DATA THAT YOU PLACE ON IT. You should adopt whatever security measures (such as encryption) You believe are appropriate to Your business. Your sole and exclusive remedy in relation to issues of reduced connectivity which are within Our reasonable control shall be for Us to rectify the issue within a reasonable time following notice from You to Us.

3.4. EXCLUSION OF CONSEQUENTIAL LOSSES: WE WILL NOT IN ANY CIRCUMSTANCES HAVE ANY LIABILITY TO YOU FOR LOSS OF BUSINESS, LOSS OF PROFITS, LOSS OF ANTICIPATED SAVINGS, LOSS OF OR DAMAGE TO DATA, THIRD PARTY CLAIMS OR ANY CONSEQUENTIAL LOSS. WE STRONGLY RECOMMEND THAT YOU INSURE AGAINST ALL SUCH POTENTIAL LOSS, DAMAGE, EXPENSE OR LIABILITY.

3.5. Financial limits to our liability: In all cases, our liability to You is subject to the following limits:

3.5.1. without limit for personal injury or death;

3.5.2. up to a maximum of GBP 1 million (or USD 1.5 million or EUR 1 million or other local equivalent) for any one event or series of connected events for damage to Your personal property; and

3.5.3. in respect of any other loss or damage, up to a maximum equal to 125% of the total fees paid between the date services under an agreement commenced and the date on which the claim in question arises; or if higher, for office agreements only, GBP 50,000 / USD 100,000 / EUR 66,000 (or local equivalent).

4. Fees

4.1. Service Retainer/Deposit: Your service retainer / deposit will be held by Us without generating interest as security for performance of all Your obligations under an agreement. All requests for the return must be made through Your online account or App after which the service retainer/deposit or any balance will be returned within 30 days to You once your agreement has ended and when You have settled Your account. We will deduct any outstanding fees and other costs due to Us before returning the balance to You. We may require You to pay an increased retainer if the monthly office or virtual office fee increases upon renewal, outstanding fees exceed the service retainer/deposit held and/or You frequently fail to pay invoices when due.

4.2. Taxes and duty charges: You agree to pay promptly (i) all sales, use, excise, consumption and any other taxes and license fees which You are required to pay to any governmental authority (and, at Our request, You will provide to Us evidence of such payment) and (ii) any taxes paid by Us to any governmental authority that are attributable to Your accommodation, where applicable, including, without limitation, any gross receipts, rent and occupancy taxes, tangible personal property taxes, stamp tax/duty or other documentary taxes and fees.

4.3. Payment: We are continually striving to reduce our environmental impact and support You in doing the same. Therefore, We will send all invoices electronically and You will make payments via an automated method such as Direct Debit or Credit Card, wherever local banking systems permit.

4.4. Late payment: If You do not pay fees when due, a fee will be charged on all overdue balances. This fee will differ by country and is listed in the House Rules. If You dispute any part of an invoice You must pay the amount not in dispute by the due date or be subject to late fees. We also reserve the right to withhold services (including for the avoidance of doubt, denying You access to the Centre where applicable) while there are any outstanding fees and/or interest, or You are in breach of an agreement.

4.5. Insufficient Funds: Due to the additional administration We incur You will pay a fee for any returned or declined payments due to insufficient funds. This fee will differ by country and is listed in the House Rules.

4.6. Indexation: If an agreement is for a term of more than 12 months, We will increase the monthly fee on each anniversary of the start date in line with the relevant inflation index detailed in the House Rules.

4.7. Standard services: Monthly fees, plus applicable taxes, and any recurring services requested by You are payable monthly in advance. Where a daily rate applies, the charge for any such month will be 30 times the daily fee. For a period of less than a month the fee will be applied on a daily basis.

4.8. Pay-as-you-use and Additional Variable Services: Fees for pay-as-you-use services, plus applicable taxes, are payable monthly in arrears at our standard rates which may change from time to time and are available on request.

4.9. Discounts, Promotions and Offers: If You benefited from a special discount, promotion or offer, We will discontinue that discount, promotion or offer without notice if You materially breach Your agreement.

LICENSE AGREEMENT

THIS Agreement (“License Agreement”) is entered into this 20th day of November, 2019 (“Effective Date”) between NORTH CAROLINA STATE UNIVERSITY, a constituent institution of the University of North Carolina and a nonprofit educational and research institution organized under the laws of North Carolina ("NCSU"), having its principal office at Campus Box 8210, Raleigh, North Carolina 27695-8210, and HOTH THERAPEUTICS ,INC., a corporation organized under the laws of Nevada ("Licensee"), with its corporate headquarters in New York and having its principal office at 1 Rockefeller Plaza, 10th Floor, New York, NY, 10020.

RECITALS

A. NCSU owns certain Patent Rights (defined below) and has the right to grant licenses under the Patent Rights.

B. NCSU desires to have the Patent Rights developed and commercialized to benefit the public and is willing to grant a license to the Licensee for that purpose.

C. Licensee is sponsoring research at NCSU to help further develop and validate the technology disclosed and claimed in with the Patent Rights.

D. Licensee desires to obtain a license under the Patent Rights upon the terms and conditions set forth in this License Agreement.

Therefore, in consideration of these Recitals, any sums to be paid, any rights granted, and the mutual promises contained in this License Agreement, the parties agree to the following

TERMS AND CONDITIONS:

ARTICLE 1 – DEFINITIONS

For the purposes of this License Agreement, the terms and phrases below have the following definitions:

1.01 “Affiliate” means any corporation or non-corporate entity that controls, is controlled by or is under the common control with Licensee. A corporation or a non-corporate entity, as applicable, is deemed to be in control of another corporation if (a) it owns or directly or indirectly controls at least 50% of the voting stock of the other corporation or (b) in the absence of ownership of at least 50% of the voting stock of a corporation, or in the case of a non-corporate entity, if it possesses directly or indirectly, the power to direct or cause the direction of the management and policies of such corporation or non-corporate entity, as applicable.

1.02 “Field of Use” means all fields of use.

1.03 “First Commercial Sale” means any transfer for value of a Licensed Product(s) in an arms-length transaction to an independent Third Party distributor, agent or end user in a country after obtaining, all approvals or authorizations from applicable authorities (including, if applicable, regulatory authorities) required for the manufacture, importation, marketing, promotion, pricing, reimbursement and sale of the Licensed Product(s) in such country.

1.04 “Licensed Products” means products the discovery, development, manufacture, use, sale, offer for sale or import of which, in the absence of this License Agreement, would infringe at least one claim of an issued patent or patent application within the Patent Rights or products that are made using a process or machine the use of which, in the absence of this License Agreement, would infringe a claim of an issued patent or patent application within the Patent Rights and/or any product or service that is based on, derived from, incorporates, or utilizes, wholly or in part the technical know-how included within the specifications of an issued patent or patent application within the Patent Rights.

1.05 “Licensed Service” means any service that (a) is provided by Licensee to a third party and (b) utilizes Patent Rights or Licensed Product;

1.06 “Licensed Territory” means worldwide.

1.07 “Net Sales” for the purpose of computing royalties under this License Agreement means the total invoiced sales price directly associated with the Licensed Product and/or Licensed Services less any documented charges for (i) sales taxes or other taxes separately stated on the invoice, (ii) shipping and insurance charges associated with the License Product, (iii) deductions for actual allowances for returned or defective goods, (iv) trade discounts, but not cash discounts, and (v) rebates, credits, and chargeback payments (or the equivalent thereof) granted to managed health care organizations, wholesalers, or to federal, state/provincial, local and other governments, including their agencies, purchasers, and/or reimbursers, or to trade customers. In order to assure NCSU the full royalty payments contemplated in this License Agreement, Licensee agrees that in the event any Licensed Products and Licensed Services are sold for purposes of resale, the royalties to be paid in respect to such Licensed Products and/or Licensed Service will be computed on the Net Sales price at which the purchaser for resale sells such products rather than upon the Net Sales price of the Licensee. Specifically excluded from the definition of “Net Sales” are amounts attributable to (i) any sale of any Licensed Product and Licensed Service between or among Licensee and its Affiliates and/or sublicensees, unless the transferee is the end purchaser, user, or consumer of such Licensed Product and/or Licensed Service, or (ii) the provision of reasonable, documented quantities of Licensed Products and/or Licensed Services that are provided for free only for sampling and educational use purposes.

1.08 “Patent Rights” means (a) the patent applications listed and identified as such in Appendix A (hereafter referred to as “Patent Applications”); (b) any patent already issued or issuing on any such Patent Applications; and (c) all divisionals, continuations, continuations-in-part, reissues, certificates, extensions or foreign counterparts of such applications or patents. Continuations-in-part, for the purposes of this License Agreement, means all continuation-in-part applications only to the extent that they cover technology disclosed, claimed in and dominated by the Patent Applications. Notwithstanding the foregoing, Patent Rights does not include those patents and/or patent applications that, during the Term of this License Agreement, cease to be Patent Rights pursuant to Article 8.01 01 (“Prosecution”) or 8.03 (“Surrender of Patent Rights”).

1.09 “Sale or Sold”, for purposes of computing royalties, means when invoiced, rented, exchanged or otherwise transferred by gift or otherwise, including the use of Licensed Products by Licensee or any other person authorized by Licensee, except to the extent that such Licensed Products and/or Licensed Services are used strictly for development of a Licensed Product. Where products are not sold but otherwise transferred, Net Sales for the purposes of computing royalties will be the selling price at which products of similar kind and quality, sold in similar quantities, are currently being offered for sale by Licensee. Where such products are not currently being offered for sale by Licensee, the Net Sales of products otherwise transferred will be the average selling price at which products of similar kind and quality, sold in similar quantities, are then currently being offered for sale by other manufacturers.

1.10 “Sublicense(s), Sublicensed, or Sublicensable” means grant of a sublicense or any other right, license, privilege, or immunity (including but not limited to the grant of the option to acquire a sublicense or rights to negotiate for a sublicense) under the Patent Rights by the Licensee (in accordance with Article 7) to a Third Party.

1.11 “Sublicense Revenues” means all consideration received by Licensee or its Affiliate (net of any tax or similar withholding obligations imposed by any tax or other government authority that are not reasonably recoverable by Licensee) from any Third Party from the grant of a Sublicense to such Third Party by Licensee in the applicable transaction or series of transactions, including, but not limited to, any initial sublicensing fees, option fees, milestone payments (including but not limited to payments received for achieving preclinical, clinical, regulatory, developmental, scale up, sales, or any other milestone), or running royalty payments, but excluding (a) running royalty payments due to NCSU under Article 3.04, (b) purchases of equity or debt of Licensee at the fair market value of such equity, (c) payments for research and development to specifically further the commercialization of any Licensed Products and Licensed Services, and (d) amounts identified and paid for in the Sublicense specifically for the reimbursement of reasonable out of pocket patent prosecution and maintenance costs for the Patent Rights.

1.12 “Term” means the period during which this License Agreement is active in accordance with Article 12.01.

1.13 “Third Party(ies)” means any individual or entity that is not party to this License Agreement or an Affiliate of a party to this License Agreement.

1.14 Certain other defined terms have the meanings given them elsewhere in this License Agreement. As used herein, the term “and/or” when used in the context of listing of entities, refers to the entities being present singly or in combination (for example, the phrase “A and/or B includes A and B individually, but also includes any combinations of A and B).

ARTICLE 2 – LICENSE

2.01 Grant

Subject to the terms and conditions of this License Agreement, NCSU grants to Licensee and Licensee accepts from NCSU an exclusive, Sublicensable license (subject to Article 7) under the Patent Rights for the Field of Use in the Licensed Territory to discover, develop, make, have made, use, lease, import, export, offer to sell and/or sell Licensed Products, and to sell, offer to sell, use, and practice Licensed Services. The foregoing license includes the right to engage Licensee's Affiliates and Third Party contractors in exercising such rights and in carrying out its activities and obligations under this License Agreement. In addition, the rights licensed to Licensee hereunder shall be extended to Affiliates designated in writing by Licensee, provided that each such Affiliate first agrees in writing to be bound by all the terms and conditions of this License Agreement. Licensee shall deliver to NCSU a copy of said writing within thirty (30) days of its execution. Termination of this License Agreement for any reason whatsoever will result in the automatic and immediate termination of any and all of the aforementioned rights and privileges extended by the Licensee to any of its Affiliates.

2.02 Reservation of Rights

NCSU retains the right, on behalf of themselves and all other non-profit academic or governmental research institutions, to make and use for non-commercial research purposes, including sponsored research and collaborations, the subject matter described and claimed in Patent Rights. As used herein, the term "non-commercial research purposes" means the use of Patent Rights for academic research or other not-for-profit or scholarly purposes which are undertaken at a non-profit or governmental institution that does not use Patent Rights in the production or manufacture of products for sale or the performance of services for a fee.

2.03 No Implied License

Except as expressly provided herein, the license granted hereunder does not confer any rights upon Licensee by implication, estoppel or otherwise as to any technology or intellectual property (including, but not limited to, patent applications, patents, and know-how).

2.04 Government Rights

The United States Government may have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced throughout the world, for or on behalf of the United States, the inventions described in the Patent Rights. To the extent applicable, the rights granted herein are additionally subject to the requirement that any products sold in the United States based upon Patent Rights must be substantially manufactured in the United States to the extent required by 35 U.S.C. Sec. 204, and any and all other rights as set forth in Public Law 96-517, codified at 35 U.S.C. 200 et seq., and 37 CFR 401 et seq.

Licensee agrees to comply with all obligations resulting from such government rights.

ARTICLE 3 – CONSIDERATION

3.01 On the Effective Date, Licensee will owe to NCSU a non-refundable, non-creditable lump sum license fee of US$25,000.00 (US Twenty Five Thousand Dollars). Licensee will pay the foregoing US$25,000.00 (US Twenty Five Thousand Dollars) to NCSU within thirty (30) of receipt of an invoice, which will be issued by NCSU on or after the Effective Date. Failure to pay NCSU the aforementioned license fee within thirty (30) days of receipt of an invoice is a default for which NCSU at its sole discretion may terminate this License Agreement in accordance with Article 12.03 ("Termination by NCSU").

3.02 Accrued Patent Expenses

Licensee is not responsible to reimburse NCSU for any patent expenses incurred prior to the Effective Date and associated with the preparation, filing, prosecution, issuance and maintenance of all patent applications within the Patent Rights.

3.03 Future Patent Expenses

Licensee will pay all patent expenses incurred during the Term of this License Agreement starting from the Effective Date and associated with the preparation, filing, prosecution, issuance, post grant/issuance proceedings (such as, but not limited to, post-grant reviews, inter partes review, and ex parte reexamination), and maintenance of all patent applications within the Patent Rights. Licensee must pay all such fees and costs within thirty (30) days of receipt of an invoice, and failure to pay such invoice within such thirty (30) day period is a default for which NCSU may terminate this License Agreement in accordance with Article 12.03.

3.04 Running Royalty

At the times and in the manner set forth in this License Agreement, Licensee must pay to NCSU a royalty equal to two and one-half percent (2.5%) of the Net Sales of Licensed Product and/or Licensed Services Sold by Licensee or its sublicensee.

3.05 Milestone Payments

Licensee must pay to NCSU the non-refundable, non-creditable milestone payments set forth in Appendix B upon the achievement of the milestones described therein (hereafter, “Performance Milestone Fees”). Each Performance Milestone Fee is due and payable within thirty (30) days of Licensee’s achievement of the relevant milestone.

3.06 Sublicensing Fees/Other Consideration

In addition to the running royalty provided in Article 3.04 (“Running Royalty”), Licensee shall pay to NCSU ten percent (10.0%) of any Sublicense Revenues received by Licensee as consideration for a Sublicense grant under the Patent Rights. It is agreed that Licensee shall not receive from a sublicensee anything of value in lieu of cash payments in consideration for any Sublicense under this License Agreement without the prior written permission of NCSU, such consent not to be unreasonably withheld or delayed.

3.07 Minimum Royalties

Licensee's obligation to pay minimum annual royalties begins on January 1, 2023. Non-refundable, non-creditable minimum annual royalties are payable to NCSU within thirty (30) days after the beginning of the application calendar year as specified below and in Article 5.02 (“Royalty Reports”). The actual royalty due under Article 3.04 (“Running Royalty”) for a particular calendar year will be credited against the minimum royalties due in that year. Minimum annual royalties payable to NCSU are as follows:

(a) Calendar year 2019, 2020, 2021, and 2020: US$0.00;

(b) Calendar year 2023: US$2,500.00;

(c) Calendar year 2024 and 2025: US$7,500.00;

(d) Calendar year 2026 and 2027: US$15,000.00;

(e) Calendar year 2028 and 2029: US$35,000.00;

(f) Calendar year 2030 and each calendar year thereafter in which this License Agreement is in effect: US$50,000.00.

3.08 Interest

Payments required under this License Agreement shall be made on or before the due date or within thirty (30) days of any invoice date on invoices received from NCSU. If overdue, payments shall bear interest until payment at the rate for past-due accounts receivable set by the Secretary of the North Carolina Department of Revenue and in effect on the due date. N.C.G.S. §105-241.21 and N.C.G.S. §147-86.23. The payment of such interest does not foreclose NCSU from exercising any other rights it may have as a consequence of the lateness of the payment, including termination in accordance with Article 12.03 (“Termination by NCSU”) herein.

3.09 Currency Conversion

If Licensed Products and Licensed Services are sold in a currency other than United States dollars, the Net Sales shall first be determined in the foreign currency of the country in which such Products or Services are sold and then converted to United States dollars at the rate published by the Wall Street Journal (United States edition) or its successor for conversion of that foreign currency into United States dollars on the last day of the quarter for which such payment is due. Licensee shall be responsible and pay all fees associated with any wire transfer and all loss of exchange value, taxes, or other expenses incurred in the transfer or conversion of foreign currency into United States dollars, and any income, remittance, or other taxes on such royalties required to be withheld at the source, and shall not decrease the amount of royalties due to NCSU thereby. Royalty Reports under Article 5.01 will show sales both in local currency and United States dollars, with the exchange rate used.

ARTICLE 4 – DUE DILIGENCE REQUIREMENTS

4.01 Licensee must use its commercially reasonable efforts to bring Licensed Products and Licensed Services to market through a thorough, vigorous and diligent program for exploitation of the Patent Rights, to develop manufacturing capabilities, and to continue active, diligent marketing efforts for Licensed Products and Licensed Services throughout the term of this License Agreement. In addition to this general commitment to commercialization, Licensee agrees to meet the milestones set forth in the Development and Commercialization Schedule established in attached Appendix C. The parties agree that the Development and Commercialization Schedule established in attached Appendix C is reasonable.

4.02 Licensee's failure to meet any milestone set forth in Appendix C that is scheduled for completion on or before December 31st, 2024 shall be a material breach of this License Agreement unless, at least sixty (60) days prior to the original due date Licensee sends written notice to NCSU explaining the reasons for mission the deadline and demonstrating that Licensee has used reasonable efforts to bring the License Products and/or Services to market. NCSU will automatically grant a one-time extension for such milestone for a period of six (6) months.

4.03 Variations from Appendix C that occur after December 31st, 2024 must be expressly approved by NCSU in writing, such approval not to be unreasonably withheld.

4.04 Notwithstanding the foregoing, the parties acknowledge that the dates or timelines outlined or established for the achievement of such milestones assume that product candidates do not encounter regulatory or other delays for reasons outside of Licensee's reasonable control. Licensee and NCSU shall negotiate in good faith the extension of these dates in the event any matters outside of Licensee's reasonable control adversely affect achievement of any stated milestones by the dates or timelines outlined or established therefore.

ARTICLE 5 – REPORTS

5.01 Progress Reports

Six (6) months after the Effective Date, and semi-annually thereafter, Licensee shall provide to NCSU progress reports detailing activities of Licensee relevant to Licensee's Development and Commercialization Schedule (Appendix C). The progress report will include a summary of Licensee's development progress for the previous six (6) month period, Licensee's development plans for the six (6) month period following the report, and any additional information required for NCSU to meet its government reporting obligations. The progress report will include an update on Licensee's progress towards first commercial sale and the milestones, if any, listed in Appendix C. Licensee may submit the progress report electronically to NCSU email address ncsulicenses@ncsu.edu.

5.02 Royalty Reports

After the First Commercial Sale of a Licensed Product or Licensed Service, and in addition to the reports required under Article 5.01 ("Progress Reports"), Licensee must render to NCSU quarterly a written report setting forth for the preceding calendar quarter all applicable information specified in Appendix E ("Royalty Report"). Royalty Reports shall be due within thirty (30) days of March 31, June 30, September 30, and December 31 and each Royalty Report shall be accompanied by the payment of all royalties due for the calendar quarter preceding. Licensee may submit the Royalty Report electronically to NCSU email address ncsulicenses@ncsu.edu within thirty (30) days of the end of the quarter. If Licensee submits the Royalty Report electronically, Licensee's royalty payment must also be received within thirty (30) days of the end of the quarter. Royalty Reports tendered must include the date of First Commercial Sale, the commercial name of the Licensed Product or Licensed Service, the calculation of royalties by product by country, and any additional information required for NCSU to meet its government reporting obligations. Licensee must list any and all patents associated with each product, in substantially the format provided in Appendix E.

ARTICLE 6 – RECORDS

6.01 Licensee must keep full, true and accurate books of accounts and other records containing all particulars necessary to properly ascertain and verify the amounts payable to NCSU hereunder. These books of account must be kept at Licensee's principal place of business or the principal place of business of the appropriate division of Licensee to which this License Agreement relates for a minimum of five (5) years following the end of the calendar year to which they pertain.

6.02 NCSU shall have the right, from time to time and at reasonable times during normal business hours, through an independent certified public accountant or auditor (each as to whom Licensee has no reasonable objection) to examine the records of Licensee, including, but not limited to, sales invoice registers, sales analysis reports, original invoices, inventory records, price lists, sublicense and distributor agreements, accounting general ledgers, third-party royalty reports, cost information, pricing policies, sales tax returns, and agreements with Third Parties (including sublicensees, designees, Affiliates of Licensee, and customer) to the extent necessary to verify the calculation of any royalties and/or fees payable under this License Agreement. Such examination and verification shall not occur more than once each calendar year. Licensee agrees to cooperate fully with NCSU's accountant or auditor in connection with any such review. If any such examination and verification reveals an underpayment by Licensee to NCSU of more than five (5.0%) for any quarter examined, Licensee shall immediately pay NCSU the amount of such underpayment plus interest, in accordance with Article 3.12 ("Interest") and shall reimburse NCSU for all expenses incurred in the examination and verification of the records by the independent certified public accountant. Any overpayment by Licensee shall be a credit against future royalties owed hereunder.

ARTICLE 7 – SUBLICENSES

7.01 Permission to Grant

Licensee may grant Sublicenses to Third Parties provided that: (i) the terms of the Sublicense are consistent with this License Agreement; and (ii) Licensee is represented in Sublicense negotiations by external legal counsel who shall have reviewed this License Agreement. Licensee will provide an unredacted copy of any Sublicense agreement, and any and all amendments thereto, to NCSU within thirty (30) days of execution.

7.02 Terms of Sublicense

Any grant to a Third Party of a Sublicense within the Field of Use under the Patent Rights shall be on the following conditions:

(i) be consistent with the terms, conditions and limitations of this License Agreement;

(ii) contain the acknowledgment by the sublicensee of the disclaimer of warranty and limitation of NCSU's liability, as provided in this License Agreement;

(iii) require sublicensee to indemnify NCSU for any actions of sublicensee;

(iv) contain a prohibition on further transfer of Patent Rights by sublicensee; provided, however, this prohibition will not apply to a sublicensee who has been granted an exclusive license to exercise the Patent Rights in a specific subfield within the Field of Use;

(v) ensure the sublicensee submits reports to Licensee in accordance with Article 5;

(vi) unless expressly stated in this License Agreement, no such Sublicense or attempt to obtain a sublicensee relieves the Licensee of its obligations under Article 4 nor does it relieve the Licensee from its obligations to pay NCSU any and all fees, royalties, and other payments due under this License Agreement; and

(vii) NCSU is a Third Party beneficiary of such Sublicense, entitled to enforce it in accordance with its terms.

7.03 Licensee Responsible for Compliance

Licensee remains fully liable to NCSU for the performance of its sublicensees.

ARTICLE 8 – PATENT PROSECUTION

8.01 Prosecution

NCSU will retain outside patent counsel to apply for, prosecute, engage in post grant/issuance proceedings (such as, but not limited to, post-grant reviews, inter partes review, and ex parte reexamination), and maintain during the term of this License Agreement, all patents and patent applications specified as Patent Rights in the United States and in the foreign countries designated by Licensee. Licensee must inform NCSU in writing which foreign countries, if any, in which Licensee desires patent protection and Appendix A will be amended in writing to reflect those designations. If Licensee does not elect patent protection in a foreign country within sixty (60) days after notification by NCSU that such election shall be made, Licensee will forfeit rights in that country and the foreign patent application and resulting patents for such country will be excluded from Patent Rights.

8.02 Licensee Review and Advice

Licensee will be given reasonable opportunities to advise NCSU in the filing, prosecution, and maintenance of Patent Rights and will cooperate with NCSU in such filing, prosecution, and maintenance. At Licensee's request and expense, NCSU will instruct patent counsel to provide copies of all prosecution documents relating to Patent Rights so that Licensee may have the opportunity to offer comments and remarks thereon, such comments and remarks to be given due consideration by NCSU. However, notwithstanding anything to the contrary in this License Agreement, all decisions with respect to the filing, prosecution, and maintenance of Patent Rights are reserved solely to NCSU.

8.03 Surrender of Patent Rights

If Licensee provides NCSU with written notification that it will no longer support the filing, prosecution, or maintenance of a specified patent(s) and/or patent application(s) within the Patent Rights, then Licensee's responsibility for fees and costs related to the filing, prosecution, and maintenance of such subject Patent Rights will terminate sixty (60) days after NCSU's receipt of such written notification. However, in such instances, sixty (60) days after NCSU's receipt of, such patents and/or patent applications will no longer be included in Patent Rights (and Appendix A is deemed to be so amended accordingly), and Licensee surrenders all rights under this License Agreement to such patents, patent applications, and any patents issuing therefrom.

8.04 Patent Marking

Licensee must mark any Licensed Product, and Licensed Service sold in the United States and/or their containers, labels, and/or other packaging with all applicable United States patent numbers either by fixing thereon the word "patent" or the abbreviation "pat.", together with the number of the patent, or as otherwise prescribed in 35 U.S.C. §287. All Licensed Products and Licensed Services shipped to or sold in other countries must be marked in such a manner as to conform to the patent laws and practices of the country of manufacture or sale.

8.05 Patent Extensions

Licensee and NCSU agree that the Patent Rights shall be extended by all means provided by law or regulation, including without limitation extensions provided under United States law at 35 U.S.C. §§154(b) and 156 or under equivalent legislation throughout the world including supplementary protection certificates in the EU. The parties hereby agree to provide each other and counsel with all necessary assistance in securing such extensions, including without limitation, providing all information regarding applications for regulatory approval, approvals granted, and the timing of same. Licensee acknowledges that extensions under 35 U.S.C. §156 must be applied for within sixty (60) days of the date that a Licensed Product receives permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use, and that Licensee's failure to promptly provide the necessary information or assistance to NCSU during such sixty (60) day period will cause serious injury to NCSU, for which Licensee will be liable.

8.06 Challenge of Patent Validity or Enforceability

A. In the event the Licensee, its Affiliate(s), its sublicensee, or any entity or person acting on Licensee's behalf (all individually and collectively referred to herein as "Licensee Challenger(s)") initiates or assists a Third Party in any proceeding or otherwise asserts any claim challenging the validity or enforceability of any of the Patent Rights in any court, administrative agency or other forum ("Challenge"), Licensee will or will require the Licensee Challenger(s) to:

    a. Provide to NCSU, at least one hundred and ninety (90) days prior to initiating any Challenge, a notification in writing ("Notice of Challenge") that includes:

        i. Identification of the Licensee Challenger(s) who intends to submit such Challenge;

ii. The court(s), administrative agency(ies) or other forum(ies) (or combination thereof) where such Challenge(s) will be filed and the date when such Challenge(s) will be filed; and

iii. Details of any and all the facts, legal grounds, and legal arguments on which such Challenge(s) is based, including but not limited, to any prior art that forms the basis of any such Challenge.

B. Thirty (30) days after providing the Notice of Challenge, Licensee will enter into good faith negotiations with NCSU for a period of at least sixty (60) days to explore a mutually acceptable solution that would eliminate the need by the Licensee Challenger(s) to file a Challenge.

C. If any Licensee Challenger files a Challenge and at least one Valid Claim of a Patent Right covering the Licensed Product or Licensed Service that is subject to such Challenge survives the Challenge by not being found invalid or unenforceable by a court, administrative agency or other forum, regardless of whether the claim is amended as part of the Challenge, then Licensee will immediately owe to NCSU all costs and expenses incurred by NCSU (including actual attorneys' fees) associated with the preparation and defense for each and every Challenge that is brought before such court, administrative agency or other forum. Licensee will make such payment within thirty (30) days of such decision by a court, administrative agency or other forum where each such Challenge is brought. Failure to make aforementioned payment within such thirty (30) days is a default for which NCSU at its sole discretion may terminate this License Agreement in accordance with Article 12.03 ("Termination by NCSU").

D. In the event at least one claim of the Patent Rights that is subject to a Challenge before a court, administrative agency or other forum survives the Challenge by not being found invalid or unenforceable by such court, administrative agency or other forum, regardless of whether the claim is amended as part of the Challenge, all royalty rates, minimum annual royalties, Sublicensing Revenue and other payment rates set forth in this License Agreement shall be automatically doubled immediately from the date of such finding for the remaining Term of this License Agreement.

ARTICLE 9 – INFRINGEMENT OF THIRD-PARTY RIGHTS

9.01 Licensee agrees to defend, hold harmless and indemnify NCSU for and against any third party claim of patent infringement arising from Licensee's, its Affiliate's, or its sublicensee's exercise of Patent Rights granted in this License Agreement.

9.02 Licensee shall have the right to control the defense of any such claim, but due to its proprietary interest in the Patent Rights, NCSU must approve any settlement, consent judgment or disposition of the claim that (i) limits the scope, validity, or enforceability of patents included in the Patent Rights or (ii) admits fault or wrongdoing on the part of NCSU, such approval not to be unreasonably withheld. Licensee's request for approval will include all information relating to such settlement, consent judgment or disposition of the claim. NCSU shall provide Licensee notice of its approval or denial within thirty (30) days of any written request for such approval by Licensee, provided that in the event NCSU wishes to deny such approval, such notice shall include a detailed written description of NCSU's reasonable objections to the proposed settlement, consent judgment, or other voluntary disposition. NCSU will, subject to policies of the Board of Governors of the University of North Carolina, cooperate with Licensee in any reasonable manner deemed by Licensee to be necessary in the defense of the claim. Licensee will reimburse NCSU for any out of pocket expenses in providing assistance.

ARTICLE 10 – INFRINGEMENT OF NCSU's PATENT RIGHTS BY THIRD PARTIES

10.01 Prompt Notice

Each party to this License Agreement must inform the other promptly in writing of any alleged infringement of Patent Rights by a third party and of any available evidence of infringement.

10.02 Licensee Right to Enforce

In the event that Patent Rights are infringed by a Third Party within the Field of Use, Licensee has the right, but not the obligation, to either:

(a) settle the infringement by sub-licensing the alleged infringer (but only in accordance with the provisions of this License Agreement) or by other means reasonably acceptable to NCSU; or

(b) prosecute at its own expense or defend any declaratory judgement action with respect to any infringement of the Patent Rights. In the event Licensee prosecutes such infringement, Licensee may, if necessary for the purpose of standing, request to use the name of NCSU as party plaintiff. NCSU, at its discretion and with the permission of the Board of Governors of The University of North Carolina, may agree to become a party plaintiff, and costs associated therewith must be borne by Licensee in accordance with Article 10.03. If NCSU is so requested and the courts requires NCSU to be a party for the purposes of standing, NCSU will request and use reasonable efforts to obtain permission from the Board of Governors in the University of North Carolina to join. NCSU will participate in the litigation as a party if it obtains such permission.

While the Licensee has certain rights in accordance with Articles 10.02(a) and 10.02(b), if such action results in the Third Party challenging the validity or enforceability of the Patent Rights then, due to its proprietary interest in the Patent Rights, NCSU must approve any settlement, consent judgment, or disposition of the claims that (i) limit the scope, validity, or enforceability of any patents licensed under this License Agreement, or (ii) admits fault or wrongdoing on the part of NCSU, such approval not to be unreasonably withheld. Licensee's request for approval will include all information relating to such settlement, consent judgement, or disposition of the claim. NCSU shall provide Licensee notice of its approval or denial within thirty (30) days of any written request for such approval by Licensee, provided that in the event NCSU wished to deny such approval, such notice shall include a detailed written description of NCSU's reasonable objections to the proposed settlement, consent judgement, or other voluntary disposition. NCSU will, subject to the policies of the Board of Governors of the University of North Carolina, cooperate with Licensee in any reasonable manner deemed by Licensee to be necessary in the defense of the claim. Licensee will reimburse NCSU for any out of pocket expenses in providing assistance.

10.03 Expenses and Damages

If Licensee undertakes the enforcement and/or defense of the Patent Rights by litigation, NCSU will, subject to the policies of the Board of Governors of the University of North Carolina, provide all reasonable assistance in the litigation. The cost of any such action commenced or defended by Licensee, including reasonable expenses of NCSU (except for the attorneys' fees of any independent counsel retained by NCSU, unless such independent counsel has been retained because an ethical conflict precludes Licensee's counsel from representing NCSU, in which case the following sentence shall apply), shall be borne by Licensee. Licensee will bear the documented attorneys' fees for independent counsel retained by NCSU due to an ethical conflict. Any recovery of damages by Licensee as a result of such action will be applied first in satisfaction of any unreimbursed expenses and attorneys' fees of Licensee relating to the action, and second in satisfaction of unreimbursed legal expenses and attorneys' fees of NCSU, if any, relating to the action. Licensee will pay ten percent (10.0%) of any balance of recovered damages or settlement after payment of expenses as provided in the preceding sentence. Licensee is entitled to settle any such litigation by agreement, consent, judgment, voluntary dismissal, or otherwise, with the consent of NCSU, which consent may not be withheld unreasonably.

10.04 NCSU Right to Enforce

If Licensee does not settle the infringement or institute legal action against the infringing activity within three (3) months of having been made aware of it, NCSU has the right, but is not obligated, to prosecute at its own expense any such infringements of the Patent Rights and to recover damages, whether through settlement or award, for its own account.

10.05 Loss of Patent Rights

Any of the foregoing notwithstanding, if at any time during the term of this License Agreement any of the Patent Rights are held invalid or unenforceable in a decision which is not appealable or is not appealed within the time allowed, Licensee has no further obligations to NCSU with respect to its future use or sale of any Licensed Product or Licensed Service covered by such Patent Rights. Nevertheless, in such circumstances Licensee does not have a damage claim or a claim for refund or reimbursement against NCSU.

ARTICLE 11 – REGULATORY APPROVALS

11.01 Regulatory Approvals

To the extent regulatory approval is required, Licensee must use its commercially reasonable best efforts to have the Licensed Products and/or Licensed Services approved for marketing in those countries in which Licensee intends to sell Licensed Products and/or Licensed Services. To accomplish these approvals at the earliest possible date, Licensee agrees to file or have filed any necessary data with appropriate government agencies as set forth in the Development and Commercialization Schedule in Appendix C.

11.02 Data

If this License Agreement terminates for any reason, Licensee must, within forty five (45) days following such termination and at its own expense, provide NCSU copies of (a) all regulatory approval applications described in Article 11.01 ("Regulatory Approvals") (including all data and documentation relating thereto) and (b) all data, and all documentation related to the data, that could relate to market clearance applications, including, but not limited to, all *in vitro* and *in vivo* pre-clinical data, pharmacology data, toxicology data, human data and the like to the extent such information is in the exclusive control of the Licensee and/or sublicensee and not subject to obligations of confidentiality to any third party(ies) (together with the Regulatory Approvals, the "Licensee Assets"). Licensee shall grant to NCSU the right to access and to refer to all such Licensee Assets and to provide a copy thereof to potential licensees, under conditions of confidentiality consistent with Article 13 ("Confidentiality"), solely for use in NCSU's efforts to license the Patent Rights to any third party. NCSU shall not be entitled to license, grant, or transfer to any third party any rights in such Licensee Assets. In the event NCSU agrees in writing to material economic terms with a Third Party concerning the grant of a license to such Third Party under the Patent Rights formerly licensed to Licensee hereunder, NCSU shall provide written notice thereof to Licensee and Licensee shall enter into good faith negotiations with such Third Party concerning the granting of rights to, or transfer of title in, the Licensee Assets to such Third Party on commercially reasonable terms, subject to any rights any sublicensees or other Third Parties may have with respect to any of the foregoing that survive termination of this Agreement.

ARTICLE 12 – TERM AND TERMINATION

12.01 Term

Unless sooner terminated as otherwise provided in this License Agreement, the Term of this License Agreement shall commence on the Effective Date and shall continue until the date of expiration of the last to expire of the Patent Rights, including any renewals or extensions thereof.

12.02 Termination by Licensee

Licensee may terminate this License Agreement at its sole discretion by giving NCSU written notice at least three (3) months prior to such termination. Should Licensee, at any time during the term of this License Agreement, cease efforts to commercialize Patent Rights, Licensee shall so notify NCSU and this License Agreement will terminate on the ninety first (91st) day after such notice. It is understood that Licensee will remain responsible for all monetary payments or other obligations that mature prior to the effective date of termination, as well as the payment of the license fees and Milestone Fee described in Articles 3.01 and 3.05.

12.03 Termination by NCSU

NCSU shall have the right to terminate this License Agreement upon the occurrence of any one or more of the following events:

a) failure of Licensee to make any payment required pursuant to this License Agreement when due;

b) failure to diligently commercialize as set forth in Article 4 (“Due Diligence Requirement”);

c) failure of Licensee to render reports to NCSU as required by this License Agreement;

d) the insolvency of the Licensee or the institution of any proceeding by Licensee under any bankruptcy or insolvency law or placement of Licensee’s assets in the hands of a trustee or receiver;

e) failure of Licensee to follow any and all of the requirements of Article 8.06; or

f) the material breach of any other material term of this License Agreement.

12.04 Automatic Termination and Reversion of License

Licensee shall give written notice to NCSU of its insolvency, intent to file a voluntary petition in bankruptcy, or of a third party’s intention to file an involuntary petition in bankruptcy against Licensee at least thirty (30) days prior to the filing of the petition. This License Agreement will terminate and the license will revert to NCSU without notice to Licensee upon the occurrence of either of the following events:

(a) the insolvency of the Licensee; or

(b) Licensee’s filing of a voluntary petition in bankruptcy without notice to NCSU.

Licensee’s filing of a voluntary petition without notice to NCSU shall be deemed a material, pre-petition, incurable breach.

12.05 Exercise and Right to Cure

In all cases of breach, other than those set forth in Article 12.04 (“Automatic Termination and Reversion of License”), NCSU may exercise its right of termination by giving Licensee or Licensee’s trustees, receivers, or assigns, thirty (30) days prior written notice of NCSU’s election to terminate. Upon expiration of such period, this License Agreement shall automatically terminate unless Licensee has cured the breach. Such notice and termination shall not prejudice NCSU’s right to receive accrued royalties or other sums due hereunder and shall not prejudice any cause of action or claim of NCSU accrued or to accrue on account of any breach or default by Licensee. Licensee’s ability to cure a breach will apply only to the first two breaches properly noticed under the terms of this License Agreement; any subsequent breach will entitle NCSU to terminate upon notice.

12.06 Post Expiration or Termination

(a) Within thirty (30) days of expiration or termination of this License Agreement, Licensee must, as directed by NCSU, return or destroy all information, data, organisms, biological materials, and/or models provided to Licensee by NCSU during the term of this License Agreement, retaining no copies. Further, Licensee must provide NCSU with a written statement signed by an authorized representative of Licensee certifying the destruction of all information data, and relevant materials in a safe and legal manner.

(b) Upon the termination of this License Agreement, Licensee shall cease manufacturing, processing, producing, using or selling Licensed Products; provided, however, that Licensee may continue to sell in the ordinary course of business Licensed Products that are fully manufactured and in Licensee's normal inventory at the date of termination and provided, that Licensee pays NCSU any fees, royalties or other financial consideration as provided for in this License Agreement.

(c) Upon termination of this License Agreement, Licensee shall assign to NCSU all Sublicense agreements under the Patent Rights (to the extent permitted under such sublicenses), which Sublicenses shall continue according to their own terms as direct licenses from NCSU under the Patent Rights; provided, however, such terms are consistent with the terms of this License Agreement and the sublicensee assumes any and all obligations, including all financial obligations, of the Licensee to NCSU under this License Agreement.

ARTICLE 13 – CONFIDENTIALITY

13.01 Non-Disclosure

NCSU and Licensee will treat any confidential information or non-public information disclosed to it by the other party during the Term of this License Agreement ("Confidential Information") with reasonable care and will not disclose such information to any other person, firm or corporation, unless such Third Party is bound by the obligations of confidentiality, non-disclosure and restricted use set forth in this Article 13. The receiving party may not use the disclosing party's Confidential Information other than for the benefit of the parties hereto and for the performance of this License Agreement. These obligations of confidentiality, non-disclosure and restricted use remain in effect for each subject disclosure of Confidential Information during the term of this Agreement and for five (5) years thereafter. However, neither party is obligated, with respect to Confidential Information disclosed to it, or any part thereof, which:

(a) is already known to the receiving party at the time of the disclosure;

(b) becomes publicly known without the wrongful act or breach of this License Agreement by the receiving party;

(c) is rightfully received by the receiving party from a Third Party not having confidentiality obligations to the disclosing party;

(d) is subsequently and independently developed by employees of the receiving party who had no knowledge of the information, as verified by written records;

(e) is approved for release by prior written authorization of the disclosing party; or

(f) is disclosed pursuant to the requirements of applicable law or pursuant to any judicial or government requirement or order, provided that the party so disclosing takes reasonable steps to provide the other party sufficient prior notice in order to contest such request, requirement or order and provided that such disclosed confidential information otherwise remains subject to the obligations of confidentiality set forth in this Article 13.

13.02 Disclosure in Writing

NCSU and Licensee agree that any information to be treated as Confidential Information under this Article 13 must be disclosed in writing or in another tangible medium and must be clearly marked “CONFIDENTIAL”. Information disclosed orally must be described as confidential at the time disclosed and summarized and reduced to writing and communicated to the other party within thirty (30) days of such disclosure.

13.03 Licensee Commercialization Efforts.

Notwithstanding the foregoing, Licensee may use and disclose any Confidential Information related to the Patent Rights to investors, prospective investors, employees, consultants and agents with a need to know, collaborators, prospective collaborators or acquirors and other third parties in the chain of manufacturing and distribution, but if and only if Licensee obtains from each such recipient a written confidentiality agreement, the provisions of which are at least as protective of NCSU’s Confidential Information as those provided in this Article 13. Licensee may also disclose the terms and conditions of this License Agreement to any of the foregoing parties in its discretion. Subject to NCSU’s obligations under the North Carolina Public Records Act, NC-GS § 132, Licensee’s proprietary information contained in this License Agreement shall be deemed Licensee's Confidential Information.

13.04 Patent Rights

Notwithstanding anything to the contrary in this License Agreement, all unpublished research data and information relating to filing, prosecution, maintenance, defense, infringement, and the like regarding the Patent Rights (no matter how disclosed) is the Confidential Information of NCSU and subject to the provisions of Article 13.

ARTICLE 14 – NOTICES

14.01 For the purpose of all written communications and notices between the parties, other than reports and invoices/payments their addresses are:

NCSU

NCSU Notice

For delivery via the U.S. Postal Service

Office of Research Commercialization
North Carolina State University
Attn: Assistant Vice Chancellor
Campus Box 8210
Raleigh, NC 27695-8210 USA

For delivery via courier

Office of Research Commercialization
North Carolina State University
Attn: Director of Licensing
Poulton Innovation Center
1021 Main Campus Drive
Raleigh, NC 27606 USA

Licensee

COMPANY Notice

Hoth Therapeutics Inc.

Attn: Hayley Behrmann
One Rockefeller Plaza, Suite 1039
New York, NY, 10020
hayley@hoththerapeutics.com

Or any other addresses of which either party shall notify the other party in writing.

14.02 For the purpose of all communication between the parties regarding reports due under Article 5 ("Reports") by the Licensee under this License Agreement, their addresses are:

NCSU

Please send all reports via email to:
ncsulicenses@ncsu.edu

Licensee – Contact for reports

Attn: Hayley Behrmann
One Rockefeller Plaza, Suite 1039
New York, NY, 10020
hayley@hoththerapeutics.com

Or any other addresses of which either party shall notify the other party in writing.

14.03 For the purpose of all communication between the parties regarding payments due by the Licensee under this License Agreement, their addresses are:

NCSU

Please remit payment to:

NC State Treasurer
NC State University: FID 56-6000756
Accounts Receivable
Campus Box 7203
Raleigh, NC 27695-7203 USA

Licensee – Contact for billing

Please send invoice to:

Hoth Therapeutics, Inc.
Attn: Hayley Behrmann
One Rockefeller Plz Ste 1039
New York, NY 10020

email: hayley@hoththerapeutics.com

Or any other addresses of which either party shall notify the other party in writing.

14.04 The date of giving any such notice, request, report, statement, disclosure or other communications, and the date of making any payment hereunder required (provided such payment is received), is the date of the U.S. postmark of such envelope if marked or the actual date of receipt if not marked or if delivered otherwise.

ARTICLE 15 – ASSIGNMENT

15.01 Licensee possesses unique expertise and resources to fully develop and commercialize the Patent Rights. This License Agreement may not be assigned, in whole or in part, by Licensee without the prior written consent of NCSU, except in connection with the sale of substantially all of Licensee's assets or stock or sale of Licensee's entire business or that part of the Licensee's business to which this License Agreement relates; provide, however (i) such sale or transfer is not associated with bankruptcy or foreclosure proceedings that involves the Licensee, and/or (ii) there is no outstanding material breach of the License Agreement that has not been fully cured by the Licensee. Any other assignment of this License Agreement without the prior written consent of NCSU shall be void. This License Agreement shall bind and inure to the benefit of the successors and permitted assigns of the parties.

ARTICLE 16 – REPRESENTATIONS

16.01 NCSU represents and warrants that it has the authority to enter into this License Agreement and grant the exclusive rights to the Patent Rights.

16.02 NCSU represents that as of the Effective Date, to the current knowledge of Office of Research Commercialization, the entire right, title, and interest in the Patent Rights (including the inventions disclosed therein) have been assigned to NCSU and NCSU has the requisite power and authority to grant the licenses contained in this License Agreement.

16.03 Except for what is expressly provided in Article 16.01 and 16.02, NCSU MAKES NO OTHER REPRESENTATIONS OR WARRANTIES OF ANY KIND. IN PARTICULAR, THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE NOR IS THERE A WARRANTY THAT THE USE OF THE PATENT RIGHTS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER RIGHTS. IN ADDITION, NOTHING IN THIS LINCESE AGREEMENT MAY BE DEEMED TO BE A REPRESENTATION OR WARRANTY BY NCSU OF THE VALIDITY OF ANY OF THE PATENTS OR THE ACCURACY, SAFETY, EFFICACY, OR USEFULNESS, FOR ANY PURPOSE, OF THE PATENT RIGHTS. NCSU HAS NO OBLIGATION, EXPRESS OR IMPLIED, TO SUPERVISE, MONITOR, REVIEW OR OTHERWISE ASSUME RESPONSIBILITY FOR THE PRODUCTION, MANUFACTURE, TESTING, MARKETING OR SALE OF ANY LICENSED PRODUCT OR LICENSED SERVICE.

ARTICLE 17 – INDEMNITY AND INSURANCE

17.01 NCSU, and its trustees, officers, employees, students, and agents will be indemnified, defended by counsel acceptable to NCSU, and held harmless by Licensee from and against any claim, liability, cost, expense, damage, deficiency, loss or obligation, of any kind or nature (including, without limitation, reasonable attorneys' fees and other costs and expenses of defense) based upon, arising out of, or otherwise relating to Licensee's or its Affiliates' or sublicensees' exercise of the license(s) granted under this License Agreement, including but not limited any action related to product liability.

17.02 Licensee must maintain in force throughout the Term of this License Agreement or for five (5) years after the last commercial sale of a Licensed Product or Licensed Service, whichever is later, at its sole cost and expense, with licensed and reputable insurance companies, general liability insurance and, prior to use in humans, clinical trials, or otherwise commercialized, products liability insurance coverage in amounts reasonably sufficient to protect against liability under Article 17.01. NCSU has the right to ascertain from time to time that such coverage exists, such right to be exercised in a reasonable manner.

17.03 Neither party is an agent of the other party for any purpose whatsoever.

ARTICLE 18 – EXPORT CONTROLS

18.01 The license granted in this License Agreement is conditioned upon compliance with all of the United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities and technology. The transfer of certain technical data and commodities may require a license from the cognizant agency of the United States Government and/or written assurances by Licensee that Licensee will not export data or commodities to certain foreign countries without prior approval of such agency. NCSU makes no promise or representation that a license is not required nor that, if required, it will be issued.

ARTICLE 19 – USE OF A PARTY'S NAME

19.01 Neither party may, without the prior written consent of the other party:

(a) use in any publication, advertising, publicity, press release, promotional activity or otherwise, any trade-name, personal name, trademark, trade device, service mark, symbol, image, icon, or any abbreviation, contraction or simulation thereof owned by the other party or owned by the other party; or

(b) use the name or image of any employee or agent of the other party in any publication, publicity, advertising, press release, promotional activity or otherwise; or

(c) represent, either directly or indirectly, that any product or service of the other party is a product or service of the representing party or that it is made in accordance with or utilizes the information or documents of the other party.

All requests for such consent related to an NCSU name, image, employee or agent must be directed to the NCSU Office of Research Commercialization.

19.02 Both parties may release factual statements regarding the existence of this License Agreement such as “NCSU and Licensee have entered into an exclusive license agreement for XXX technology”. Any other type of statement, advertisement, press release, promotional activity or otherwise by either party that uses the name of the other party will require the prior written consent of the named party.

ARTICLE 20 – SEVERANCE AND WAIVER

20.01 Each clause of this License Agreement is a distinct and severable clause and if any clause is deemed illegal, void or unenforceable, the validity, legality or enforceability of any other clause or portion of this License Agreement will not be affected.

20.02 The failure of a party in any instance to insist upon the strict performance of the terms of this License Agreement is not a waiver or relinquishment of any of the terms of this License Agreement, either at the time of the party’s failure to insist upon strict performance or at any time in the future, and such terms will continue in full force and effect.

ARTICLE 21 – TITLES

21.01 All titles and article headings contained in this License Agreement are inserted only as a matter of convenience and reference. They do not define, limit, extend or describe the scope of this License Agreement or the intent of any of its provisions.

ARTICLE 22 – SURVIVAL OF TERMS

22.01 The provisions of Articles 2.04 (“Government Rights”), 11.02 (“Data”), 12.02 (“Termination by Licensee”), 12.05 (“Exercise and Right to Cure”), 12.06 (“Post Expiration or Termination”), 13 (“Confidentiality”), 17 (“Indemnity and Insurance”), and 19 (“Use of a Party’s Name”) shall survive the expiration or termination of this License Agreement.

ARTICLE 23 – GOVERNING LAW

23.01 This License Agreement is entered into in the State of North Carolina and must be interpreted in accordance with and its performance governed by the laws of the State of North Carolina, without reference to its conflicts of laws provisions. Any and all litigation relating to this License Agreement or the parties' performance hereunder must be in the State Courts of North Carolina with the venue being Wake County.

ARTICLE 24 – ENTIRE UNDERSTANDING

24.01 This License Agreement represents the entire understanding between the parties, and supersedes all other agreements, express or implied, between the parties concerning the subject matter hereof, and is not subject to any change or modification except by the execution of a written instrument subscribed to by authorized representatives of the parties.

ARTICLE 25 – ELECTRONIC COPY

25.01 The parties to this document agree that a copy of the original signature (including an electronic copy) may be used for any and all purposes for which the original signature may have been used. The parties further waive any right to challenge the admissibility or authenticity of this document in a court of law based solely on the absence of an original signature.

IN WITNESS WHEREOF, the parties have executed this License Agreement on the dates set forth below.

NORTH CAROLINA STATE UNIVERSITY

By: /s/ Kultaran Chohan
Kultaran Chohan, Ph.D., LL.M, CLP
Director of Licensing
Office of Research Commercialization

Date: November 20, 2019

HOTH THERAPEUTICS INC.

By: /s/ Robb Knie
Name: Robb Knie
Title: CEO

Date: November 20, 2019

APPENDICES

APPENDIX A—PATENT RIGHTS

APPENDIX B—MILESTONE FEES

APPENDIX C—DEVELOPMENT AND COMMERCIALIZATION SCHEDULE

APPENDIX D—ROYALTY REPORT FORM

APPENDIX A—PATENT RIGHTS

1. US Provisional Patent Application No. TBD titled “Exon Skipping of FC-Epsilon-RI-Beta and MS4A6A in Combination for the Treatment of Allergic Diseases” filed on November 8th, 2019 (NCSU Ref. No. 18138).

APPENDIX B—MILESTONE FEES

1. A non-refundable, non-creditable milestone payment of US$35,000.00 (US Thirty Five Thousand Dollars) upon receiving FDA approval for the first Investigational New Drug Application (IND) incorporating the Patent Rights (as defined in the US Federal Food, Drug, and Cosmetic Act) in the US or equivalent in any non-US country, for each new intended use of a License Product.

2. A non-refundable, non-creditable milestone payment of US$200,000.00 (US Two Hundred Thousand Dollars) upon initiation of a Phase II clinical trial incorporating the Patent Rights (as defined in the US Federal Food, Drug, and Cosmetic Act) in the US or equivalent in any non-US country, for each new intended use of a License Product.

3. A non-refundable, non-creditable milestone payment of US$350,000.00 (US Three Hundred and Fifty Thousand Dollars) upon receiving FDA approval for a New Drug Application (NDA) or Biologics License Application (BLAs) incorporating the Patent Rights (as defined in the US Federal Food, Drug, and Cosmetic Act) in the US or equivalent in any non-US country, for each new intended use of a License Product.

APPENDIX C—DEVELOPMENT AND COMMERCIALIZATION SCHEDULE

1. By December 31st, 2022, Licensee will work with NCSU to complete an in vivo GLP study incorporating a Licensed product in a small animal model.

2. By December 31st, 2024, Licensee or its sublicensee will submit an Investigational New Drug Application incorporating a Licensed product to the US FDA.

3. By December 31st, 2026, Licensee or its sublicensee will initiate Phase II clinical trials incorporating a Licensed Product.

4. By December 31st, 2030, Licensee or its sublicensee will make its First Commercial Sale of a Licensed Product.

APPENDIX D—ROYALTY REPORT FORM

Hoth Therapeutics Inc. License Agreement Royalty Report for the Period

_____through_____

Instructions: Please fill in all boxes (write "none" if not applicable), and sign and date at bottom.

Prod.#_____ Prod. Name: _____
NCSU Patents: _____
Please provide patent numbers and patent application numbers of all NCSU patents covering this product.

Government Approvals: _____
Date of First Commercial Sale: _____

Country	Gross Billings	Deductions	Type of Deduction	Net Sales	Royalty Rate	Royalties Due
					Subtotal for Product	

Prod.#_____ Prod. Name: _____
NCSU Patents: _____
Please provide patent numbers and patent application numbers of all NCSU patents covering this product.

Government Approvals: _____
Date of First Commercial Sale: _____

Country	Gross Billings	Deductions	Type of Deduction	Net Sales	Royalty Rate	Royalties Due
					Subtotal for Product	

USE ADDITIONAL SHEETS FOR ADDITIONAL PRODUCTS.

Total amount enclosed $_____

Hoth Therapeutics Inc.

By: _____ Date: _____

Name and Title: _____

Exhibit 21.1

List of Subsidiaries of Hoth Therapeutics, Inc.

Name	State/Country of Organization or Incorporation
Hoth Therapeutics Australia Pty Ltd	Australia

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference of our report dated March 2, 2020, relating to the consolidated financial statements of Hoth Therapeutics, Inc. as of and for the years ended December 31, 2019 and 2018, included in this Annual Report on Form 10-K into the Company's previously filed Registration Statement on Form S-1 (File No. 333-233563).

/s/ WithumSmith+Brown, PC

New York, New York
March 2, 2020

Exhibit 31.1

Certification of Chief Executive Officer of Hoth Therapeutics, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Robb Knie, certify that:

1. I have reviewed this Annual Report on Form 10-K of Hoth 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 consolidated 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 15(d)-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 consolidated 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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.

Date: March 2, 2020

/s/ Robb Knie

Robb Knie
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer of Hoth Therapeutics, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, David Briones, certify that:

1. I have reviewed this Annual Report on Form 10-K of Hoth 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 consolidated 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 15(d)-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 consolidated 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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.

Date: March 2, 2020

/s/ David Briones
David Briones
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

Statement of Chief Executive Officer and Chief Financial Officer
Pursuant to Section 1350 of Title 18 of the United States Code

Pursuant to Section 1350 of Title 18 of the United States Code as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned, Robb Knie and David Briones, the Chief Executive Officer and Chief Financial Officer, respectively, of Hoth Therapeutics, Inc. (the "Company"), hereby certify that based on the undersigned's knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: March 2, 2020

/s/ Robb Knie
Robb Knie
Chief Executive Officer and President
(Principal Executive Officer)

Date: March 2, 2020

/s/ David Briones
David Briones
Chief Financial Officer
(Principal Financial and Accounting Officer)