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

FORM 10-K

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

For the fiscal year ended December 31, 2020

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

For the transition period from _____ to _____

Commission file number 001-32188

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

Florida **(State or Other Jurisdiction of Incorporation or Organization)**	**59-3410522** **(IRS Employer Identification No.)**
4902 Eisenhower Blvd., Suite 125 **Tampa, FL** **(Address of Principal Executive Offices)**	**33634** **(Zip Code)**

813-286-7900
(Issuer's Telephone Number, Including Area Code)

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock $0.001 par value per share	**OGEN**	**NYSE AMERICAN**

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 [X]

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

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions 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
[X]Non-accelerated filer	[X] 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes[ ] No [X]

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2). Yes [ ] No [X]

The aggregate market value of the voting and non-voting common equity stock held by non-affiliates of the registrant, was approximately $36,813,271 computed based upon a last sales price of $0.69 as reported by the NYSE American as of June 30, 2020.

As of February 25, 2021, there were 109,646,119 shares of the registrant's Common stock outstanding.

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FORWARD LOOKING STATEMENTS AND CERTAIN CONSIDERATIONS

This report, along with other documents that are publicly disseminated by us, contains or might contain forward-looking statements within the meaning of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements included in this report and in any subsequent filings made by us with the Securities and Exchange Commission (the "SEC") other than statements of historical fact, that address activities, events or developments that we or our management expect, believe or anticipate will or may occur in the future are forward-looking statements. These statements represent our reasonable judgment on the future based on various factors and using numerous assumptions and are subject to known and unknown risks, uncertainties and other factors that could cause our actual results and financial position to differ materially. We claim the protection of the safe harbor for forward-looking statements provided in the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act and Section 21E of the Exchange Act. Examples of forward-looking statements include: (i) projections of revenue, earnings, capital structure and other financial items, (ii) statements of our plans and objectives, (iii) statements of expected future economic performance, and (iv) assumptions underlying statements regarding us or our business. Forward-looking statements can be identified by, among other things, the use of forward-looking language, such as "believes," "expects," "estimates," "may," "will," "should," "could," "seeks," "plans," "intends," "anticipates" or "scheduled to" or the negatives of those terms, or other variations of those terms or comparable language, or by discussions of strategy or other intentions.

Forward-looking statements are subject to known and unknown risks, uncertainties and other factors that could cause the actual results to differ materially from those contemplated by the statements. The forward-looking information is based on various factors and was derived using numerous assumptions. Important factors that could cause our actual results to be materially different from the forward-looking statements include the following risks and other factors discussed under the Item 1A "Risk Factors" in this Annual Report on Form 10-K. These factors include:

- We have incurred significant operating losses since our inception and cannot assure you that we will generate revenues or achieve profitability;
- We will need to raise additional capital to fully implement our business strategy and we may not be able to do so;
- Our financial capacity and performance, including our ability to obtain funding, non-dilutive or otherwise, necessary to do the research, development, manufacture and commercialization of any one or all of our product candidates;
- The timing, progress and results of clinical trials of our product candidates, including statements regarding the timing of initiation and completion of preclinical studies or clinical trials or related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- The timing of any submission of filings for regulatory approval of our product candidates and our ability to obtain and maintain regulatory approvals for our product candidates for any indication;
- Our expectations regarding the potential benefits, activity, effectiveness and safety of our product candidates including as to distribution and storage;
- Our expectations regarding the size of the patient populations, market acceptance and opportunity for and clinical utility of our product candidates, if approved for commercial use;
- Our manufacturing capabilities and strategy, including the scalability and commercial viability of our manufacturing methods and processes, and those of our contractual partners;
- Our expectations regarding the scope of any approved indications for our product candidates;
- Our ability to successfully commercialize our product candidates;
- The potential benefits of, and our ability to maintain, our relationships and collaborations with the NIAID, the NIH, Eleszto Genetika, Inc. and other potential collaboration or strategic relationships;
- Our ability to use our lantibiotic platform to develop future product candidates;

- Our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional funding, including any application for future grants or funding;
- Our ability to identify, recruit and retain key personnel;
- Our ability to obtain, retain, protect and enforce our intellectual property position for our product candidates, and the scope of such protection;
- Our ability to advance the development of our new Terra CoV-2 vaccine product candidate under the timelines and in accord with the milestones it projects;
- Our inability to achieve success in our identification of lantibiotic homologs or the manufacture and nonclinical testing of our lantibiotic product candidates;
- Our need to comply with extensive and costly regulation by worldwide health authorities, who must approve our product candidates prior to substantial research and development and could restrict or delay the future commercialization of certain of our product candidates;
- Our ability to successfully complete preclinical and clinical development of, and obtain regulatory approval of our product candidates and commercialize any approved products on our expected timeframes or at all;
- The safety, efficacy and benefits of our product candidates;
- The content and timing of submissions to and decisions made by the FDA, other regulatory agencies and nongovernmental bodies and actors, such as investigational review boards;
- The effects of government regulation and regulatory developments, and our ability and the ability of the third parties with whom we engage to comply with applicable regulatory requirements;
- The capacities and performance of our suppliers and manufacturers and other third parties over whom we have limited control;
- Our ability to maintain our listing on the NYSE American;
- The impact of the COVID-19 pandemic on our financial condition and business operations and our ability to continue research and development for existing product candidates on previously-projected timelines or in accord with ordinary practices, as well as the broader governmental, global health and macro- and microeconomic responses to and consequences of the pandemic;
- We may be adversely impacted by any significant broad-based financial crises and its impact on consumers, retailers and equity and debt markets as well as our inability to obtain required additional funding to conduct our business;
- As a public company, we must implement additional and expensive finance and accounting systems, procedures and controls as we grow our business and organization to satisfy reporting requirements, which add to our costs and require additional management time and resources;
- Our competitive position and the development of and projections relating to our competitors or our industry; and
- The impact of laws and regulations, including those that may not yet exist.

We caution investors that actual results or business conditions may differ materially from those projected or suggested in forward-looking statements as a result of various factors including, but not limited to, those described above and in the Risk Factors section of this report. We cannot assure you that we have identified all the factors that create uncertainties. Moreover, new risks emerge from time to time and it is not possible for our management to predict all risks, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. Readers should not place undue reliance on forward-looking statements. Except as required by applicable law, we undertake no obligation to publicly release the result of any revision of these forward-looking statements to reflect events or circumstances after the date they are made or to reflect the occurrence of unanticipated events.

PART I

ITEM 1. BUSINESS.

This description contains certain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from the results discussed in the forward-looking statements as a result of certain of the risks set forth herein. We assume no obligation to update any forward-looking statements contained herein.

Overview

We are focused on the creation of the Terra CoV-2 immunization product candidate to combat the novel coronavirus pandemic and the further development of novel antibiotics against infectious disease.

Our SARS-CoV-2 Vaccine Product Candidate— Terra CoV-2

As a result of our acquisition of one hundred percent (100%) of the total issued and outstanding common stock of Noachis Terra, Inc. ("Noachis Terra") we are now focused on the development and commercialization of a vaccine product candidate to provide long lasting immunity from the novel Severe Acute Respiratory Syndrome coronavirus ("SARS-CoV-2"), which causes the coronavirus disease 2019 ("COVID-19"). Noachis Terra is a party to a worldwide, nonexclusive intellectual property and biological materials license agreement with the National Institute of Allergy and Infectious Diseases ("NIAID"), an institute within the National Institutes of Health ("NIH"), relating to certain research, patent applications and biological materials involving pre-fusion stabilized coronavirus spike proteins and their use in the development and commercialization of a vaccine to provide specific, long lasting immunity from SARS-CoV-2.

Coronaviruses are a family of viruses that can lead to upper-respiratory infections in humans. Recent clinical reports also suggest that the SARS-CoV-2 virus can affect other body-systems, including the nervous, cardiovascular, gastrointestinal and renal systems. Among the recent iterations of coronaviruses to move from animal to human carriers is SARS-CoV-2 (often referred to as COVID-19), which, beginning in Wuhan, China, in late 2019, caused a global pandemic due to its rapid spread and the relatively high mortality rate (as compared to the seasonal influenza). In late January of 2021, the World Health Organization's estimates indicate the number of worldwide COVID-19 infections have exceeded 100,000,000 and the number of deaths directly attributed to COVID-19 have exceeded 2,000,000. Both Pfizer and Moderna have announced preliminary safety and efficacy data from their Phase 3 COVID-19 vaccine studies and recent Emergency Use Authorization by the FDA. We believe given the size of the worldwide pandemic that even with multiple vaccines projected to be available in the coming months, there will be demand for the Terra CoV-2 vaccine, once development is successfully completed. We intend to combine the research, patent applications and biological materials covered by our NIAID license with our existing clinical research and manufacturing capabilities to respond rapidly to this ongoing, global, public health crisis. We believe our Terra CoV-2 vaccine holds the possibility of playing an important role in addressing this crisis.

Coronaviruses, such as SARS -CoV-2, possess signature protein spikes on their outer capsule. The NIAID license covers patents and data on a vaccine candidate that were created based on a stabilized pre-fusion spike trimeric protein. By stabilizing the spike protein in the pre-fusion state, the number of immunogenic centers is increased thereby allowing for a greater likelihood of successful antibody binding, resulting in an improved immunogenic response. The genetic code, acquired from the NIH, for the stabilized pre-fusion spike protein was provided to Aragen Bioscience, Inc. ("Aragen") for the purpose of insertion of the spike protein gene sequence into a Chinese Hamster Ovary ("CHO") cell line. Aragen is a leading contract research organization focused on accelerating preclinical biologics product development, has extensive experience building CHO cell lines for recombinant proteins, such as monoclonal antibodies. Aragen has successfully inserted the NIH pre-fusion spike protein gene sequence into a CHO cell line and is currently developing both the analytical tests and identifying preliminary cell line growth conditions to optimize the spike protein titers. Currently, "mini-pool" production and analytical development is underway. The process to transfer to full-scale manufacture has begun.

The NIH's preclinical study shows that this spike protein, adjuvanted with the mouse specific TLR-4-agonist Sigma Adjuvant System ("SAS", a TLR-4 agonists) that induces T cell activation), generates neutralizing antibody titers in both a pseudovirus neutralization assay and a plaque reduction neutralization titer (PRNT) assay. Recently released information indicated that pretreatment of mice with the NIH-created COVID-19 spike protein in combination with an adjuvant (TLR-4 agonist Sigma Adjuvant System) completely inhibited viral growth in the nasal cavities and lungs of infected animals compared to unvaccinated control animals. In October 2020, we received feedback to our Type B Pre-IND Meeting Request from the FDA. The response indicated that the FDA broadly supported our planned approach to the pre-clinical program that will support the clinical development of the Terra CoV-2, vaccine. As a result, we anticipate filing the Investigational New Drug ("IND") application in the fourth quarter of 2021 and immediately upon the receipt of approval from the FDA, commencing the Phase 1 clinical study, the protocol for which is currently under development.

We recently announced we had entered into an agreement with Adjuvance Technologies Inc. for the use of TQL1055, a novel, rationally designed semi-synthetic analogue of the saponin adjuvant QS-21 with potential improved attributes, including stability and manufacturing efficiency. We also anticipate that our Terra CoV-2 vaccine will provide long lasting protection from the SARS-CoV-2 virus with only one or two doses, with a more rapid immune response compared to vaccines developed without the inclusion of an adjuvant.

As presently designed, we believe the Terra CoV-2 vaccine is expected to permit cost effective storage and distribution at refrigerated temperatures, which should facilitate the distribution and thereby avoid challenges facing the two mRNA vaccines currently available under the FDA's Emergency Use Authorization in the U.S.

We expect to use our currently available cash resources to continue to advance the development of Terra CoV-2 through IND-enabling studies, including immunogenicity, viral challenge studies, toxicology studies, and the Phase 1 trial with further clinical development being contingent upon the receipt of additional funding, including non-dilutive government grant funding which we continue to pursue or partnering or out-licensing opportunities.

Our Antibiotic Product Candidate-OG716

Members of our scientific team discovered that a certain bacterial strain. *Streptococcus mutans,* produces MU1140, a molecule belonging to the novel class of antibiotics known as lantibiotics. Lantibiotics, such as MU1140, are highly modified peptide antibiotics made by a small group of Gram-positive bacterial species. Approximately 60 lantibiotics have been discovered, to date. We believe lantibiotics are generally recognized by the scientific community to be potent antibiotic agents.

In nonclinical testing, MU1140 has shown activity against all Gram-positive bacteria against which it has been tested, including those responsible for a number of healthcare associated infections, or HAIs. A high percentage of hospital-acquired infections are caused by highly antibiotic-resistant bacteria such as methicillin-resistant Staphylococcus aureus (MRSA) or multidrug-resistant Gram-negative bacteria. We believe the need for novel antibiotics is increasing as a result of the growing resistance of target pathogens to existing FDA approved antibiotics on the market along with the increased use of currently available antibiotics due to secondary infections in SARS-CoV-2 infected patients.

Lantibiotics have been difficult to investigate for their clinical usefulness as therapeutic agents in the treatment of infectious diseases due to a general inability to produce or synthesize sufficient quantities of pure amounts of these molecules. Traditional fermentation methods can only produce minute amounts of the lantibiotic.

In June 2012, we entered into a worldwide exclusive channel collaboration agreement with Precigen (formerly known as Intrexon Corporation) for the development and commercialization of the native strain of MU1140 and related homologs to use its advanced transgene and cell engineering platforms. At that time we also entered into a stock issuance agreement with Precigen. Through our work pursuant to the collaboration agreement, we have been able to produce a significant increase in the fermentation titer of MU1140 compared to standard fermentation methods and have discovered a new purification process for MU1140. Our work generated a substantial number of homologs of MU1140 and the exclusive channel collaboration was thereafter amended to clarify the applicable field and to adjust the milestone payments and provide that they will be paid in cash. In January 2020 Precigen consummated a reorganization of its ongoing active pharmaceutical ingredients (API) fermentation operations and assets which included transfer of the exclusive collaboration agreement and related stock issuance agreement. Following such reorganization, Precigen divested certain of its assets to TS Biotechnology Holdings, LLC which included shares of Oragenics securities and the subsidiary Eleszto Genetika, Inc. ("EGI" formerly known as ILH Holdings, Inc.) that held the collaboration agreement and stock issuance agreements with us, and. On March 1, 2021, due to such prior amendments, assignments and transfers we entered into an amended and restated exclusive channel collaboration agreement with EGI which (i) included the prior amendments, (ii) updated the names of the parties, and (iii) incorporated any remaining applicable terms from the stock issuance agreement and thereafter terminated the stock issuance agreement(the "Lantibiotic ECC"). We expect to continue our research and development and collaboration efforts with EGI to develop potential derivatives of the MU1140 molecule using genetically modified bacteria.

In our pre-clinical studies to support a potential IND filing with the FDA, we tested a total of six homologs of MU1140 for certain compound characteristics, including but not limited to: drug activity (based on minimum inhibitory concentration or "MIC") equal or better than "standard of care" drugs against certain drug-resistant bacteria, safety, toxicity, stability, and manufacturability. An animal study specifically evaluated homolog efficacy in relation to survival, measurable amounts of *Clostridium difficile ("C. diff")* colony forming units, and toxin levels. Three homologs demonstrated promising results with one homolog, OG253 achieving a 100% survival rate throughout the entire study in contrast to an approximately 30% survival rate for the vancomycin positive control.

Based on these early results, we selected a lead candidate, OG253, for which we had a pre-IND meeting with the FDA in November of 2015 regarding the pursuit of an IND for OG253. Following additional research and development on second generation lantibiotics, in August of 2016, we opted to select a second generation lantibiotic, OG716, for treatment of *C. diff* as our new lead candidate. OG716 is a new, orally-active homolog, that has exhibited positive results in an animal model for potential treatment of *C. diff*. Generated from our MU1140 platform, this new lantibiotic showed promising efficacy in reducing clinically relevant *C. diff* infections as measured by increased animal survival and decreased relapse as well as reduced production of toxins A & B and *C. diff* spores.

The timing of the filing of an IND regarding OG716 is subject to our having sufficient available human, material and financing capital, which includes research subjects, both animal and human, given all of our anticipated needs and expected requirements in connection with our ongoing research and development initiatives. We will continue to advance the OG716 program to the IND filing based on the availability of both human and financial capital. Based upon the current funding available we will continue to conduct some of the requisite studies. While we commenced certain of these studies at the end of 2019, we expect to focus on efficient and cost-effective improvements in the manufacturing process of the product as we move to complete the pre-clinical studies required to support our first in man Phase 1 clinical study.

Product Candidates.

Through our wholly-owned subsidiary, Noachis Terra, we began the research and development stage for our new Terra CoV-2 vaccine product candidate. We hold a nonexclusive, worldwide intellectual property license agreement for certain research, patent applications and biological materials relating to the use of pre-fusion coronavirus spike proteins for the development and commercialization of a vaccine against SARS-CoV-2.

Additionally, we are developing our lead lantibiotic candidate, OG716, to treat *Clostridium difficile* while also creating semi-synthetic lantibiotic analogs that may be effective against systemic gram (+) multidrug infections, and analogs that may be effective in treating gram (-) infections. We seek to protect our product candidates through patents and patent applications pursuant to the terms of our license agreements.

Product/Candidate	Description	Application	Status
Terra CoV-2	Vaccine candidate (plasmid + adjuvant) to provide long lasting immunity against SARS-CoV-2	Broad, community-based vaccine immunity against SARS-CoV-2	Pre-clinical
OG716	A homolog of MU1140: Member of lantibiotic class of antibiotics	*Clostridium difficile* associated diarrhea	Pre-clinical

Our Business Development Strategy

Success in the biopharmaceutical and product development industry relies on the continuous development of novel product candidates. The large majority of product candidates do not make it past all clinical trials which forces companies to look externally for innovation. Accordingly, we expect from, time to time, to seek strategic opportunities through various forms of business development, which can include strategic alliances, licensing deals, joint ventures, collaborations, equity-or debt-based investments, dispositions, mergers and acquisitions. We view these business development activities as a necessary component of our strategies, and we seek to enhance shareholder value by evaluating business development opportunities both within and complementary to our current business as well as opportunities that may be new and separate from the development of our existing product candidates.

Our SARS-CoV-2 Vaccine Product Candidate-Terra CoV-2

Market Opportunity

The worldwide market size for COVID-19 vaccines is expected to approach $38.5 billion. Following the pandemic period, the post-pandemic maintenance phase is expected to be approximately $6 billion in annual sales beginning in 2025. In late January of 2021, the World Health Organization's estimates indicate the number of worldwide COVID-19 infections have exceeded 100,000,000 and the number of deaths directly attributed to COVID-19 have exceeded 2,000,000. About 40% of US deaths have occurred in long-term care facilities as the disease disproportionately affects the elderly.

We believe overall disease burden will continue to increase during 2021 even with vaccine introductions. Global and country policymakers have pursued immediate vaccination of healthcare workers and elderly populations as vaccine becomes available and thereafter seek to vaccinate the adult population as more vaccine volume is released and disseminated based on the FDA's emergency use authorization. In the US, the CDC is monitoring this dynamic closely to advise the states on rollout allocations. We believe label expansions to children to follow with the CDC's expected lower age recommendations as well as data released by Pfizer in 16-17 years was acknowledged by the CDC so that this population was included in the current recommendation. We believe the global population remains at risk for COVID and policy maker recommendations might be expected to cover the vast majority of the populations to stop the pandemic.

It is generally expected to take at least 12 months to achieve a broader level of immunity (herd immunity) which assumes 60-80% of the eligible population is fully vaccinated with two doses with vaccines currently available under Emergency Use Authorizations (EUA). Based on publicly available vaccine data and the spread of variants, the current timelines for the pandemic are not expected to end soon and continue to change. Current vaccines in development are based on safety/efficacy in reducing disease, not on transmission and post-marketing surveillance of licensed vaccines is expected to be monitored closely to determine whether /when to vaccinate in the post-pandemic period. To the extent COVID transmission continues despite vaccine availability, we believe that continued broad vaccination (or revaccination) will be recommended by policy makers.

As with other vaccines, COVID disease epidemiology is expected to be closely monitored and as such recommendations as to vaccinations and treatments would be expected to likewise evolve accordingly. The identification of new COVID-19 variants from South Africa, England and Brazil, and the spread of such variants are expected to alter the dynamics of not only introduction of initial immunity but the requirement of booster shots to help facilitate control of the newer viral strains.

Our Strategy

We seek to develop Terra CoV-2 vaccine candidate to the point of entering into a licensing deal or strategic partnership. In connection with the development of our Terra CoV-2 vaccine candidate we expect to focus on differentiation of our vaccine product candidate, including but not limited to, costs of the vaccine, distribution and storage at refrigerated temperatures and dosing schedules. We believe that development of a vaccine that has differentiated attributes to those currently being used based on the FDA's Emergency Use Authorization will be beneficial in helping to control the SARS–CoV-2 pandemic. Should the current COVID-19 pandemic be brought under control quickly and result in the inability to commercialize our Terra-CoV-2 vaccine, we believe we have developed the experience to identify and acquire other vaccines to develop that are capable of preventing new infectious disease threats.

Regulatory

We held a pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA), with agreements that allow us to save three to six months on pre-IND development timelines. The broad support for our approach by the FDA included a number of activities, including: (i) use of the Research Cell Bank in the early manufacturing process development; (ii) use of early pilot batch manufacture under Good Manufacturing Processes (GMP) for the anticipated Phase 1 clinical trials; and, (iii) submission of draft toxicology reports during IND filing. We have organized the conduct of the pre-clinical studies including the Syrian Hamster virus challenge study, the mouse immunogenicity study and rodent toxicology study. All will be submitted as part of the IND filing prior to initiation of the Phase 1 human clinical trial. We anticipate filing the IND application in the fourth quarter of 2021 and immediately upon the receipt of approval from the FDA, commencing the Phase 1 clinical study, the protocol for which is currently under development.

Manufacturing

The creation of the Research Cell Bank is now complete and manufacturing has been transferred to our dedicated biologics contract development and manufacturing organization Avid Bioservices, Inc. for upstream and downstream processing. Creation of the Master Cell Bank, required for later stage manufacturing will begin in 1Q21. This step is required for later stage manufacturing of clinical supplies for Phases 2 and 3. We have entered into an agreement with a company that will provide the adjuvant for our vaccine candidate. We expect to continue to seek other sources of adjuvants for our manufacturing needs. We also have an agreement with a company that is expected to formulate the vaccine and candidate. In addition, a separate company will provide services for fill/finish and packaging and labeling that will be required for both clinical trial material and commercial product.

OG716, Homologs of MU1140 and Other Lantibiotics

In the course of research and development, MU1140 was found to be a potent antibiotic that is naturally produced by the parent of the SMaRT strain. MU1140 shows antibacterial activity against all Gram-positive bacteria against which it has been tested, including those responsible for a variety of healthcare-associated infections, or HAIs.

In June 2012, we entered into a worldwide exclusive channel collaboration agreement with Precigen (formerly known as Intrexon Corporation) for the development and commercialization of the native strain of MU1140 and related homologs to use its advanced transgene and cell engineering platforms. At that time we also entered into a stock issuance agreement with Precigen. Through our work pursuant to the collaboration agreement, we have been able to produce a significant increase in the fermentation titer of MU1140 compared to standard fermentation methods and have discovered a new purification process for MU1140. Our work generated a substantial number of homologs of MU1140 and the exclusive channel collaboration was thereafter amended to clarify the applicable field and to adjust the milestone payments and provide that they will be paid in cash. In January 2020 Precigen consummated a reorganization of its ongoing active pharmaceutical ingredients (API) fermentation operations and assets which included transfer of the exclusive collaboration agreement and related stock issuance agreement. Following such reorganization, Precigen divested certain of its assets to TS Biotechnology Holdings, LLC which included shares of Oragenics securities and the subsidiary Eleszto Genetika, Inc. ("EGI" formerly known as ILH Holdings, Inc.) that held the collaboration agreement and stock issuance agreements with us, and. On March 1, 2021, due to such prior amendments, assignments and transfers we entered into an amended and restated exclusive channel collaboration agreement with EGI which (i) included the prior amendments, (ii) updated the names of the parties, and (iii) incorporated any remaining applicable terms from the stock issuance agreement and thereafter terminated the stock issuance agreement (the "Lantibiotic ECC"). We expect to continue our research and development and collaboration efforts with EGI to develop potential derivatives of the MU1140 molecule using genetically modified bacteria.

Through this collaboration we intend to develop lantibiotics, a novel class of antibiotics, as active pharmaceutical ingredients toward the goal of commercialization for the treatment of infectious diseases in humans. We previously selected a lead candidate, OG253, and had a pre-IND meeting with the FDA in November of 2015 regarding the pursuit of an IND on OG253. Following additional research and development on second generation lantibiotics, in August of 2016, we selected a second generation lantibiotic, OG716, for treatment of *C. diff*. OG716 is a new, orally-active homolog, that has exhibited positive results in an animal model for potential treatment of *C. diff*. Generated from our MU1140 platform, this new lantibiotic showed promising efficacy in reducing clinically relevant *C. diff* infections as measured by increased animal survival and decreased relapse as well as reduced production of *C. diff* spores and toxin levels when compared to a vancomycin positive control. We had our pre-IND meeting with FDA for OG716 during the third quarter of 2017. We have transferred manufacturing to a contract manufacturer and conducted our initial rat toxicology program in support of our anticipated upcoming IND filing. The timing of the filing of an IND regarding OG716 is subject to our having sufficient available capital given all of our anticipated needs and expected requirements in connection with our ongoing research and development initiatives. We currently expect the IND for a first-in-human clinical trial of OG716 to be filed with the FDA based on our ability to complete the requisite studies, contingent on sufficient funding. Based upon the funding available we expect to conduct some of the requisite studies. While we commenced certain of these studies at the end of 2019, we expect to focus on efficient and cost-effective manufacturing of the product to support and be able to conduct further broad-based studies. In addition, we have undertaken research programs to expand our capabilities to improve the physical chemical characteristics (i.e., solubility and stability) of lantibiotics for use to treat systemic gram (+) infections and also exploring lantibiotic structures that may treat gram (-) infections.

Market Opportunity

The most common gram (+) HAIs are caused by drug-resistant bacteria, including methicillin-resistant *Staphylococcus aureus*, or MRSA; vancomycin-resistant *Enterococcus faecalis*, or VRE; and *Clostridium difficile,* or *C. diff*. According to the Centers for Disease Control and Prevention, or CDC, HAIs are estimated to occur in approximately 5% of all acute-care hospitalizations. The CDC also estimates that the total direct medical cost to the U.S. healthcare system from HAIs is between $28.4 billion to $45 billion annually. Cubicin, a Gram positive lipopeptide antibiotic which was launched in the US market in November 2003 by the biotechnology company Cubist, had 2012 global sales of $926.4 million. In 2013, Cubist announced the acquisition of two companies Optimer and Trius each of which was for consideration over $800M. In 2015, Cubist was acquired by Merck for a total transaction value of $9.5 billion.

The need for novel antibiotics is increasing due to an increased pattern of resistance development by target pathogens to existing FDA approved antibiotics on the market. The CDC has estimated that up to 77% of certain nosocomial pathogenic bacteria are resistant to drugs of last resort (vancomycin-resistant E. faecium and vancomycin, respectively, in this example). HAIs are not exclusively a problem in the United States as the rest of the world has also seen a dramatic rise in HAIs during the last decade. We believe novel antibiotics have become increasingly scarce as major pharmaceutical companies focus more research and development resources on lifestyle drugs and fewer resources on specialty pharmaceuticals such as antibiotics. Between 1983 and 1987, 16 new antibiotics were approved by the FDA. Twenty years later, over an equivalent time period from 2003 to 2007, only five new antibiotics were approved by the FDA, of which only two possessed a novel mechanism of action. Since 2008, there have been no new antibiotics classes approved by FDA.

Lantibiotics such as MU1140 are highly modified peptide antibiotics made by a small group of Gram-positive bacterial species. Approximately 60 lantibiotics have been discovered since the first lantibiotic, nisin, was discovered. Lantibiotics are generally known to be potent antibiotic agents; however, attempts to investigate their clinical usefulness have generally met with failure due to the inability to produce sufficient pure amounts of any of these molecules to be able to test them as a therapeutic agent for the treatment of infectious diseases. Standard fermentation methods, such as those used to make a variety of other antibiotics, have historically resulted in the production of only minute amounts of the lantibiotic.

Our Solution

To develop homologs of MU1140 paired with high producing strains to the point of partnership, and to develop additional lantibiotics in connection with our work on MU1140. MU1140 has demonstrated activity against a wide variety of disease-causing Gram-positive bacteria, including MRSA, VRE, *C. diff, Mycobacterium tuberculosis* and *Bacillus anthracis*.

Our Strategy

In collaboration with EGI, we are developing and testing recombinantly derived homologs of the native MU1140 molecule with improved therapeutic profiles and physical-chemical characteristics. The data generated in collaboration with Precigen over the past few years enabled us to engineer hundreds of homologs of MU1140, and select those homolog candidates with improved profiles, including homologs of higher activity and stability, lower toxicity and with a scalable manufacturability. The best homolog candidates were further developed internally and through the use of several Contract Research Organizations (“CROs”). We believe that this strategy represented the best and most efficient path to produce sufficient quantities of MU1140 homologs, to support continued research, selection of a lead candidate, nonclinical studies, clinical studies and ultimately commercialization. We selected a lead candidate, OG716, in 2016 targeted toward combating *C. diff* infections. In addition, we intend to continue research activities to identify additional MU1140 homologs to treat other HAIs.

Regulatory Status

We have performed nonclinical testing on MU1140 which has demonstrated the molecule's novel mechanism of action. We began additional nonclinical activities on MU1140 under the Lantibiotic ECC with EGI in the second half of 2013 and activities have expanded with new identified homologs as available. These nonclinical activities are expected to include toxicity results, pharmacokinetic studies, and efficacy studies in animals for selected candidates, including our lead candidate OG716 under development for *Clostridium difficile* associated diarrhea. This work is being done primarily through the use of outside contractors. Pursuit of clinical trials toward the goal of ultimately obtaining regulatory approval will depend upon further successful advancements in our research collaboration efforts with Precigen and our efforts to have additional product manufactured. Developments from these efforts will dictate our regulatory path. We initially selected a lead candidate, OG253 and had a pre-IND meeting with the FDA in November of 2015 regarding the pursuit of an IND for OG253. Following additional research and development on second generation lantibiotics, in August of 2016, we selected a second generation lantibiotic homolog, OG716, for treatment of *C. diff*. We had a pre-IND meeting with FDA for OG716 during the third quarter of 2017. We expect to continue our research and development activities on OG716 subject to the availability of adequate financing as we move towards the filing of an IND.

Manufacturing

While we have been able to produce a significant increase in the fermentation titer of our lead compound OG716, we continue to work to improve on the manufacturing through collaborations with fermentation and purification experts and third party CROs. We will need to further optimize and scale up the production/purification scheme internally and through third party vendors. The need to examine many new homologs of MU1140 has resulted in the need to reproduce the fermentation and purification steps on each individual homolog candidate being studied. Each homolog requires different optimizations for both the fermentation and purification steps and in some cases requires a new approach. As such, our work on the research and development of new lantibiotic homologs using genetically modified bacteria continues. We believe these developments represent progress toward our goal of commercial production of sufficient quantities of our MU1140 homologs, including our lead compound OG716 and deliver a step in validating the lantibiotics platform targeting infectious diseases.

We are working with a third-party manufacturer to produce additional quantities of designated homologs including our lead compound OG716, based upon the developments achieved from our work with our collaboration partners and outside contractors. The production of additional quantities of designated homologs including OG716, that are needed for the consummation and pursuit of our nonclinical testing activities supporting the IND filing are currently ongoing. We will continue to explore improved methods of manufacturing to improve our yields and ultimately, potentially reduce our cost of manufacture.

Our License Agreements

Our NIH License Agreement

Through our wholly-owned subsidiary, Noachis Terra, we are party to a Patent License and Biological Materials License Agreement (the "License Agreement" or "NIH License"), dated March 23, 2020, with the United States Department of Health and Human Services (the "HHS"), as represented by the NIAID, an Institute of the NIH. Under the terms of the License Agreement, we hold a nonexclusive, worldwide license to certain specified patent rights (including patent applications, provisional patent applications and Patent Cooperation Treaty ("PCT") patent applications) and biological materials relating to the use of prefusion coronavirus spike proteins to exploit products ("Licensed Products") and practice processes ("Licensed Processes") that are covered by the licensed patent rights and biological materials for the purpose of developing and commercializing a vaccine product candidate for SARS-CoV-2. The License Agreement is subject to certain statutory limits and reserved rights, as required under federal law and NIH requirements, including the requirement to provide reasonable quantities of Licensed Products or materials made through the Licensed Processes for NIH research and to manufacture Licensed Products or materials made through the Licensed Processes substantially in the United States. We may not sublicense the intellectual property or biological materials licensed to us under the License Agreement.

Pursuant to the License Agreement, we must use reasonable commercial efforts to manufacture, practice or operate the Licensed Products and the Licensed Processes, including adhering to a commercial development plan and achieving certain benchmarks. Additionally, following the first commercial sale of any Licensed Products or the practice of any Licensed Processes, we must use reasonable commercial efforts to make the Licensed Products and the Licensed Processes reasonably accessible to the United States public and reasonable quantities of the Licensed Products and the Licensed Processes available to patient assistance program, among other educational support activities. The NIAID has agreed to assume responsibility for the preparation, filing, prosecution and maintenance of all patent applications and patents covered by the licensed patent rights.

Under the terms of the License Agreement, the NIAID is entitled to receive a noncreditable, nonrefundable upfront license issue royalty (which has already been paid), as well as reimbursement for our pro rata share of the NIAID's past and future patent prosecution-related expenses. Additionally, the NIAID is entitled to receive nonrefundable minimum annual royalties, which increase each year after the first commercial sale of any Licensed Products or the practice of any Licensed Processes, as well as benchmark royalties following our completion of certain commercial development and sales-related benchmarks. The NIH is entitled to receive earned royalties on the annual net sales of Licensed Products and the practice of any Licensed Processes (subject to certain reductions), at certain low- to mid-single digit royalty rates, which rates vary based on the total amount of annual net sales and the geographic market in which those sales occur. We must provide regular written reports to the NIAID on the development status of and royalty payments relating to the Licensed Products and the Licensed Processes.

We must indemnify and hold the NIAID and its associates harmless from and against all liability and damages in connection with or arising out of (a) the use or beneficial use of the Licensed Patent rights by us, our directors, employees or third parties and (b) the design, manufacture, distribution or use of any Licensed Products or Licensed Processes, including other products or processes developed in connection with the Licensed Patent Rights.

Unless terminated earlier, the License Agreement will terminate upon the earlier of (a) twenty (20) years from the first commercial sale where no licensed patent rights exist or have ceased to exist or (b) the expiration of the last to expire of any licensed patent rights. At this time, no patents covered by the licensed patent rights have been issued. We may terminate the License Agreement at any time, subject to advance notice. Subject to certain cure and appeal rights, the NIAID may terminate or modify the License Agreement in the event of a material breach or default, including, among others, the following:

(i) We become insolvent or the subject of a bankruptcy petition;

(ii) We fail to follow the commercial development plan, fail to achieve certain commercial development and sales-related benchmarks or cannot otherwise demonstrate progress toward a practical application of the Licensed Products or Licensed Processes;

(iii) We fail to keep any Licensed Products or Licensed Processes reasonably available to the public following the commencement of commercial use or fail to reasonably justify noncompliance with its domestic production obligation;

(iv) We cannot reasonably satisfy public health and safety needs; or

(v) The NIAID determines termination or modification is necessary because we cannot meet federal public use regulatory requirements, as issued after the effective date of the License Agreement.

Our Lantibiotic ECC

On March 1, 2021, we entered into an amended and restated worldwide exclusive channel collaboration agreement with EGI (the "Lantibiotic ECC") in which we will use its advanced transgene and cell engineering platforms for the development and production of lantibiotics, a class of peptide antibiotics that are naturally produced in Gram-positive bacteria and contain the characteristic polycyclic thioether amino acids lanthionine and methyllanthonine (collectively, the "Lantibiotics Program").

The Lantibiotic ECC provides for the establishment of committees comprised of our representatives and representatives from EGI ("Collaboration Partner") following the assignment by Precigen that will govern activities related to the Lantibiotics Program in the areas of project establishment, chemistry, manufacturing and controls matters, clinical and regulatory matters, commercialization efforts and intellectual property matters. The Joint Steering Committee establishes projects for the Lantibiotics Program and establishes the priorities, as well as approved the budgets for projects. In November of 2017 in connection with our Series B Preferred Financing, we amended the Lantibiotic ECC to revise the payments, we are obligated to make to our Collaboration Partner as described below.

The Lantibiotic ECC grants us an exclusive worldwide license to use patents and other intellectual property of Precigen in connection with the research, development, use, importing, exporting, manufacture, sale, and offer for sale of drug products involving the direct administration to humans or companion animals of a lantibiotic for the prevention or treatment of infectious disease ("Oragenics Products"). Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of Oragenics Products, and otherwise is non-exclusive. Subject to limited exceptions, we may not sublicense the rights described without Precigen's written consent.

Under the Lantibiotic ECC, and subject to certain exceptions, we are responsible for, among other things, funding the further anticipated development of lantibiotics toward the goal of commercialization, conducting nonclinical and clinical development of candidate lantibiotics, as well as for other aspects of manufacturing and the commercialization of the product(s). Among other things, our Collaboration Partner is responsible for technology discovery efforts, cell-engineering development, certain aspects of the manufacturing process, and costs of filing, prosecution and maintenance of our Collaboration Partner's patents. Under the Lantibiotic ECC our Collaboration Partner has the option to perform any manufacturing activities in connection with the Lantibiotic Program that relate to the use of our Collaboration Partner material, the manufacture of bulk drug products, the manufacturing of bulk quantities, other components of Oragenics Products, or any earlier steps in the manufacturing process for Oragenics Products. To the extent our Collaboration Partner so elects, a separate manufacturing and supply agreement may be entered into between our Collaboration Partner and the Company.

Pursuant to the terms of the Lantibiotic ECC, as amended, we are obligated to pay our Collaboration Partner on a quarterly basis 10% of net sales derived in that quarter from the sale of products developed from the Lantibiotic ECC, calculated on an Oragenics Product-by-Oragenics Product basis and we will pay our Collaboration Partner on a quarterly basis 25% of revenue obtained in that quarter from a sublicensor in the event of a sublicensing arrangement.

We have agreed to indemnify and hold our Collaboration Partner -harmless from any damages caused as a result of (i) our negligence or willful misconduct, (ii) the use, handling, storage, or transport of our Collaboration Partner Materials (as defined in the Lantibiotic ECC), (iii) our breach of a material representation, warranty or covenant in the Lantibiotic ECC, or (iv) the design, development, manufacture, regulatory approval, handling, storage, transport, distribution, sale or other disposition of any Oragenics Product.

Our Collaboration Partner may terminate the Lantibiotic ECC if we fail to use diligent efforts to develop and commercialize Oragenics Products or if we elect not to pursue the development of a Lantibiotics Program identified by our Collaboration Partner that is a "Superior Therapy" as defined in the Lantibiotic ECC. We may voluntarily terminate the Lantibiotic ECC at any time upon 90 days written notice to our Collaboration Partner.

Upon termination of the Lantibiotic ECC, we may continue to develop and commercialize any Oragenics Product that has been, at the time of termination:

(i) commercialized by us;

(ii) approved by regulatory authorities;

(iii) a subject of an application for regulatory approval that is pending before the applicable regulatory authority; or

(iv) the subject of at least an ongoing Phase 1, Phase 2 or Phase 3 clinical trial in the Field (in the case of a termination by our Collaboration Partner due to an uncured material breach by the Company or a voluntary termination by us).

Our obligation to pay 10% of net sales, 25% of sublicensing revenue and the milestone payments described below with respect to these "retained" products as well as to use diligent efforts to develop and commercialize these "retained" Oragenics Products will survive termination of the Lantibiotic ECC.

In addition, in partial consideration for each party's execution and delivery of the Lantibiotic ECC, we entered into a Stock Issuance Agreement with our Collaboration Partner. Pursuant to the Stock Issuance Agreement, we issued to our Collaboration Partner 439,243 shares of our common stock as an initial technology access fee, in consideration for the execution and delivery of the Lantibiotic ECC and granted our Collaboration Partner certain equity participation rights and registration rights.

The registration rights granted to our Collaboration Partner in the Stock Issuance Agreement by us consisted of "piggyback registration" rights which permit our Collaboration Partner to participate in any firm commitment underwritten offering of securities by us, subject to underwriter cutbacks and lockups. In addition, we are precluded from granting registration rights in connection with a private placement unless (i) all shares held by our Collaboration Partner are, at the time of such private placement, included on a registration statement, or (ii) we agree, in connection with such private placement, to grant our Collaboration Partner the right to include on the registration statement a number of our Collaboration Partner's Company shares equal to one half of the number of shares to be registered on behalf of the other holders or prospective holders.

Pursuant to the Lantibiotic ECC our Collaboration Partner is also entitled, at its election, to participate in future securities offerings by us that constitute "qualified financings" and purchase securities equal to 30% of the number of shares of common stock or other securities sold in such offering (exclusive of our Collaboration Partner's purchase). For this purpose, a "qualified financing" means a sale of common stock or equity securities convertible into common stock in a public or private offering, raising gross proceeds of at least $1,000,000, where the sale of shares is either registered under the Securities Act of 1933, as amended, at the time of issuance or we agree to register the resale of such shares.

Under the terms of the Lantibiotic ECC, we have agreed to make certain payments, in cash, to our Collaboration Partner upon our achievement of designated milestones. The milestone events and amounts payable are as follows:

(i) a one-time payment of twenty-five million United States dollars ($25,000,000) within six (6) months of the achievement of the Regulatory Approval Milestone Event meaning receiving approval from the FDA of a New Product Application (or equivalent regulatory action in a foreign jurisdiction) for an Oragenics Product;

(ii) a one-time payment of five million United States dollars ($5,000,000) within six (6) months of the achievement of the New Indication Milestone Event meaning receiving approval from the FDA of a Supplemental FDA Application (or an equivalent filing with another equivalent regulatory agency) which Supplemental FDA Application sought approval of an indication for use of the Oragenics Product other than the current regulatory-approved indication; and

(iii) a one-time payment of five million United States dollars ($5,000,000) within six (6) months of the achievement of the New Product Milestone Event meaning the receiving of approval from the FDA of a New Product that is deemed to be a different drug product that the first Oragenics Product that was clinically pursued under the Lantibiotics Program.

None of the Lantibiotic ECC milestones had been achieved as of December 31, 2020.

Other Product Candidates and Technologies

We have historically developed other product candidates and potential product candidates. For example, we developed a weight loss candidate, LPT3-04, and a topical treatment to prevent dental carries which we refer to as SMaRT Replacement Therapy. We out licensed LPT3-04 to a third party and continue to monitor our licensee's performance under the license. We do not expect the LPT3-04 license to have a material effect on our business or operations. While we retain certain intellectual property rights with respect to homologs through (i) our prior relationship with Texas A&M University Systems and (ii) our relationship with EGI that could allow for the continued research and development of compounds for the SMaRT replacement Therapy, we do not intend to pursue further development of SMaRT Replacement Therapy and as such we do not consider these rights to be a material part of our business and operations.

Government Regulations

In the United States, foods (including dietary supplements), drugs (including biological products), medical devices, cosmetics, tobacco products and radiation-emitting products are subject to extensive regulation by the FDA. The FDC Act and other federal and state statutes and regulations govern, among other things, the manufacture, distribution and sale of these products. These laws and regulations prescribe criminal and civil penalties that can be assessed, and violation of these laws and regulations can result in enforcement action by the FDA and other regulatory agencies.

FDA Regulation of Drugs-New Drug Approval Process

Pharmaceutical products are subject to extensive regulation by the FDA. The FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs or BLAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves the following steps before a biological product or new drug may be marketed in the United States:

- preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's Good Laboratory Practice and Good Manufacturing Practice regulations;
- submission to the FDA of an Investigational New Drug application (IND) for human clinical testing, which must become effective before human clinical trials may commence;
- performance of adequate and well-controlled clinical trials in three phases, as described below, to establish the safety and efficacy of the drug for each indication according to Good Clinical Practices;
- submission of an NDA or Biologics License Application (BLA) to the FDA for review;
- random inspections of clinical sites to ensure validity of clinical safety and efficacy data;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices;
- FDA approval of the NDA or BLA; and
- payment of user and establishment fees, if applicable.

Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the IND to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The trial protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board or IRB for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs or BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, after the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 clinical trial with other confirmatory evidence may be sufficient in rare instances where the trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

The length of time and related costs necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical trial results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination of our clinical trials, or cause the costs of these clinical trials to increase, include:

- slow patient enrollment due to the nature of the protocol, the proximity of patients to clinical sites, the eligibility criteria for the trial, competition with clinical trials for other drug candidates or other factors;
- inadequately trained or insufficient personnel at the trial site to assist in overseeing and monitoring clinical trials;
- delays in approvals from a trial site's IRB;
- longer than anticipated treatment time required to demonstrate effectiveness or determine the appropriate product dose;
- lack of sufficient supplies of the drug candidate for use in clinical trials;
- adverse medical events or side effects in treated patients; and
- lack of effectiveness of the drug candidate being tested.

Any drug is likely to produce some toxicities or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for sufficiently long periods of time. Unacceptable toxicities or side effects may occur at any dose level, and at any time in the course of animal studies designed to identify unacceptable effects of a drug candidate, known as toxicological studies, or in clinical trials of our drug candidates. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our drug candidates, and could ultimately prevent their marketing approval by the FDA or foreign regulatory authorities for any or all targeted indications.

The FDA's fast track and breakthrough therapy designation programs are intended to facilitate the development and expedite the review of drug candidates intended for the treatment of serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for these conditions. Under these programs, FDA can, for example, review portions of an NDA or BLA for a drug candidate before the entire application is complete, thus potentially beginning the review process at an earlier time.

We cannot guarantee that the FDA will grant any of our requests for fast track or breakthrough therapy designations, that any such designations would affect the time of review or that the FDA will approve the NDA or BLA submitted for any of our drug candidates, whether or not these designations are granted. Additionally, FDA approval of a fast track/breakthrough product can include restrictions on the product's use or distribution (such as permitting use only for specified medical conditions or limiting distribution to physicians or facilities with special training or experience). Approval of such designated products can be conditioned on additional clinical trials after approval.

In addition, the manufacturer of an investigational drug in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access.

After completion of the required clinical testing, an NDA or BLA is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before marketing of the product may begin in the U.S. The NDA or the BLA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs and BLAs is additionally subject to a substantial application user fee, currently approximately $ 2,943,000 for fiscal year 2020. These fees typically increase annually.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be filed based on the agency's threshold determination that it is sufficiently complete to permit substantive review. If the NDA or BLA submission is filed, the FDA reviews the NDA or BLA to determine, among other things, whether the proposed product is safe and effective for its intended use. The FDA has agreed to certain performance goals in the review of NDAs or BLAs. Most such applications for standard review drug products are reviewed within ten to twelve months; most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited to drugs intended to treat a serious or life-threatening disease relative to the currently approved products. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that 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. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMPs is satisfactory and the NDA or BLA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA or BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA or BLA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or BLA supplement before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA or BLA supplements as it does in reviewing NDAs or BLAs.

The required testing, data collection, analysis and compilation of an IND and a BLA or NDA are labor intensive and costly and may take a great deal of time. Tests may have to be redone or new tests performed in order to comply with FDA requirements. It can take considerable time (e.g., 5-10 years) and resources to achieve enrollment sufficient to commence such trials and complete Phase 2 or 3 clinical trials. Moreover, there is no guarantee a product will be approved.

In Canada, the Therapeutic Products Directorate and the Biologics and Genetic Therapies Directorate of HC ensure that clinical trials are properly designed and undertaken and that subjects are not exposed to undue risk. Regulations define specific Investigational New Drug Submission (or IND) application requirements, which must be complied with before a new drug can be distributed for trial purposes. The Directorates currently review the safety, efficacy and quality data submitted by the sponsor and approve the distribution of the drug to the investigator. The sponsor of the trial is required to maintain accurate records, report adverse drug reactions, and ensure that the investigator adheres to the approved protocol. Trials in humans should be conducted according to generally accepted principles of good clinical practice. Management believes that these standards provide assurance that the data and reported results are credible and accurate, and that the rights, integrity, and privacy of clinical trial subjects are protected.

Sponsors wishing to conduct clinical trials in Phases 1 to 3 of development must apply under a 30-day default system. Applications must contain the information described in the regulations, including: a clinical trial attestation; a protocol; statements to be contained in each informed consent form, that set out the risks posed to the health of clinical trial subjects as a result of their participation in the clinical trial; an investigator's brochure; applicable information on excipients (delivery vehicles); and chemistry and manufacturing information.

The sponsor can proceed with the clinical trial if the Directorates have not objected to the sale or importation of the drug within 30 days after the date of receipt of the clinical trial application and Research Ethics Board approval for the conduct of the trial at the site has been obtained. Additional information is available on Health Canada's website - www. hc-sc.gc.ca.

Outside the United States and Canada, our ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Union (EU) registration procedures are available to companies wishing to market a product in more than one EU member state. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficacy has been presented, a marketing authorization may be granted. This foreign regulatory approval process involves all of the risks associated with FDA approval discussed above and may also include additional risks.

The Orphan Drug Act provides incentives to manufacturers to develop and market drugs for rare diseases and conditions affecting fewer than 200,000 persons in the United States at the time of application for orphan drug designation. The first developer to receive FDA marketing approval for an orphan drug is entitled to a seven-year exclusive marketing period in the United States for the orphan drug indication. However, a drug that the FDA considers to be clinically superior to, or different from, another approved orphan drug, even though for the same indication, may also obtain approval in the United States during the seven-year exclusive marketing period.

Under the FDA Modernization Act of 1997, designation as a Fast-Track product for a new drug or biological product means that the FDA will take such actions as are appropriate to expedite the development and review of the application for approval of such product.

Legislation similar to the Orphan Drug Act has been enacted in other countries outside of the United States, including the EU. The orphan legislation in the EU is available for therapies addressing conditions that affect five or fewer out of 10,000 persons, are life-threatening or chronically debilitating conditions and for which no satisfactory treatment is authorized. The market exclusivity period is for ten years, although that period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product does not justify maintenance of market exclusivity.

Emergency Use Authorization

The FDA also has the authority to grant an Emergency Use Authorization ("EUA") to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives. Emergency Use Authorizations granted by the FDA would permit a drug candidate to be able to be distributed under the conditions set forth in the Emergency Use Authorization prior to FDA approval. Due to the global COVID-19 pandemic, certain of our competitors have sought and obtained EUA from the FDA for their COVID-19 vaccines. Furthermore, the FDA may revoke an Emergency Use Authorization where it is determined that the underlying health emergency no longer exists or warrants such authorizations.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs, BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted, except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by FDA to be substantially relevant to the growth or progression of a pediatric cancer that is subject to an NDA submitted on or after August 18, 2020.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity – patent or non-patent – for a drug if certain conditions are met. For BLAs, the BPCA provides a six-month extension for non-patent exclusivity if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

The Hatch-Waxman Amendments

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims covering the applicant's product or method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA labeling does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been received by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Exclusivity provisions under the FDC Act also can delay the submission or the approval of certain applications. The FDC Act provides a five-year period of non-patent exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity, or NCE. A drug is entitled to NCE exclusivity if it contains a drug substance no active moiety of which has been previously approved by the FDA. During the exclusivity period, the FDA may not accept for review an ANDA or file a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a Paragraph IV certification. The FDC Act also provides three years of market exclusivity for an NDA, including a 505(b)(2) NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions for use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs for the original conditions of use, such as the originally approved indication. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all the non-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Patent Term Extension

After NDA approval, the owner of relevant drug patent may apply for up to a five-year patent term extension. Only one patent may be extended for each regulatory review period, which is composed of two parts: a testing phase, and an approval phase. The allowable patent term extension is calculated as half of the drug's testing phase – the time between the day the IND becomes effective and NDA submission – and all of the review phase – the time between NDA submission and approval up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years and only one patent may be extended.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the U.S. Patent and Trademark Office must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Section 505(b)(2) New Drug Applications

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2), or 505(b)(2), NDA, which enables the applicant to rely, in part, on studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference or use, such as the FDA's findings of safety and/or effectiveness for a similar previously approved product, or published literature, in support of its application.

505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA 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. If the 505(b)(2) applicants can establish that reliance on the FDA's previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical trials of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Post-Approval Requirements

Once an NDA or BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA or BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA, subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing or if previously unrecognized problems are subsequently discovered. In addition, prescription drug manufacturers in the United States must comply with applicable provisions of the Drug Supply Chain Security Act and provide and receive product tracing information, maintain appropriate licenses, ensure they only work with other properly licensed entities, and have procedures in place to identify and properly handle suspect and illegitimate products.

Failure to comply with the applicable FDA requirements may subject manufacturers and distributors to administrative or judicial sanctions. These sanctions could include, among other things, warning letters, product seizures, total or partial suspension of production or distribution, injunctions, civil money penalties, fines, restitution, disgorgement, or civil or criminal penalties. Further, the FDA has authority to issue mandatory recalls for medical devices and biologics, and we may need to undertake a voluntary recall for any of our products.

In addition to regulations enforced by the FDA, we are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other federal, state and local regulations. Our research and development activities involve the controlled use of hazardous materials, chemicals, biological materials and radioactive compounds.

Biologics

Biological products used for the prevention, treatment or cure of a disease or condition of a human being are subject to regulation under the FDC Act, except the section of the FDC Act which governs the approval of NDAs. Biological products are approved for marketing under provisions of the Public Health Service Act, or PHSA, via a BLA. However, the application process and requirements for approval of BLAs are very similar to those for NDAs, and biologics are associated with similar approval risks and costs as drugs. To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the US and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, creates an abbreviated approval pathway for biological products shown to be highly similar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency. Biosimilarity must be shown through analytical studies, animal studies, and at least one clinical trial, absent a waiver by the Secretary. A biosimilar product may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. To date, only four biosimilar products and no interchangeable products have been approved under the BPCIA. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, particularly with respect to interchangeability, are still being evaluated by the FDA.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biologics for the same condition of use for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) eighteen months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) eighteen months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the 42-month period.

Regulation Outside the United States

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Regulation and Marketing Authorization in the European Union

The process governing approval of medicinal products in the European Union follows essentially the same lines as in the United States and, likewise, generally involves satisfactorily completing each of the following:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable EU Good Laboratory Practice regulations;
- submission to the relevant national authorities of a clinical trial application, or CTA, which must be approved before human clinical trials may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the relevant competent authorities of a marketing authorization application, or MAA, which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labeling;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced current cGMP;
- potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and
- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

Preclinical Studies

Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animal studies, in order to assess the potential safety and efficacy of the product. The conduct of the preclinical tests and formulation of the compounds for testing must comply with the relevant EU regulations and requirements. The results of the preclinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA.

Clinical Trial Approval

Requirements for the conduct of clinical trials in the European Union including GCP are implemented in the Clinical Trials Directive 2001/20/EC and the GCP Directive 2005/28/EC. Pursuant to Directive 2001/20/EC and Directive 2005/28/EC, as amended, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, approval must be obtained from the competent national authority of an EU member state in which a study is planned to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of member states. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier, or IMPD, and further supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

In April 2014, the EU legislators passed the new Clinical Trials Regulation, (EU) No 536/2014, which replaced the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the European Union, the new EU clinical trials legislation was passed as a regulation that is directly applicable in all EU member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation (EU) No 536/2014 becomes applicable. According to the current plans of the European Medicines Agency, or EMA, the new Clinical Trials Regulation which became applicable in 2019. The Clinical Trials Directive 2001/20/EC will, however, still apply three years from the date of entry into application of the Clinical Trials Regulation to (i) clinical trials applications submitted before the entry into application and (ii) clinical trials applications submitted within one year after the entry into application if the sponsor opts for old system.

The new Regulation (EU) No 536/2014 aims to simplify and streamline the approval of clinical trial in the European Union. The main characteristics of the regulation include:

- A streamlined application procedure via a single-entry point, the EU portal.
- A single set of documents to be prepared and submitted for the application as well as simplified reporting procedures that will spare sponsors from submitting broadly identical information separately to various bodies and different member states.
- A harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed jointly by all member states concerned. Part II is assessed separately by each member state concerned.
- Strictly defined deadlines for the assessment of clinical trial application.
- The involvement of the ethics committees in the assessment procedure in accordance with the national law of the member state concerned but within the overall timelines defined by the Regulation (EU) No 536/2014.

Marketing Authorization

Authorization to market a product in the member states of the European Union proceeds under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure or a national procedure.

Centralized Authorization Procedure

The centralized procedure enables applicants to obtain a marketing authorization that is valid in all EU member states based on a single application. Certain medicinal products, including products developed by means of biotechnological processes, must undergo the centralized authorization procedure for marketing authorization, which, if granted by the European Commission, is automatically valid in all 28 EU member states. The EMA and the European Commission administer this centralized authorization procedure pursuant to Regulation (EC) No 726/2004.

Pursuant to Regulation (EC) No 726/2004, this procedure is mandatory for:

- medicinal products developed by means of one of the following biotechnological processes:
- recombinant DNA technology;
- controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells; and
- hybridoma and monoclonal antibody methods;
- advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No. 1394/2007 on advanced therapy medicinal products;
- medicinal products for human use containing a new active substance that, on the date of effectiveness of this regulation, was not authorized in the European Union, and for which the therapeutic indication is the treatment of any of the following diseases:
- acquired immune deficiency syndrome;
- cancer;

- neurodegenerative disorder;
- diabetes;
- auto-immune diseases and other immune dysfunctions; and
- viral diseases;
- medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

The centralized authorization procedure is optional for other medicinal products if they contain a new active substance or if the applicant shows that the medicinal product concerned constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization is in the interest of patients in the European Union.

Administrative Procedure

Under the centralized authorization procedure, the EMA's Committee for Human Medicinal Products, or CHMP, serves as the scientific committee that renders opinions about the safety, efficacy and quality of medicinal products for human use on behalf of the EMA. The CHMP is composed of experts nominated by each member state's national authority for medicinal products, with an expert appointed to act as Rapporteur for the co-ordination of the evaluation with the possible assistance of a further member of the Committee acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle. The CHMP has 210 days to adopt an opinion as to whether a marketing authorization should be granted. The process usually takes longer in case additional information is requested, which triggers clock-stops in the procedural timelines. The process is complex and involves extensive consultation with the regulatory authorities of member states and a number of experts. When an application is submitted for a marketing authorization in respect of a drug that is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation, the applicant may pursuant to Article 14(9) Regulation (EC) No 726/2004 request an accelerated assessment procedure. If the CHMP accepts such request, the time-limit of 210 days will be reduced to 150 days but it is possible that the CHMP can revert to the standard time-limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. Once the procedure is completed, a European Public Assessment Report, or EPAR, is produced. If the opinion is negative, information is given as to the grounds on which this conclusion was reached. After the adoption of the CHMP opinion, a decision on the MAA must be adopted by the European Commission, after consulting the E.U. member states, which in total can take more than 60 days.

Conditional Approval

In specific circumstances, EU legislation (Article 14(7) Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if (1) the risk-benefit balance of the product candidate is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data, (3) the product fulfills unmet medical needs and (4) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Marketing Authorization under Exceptional Circumstances

Under Article 14(8) Regulation (EC) No 726/2004, products for which the applicant can demonstrate that comprehensive data (in line with the requirements laid down in Annex I of Directive 2001/83/EC, as amended) cannot be provided (due to specific reasons foreseen in the legislation) might be eligible for marketing authorization under exceptional circumstances. This type of authorization is reviewed annually to reassess the risk-benefit balance. The fulfillment of any specific procedures/obligations imposed as part of the marketing authorization under exceptional circumstances is aimed at the provision of information on the safe and effective use of the product and will normally not lead to the completion of a full dossier/approval.

Market Authorizations Granted by Authorities of E.U. Member States

In general, if the centralized procedure is not followed, there are three alternative procedures as prescribed in Directive 2001/83/EC:

- The decentralized procedure allows applicants to file identical applications to several EU member states and receive simultaneous national approvals based on the recognition by EU member states of an assessment by a reference member state.
- The national procedure is only available for products intended to be authorized in a single EU member state.
- A mutual recognition procedure similar to the decentralized procedure is available when a marketing authorization has already been obtained in at least one E.U. member state.

A marketing authorization may be granted only to an applicant established in the European Union.

Pediatric Studies

Prior to obtaining a marketing authorization in the European Union, applicants have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

Periods of Authorization and Renewals

A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

Regulatory Data Protection

EU legislation also provides for a system of regulatory data and market exclusivity. According to Article 14(11) of Regulation (EC) No 726/2004, as amended, and Article 10(1) of Directive 2001/83/EC, as amended, upon receiving marketing authorization, new chemical entities approved on the basis of complete independent data package benefit from eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic medicinal product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder, or MAH, obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the innovator is able to gain the period of data exclusivity, another company nevertheless could also market another version of the drug if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical test, preclinical tests and clinical trials. However, products designated as orphan medicinal products enjoy, upon receiving marketing authorization, a period of ten years of orphan market exclusivity. Depending upon the timing and duration of the EU marketing authorization process, products may be eligible for up to five years' supplementary protection certificates, or SPCs, pursuant to Regulation (EC) No 469/2009. Such SPCs extend the rights under the basic patent for the drug.

Regulatory Requirements After a Marketing Authorization has been Obtained

If we obtain authorization for a medicinal product in the European Union, we will be required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products:

Pharmacovigilance and other requirements

We will, for example, have to comply with the EU's stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. Other requirements relate, for example, to the manufacturing of products and APIs in accordance with good manufacturing practice standards. EU regulators may conduct inspections to verify our compliance with applicable requirements, and we will have to continue to expend time, money and effort to remain compliant. Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties in the European Union. Similarly, failure to comply with the EU's requirements regarding the protection of individual personal data can also lead to significant penalties and sanctions. Individual EU member states may also impose various sanctions and penalties in case we do not comply with locally applicable requirements.

Manufacturing

The manufacturing of authorized drugs, for which a separate manufacturer's license is mandatory, must be conducted in strict compliance with the EMA's Good Manufacturing Practices, or GMP, requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. The EMA enforces its current GMP requirements through mandatory registration of facilities and inspections of those facilities. The EMA may have a coordinating role for these inspections while the responsibility for carrying them out rests with the member states competent authority under whose responsibility the manufacturer falls. Failure to comply with these requirements could interrupt supply and result in delays, unanticipated costs and lost revenues, and could subject the applicant to potential legal or regulatory action, including but not limited to warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil and criminal penalties.

Marketing and Promotion

The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union under Directive 2001/83/EC. The applicable regulations aim to ensure that information provided by holders of marketing authorizations regarding their products is truthful, balanced and accurately reflects the safety and efficacy claims authorized by the EMA or by the competent authority of the authorizing member state. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Patent Term Extension

In order to compensate the patentee for delays in obtaining a marketing authorization for a patented product, a supplementary certificate, or SPC, may be granted extending the exclusivity period for that specific product by up to five years. Applications for SPCs must be made to the relevant patent office in each E.U. member state and the granted certificates are valid only in the member state of grant. An application has to be made by the patent owner within six months of the first marketing authorization being granted in the European Union (assuming the patent in question has not expired, lapsed or been revoked) or within six months of the grant of the patent (if the marketing authorization is granted first). In the context of SPCs, the term "product" means the active ingredient or combination of active ingredients for a medicinal product and the term "patent" means a patent protecting such a product or a new manufacturing process or application for it. The duration of an SPC is calculated as the difference between the patent's filing date and the date of the first marketing authorization, minus five years, subject to a maximum term of five years.

A six-month pediatric extension of an SPC may be obtained where the patentee has carried out an agreed pediatric investigation plan, the authorized product information includes information on the results of the studies and the product is authorized in all member states of the European Union.

Brexit and the Regulatory Framework in the United Kingdom

On June 23, 2016, the electorate in the United Kingdom, or U.K. voted in favor of leaving the E.U., which is commonly referred to as "Brexit." Thereafter, on March 29, 2017, the country formally notified the E. U. of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the U.K. from the E.U. took effect on January 31, 2020. Since the regulatory framework for pharmaceutical products in the U.K. covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from E.U. directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the U.K. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the U.K.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

There has been an increased focus on drug pricing in recent years in the United States. Although there are no direct government price controls over private sector purchases in the United States, there are rebates and other financial requirements for federal and state health care programs. The Medicare Modernization Act, enacted in December 2003, established the Medicare Part D outpatient prescription drug benefit, which is provided primarily through private entities that attempt to negotiate price concessions from pharmaceutical manufacturers. The health care reform legislation enacted in 2010, known as the Affordable Care Act, requires drug manufacturers to pay 50% of the Medicare Part D coverage gap, also known as the "donut hole," on prescriptions for branded products filled when the beneficiary reaches this coverage. The Deficit Reduction Act of 2005 resulted in changes to the way drug prices are reported to the government and the formula using such information to calculate the required Medicaid rebates. The Affordable Care Act increased the minimum basic Medicaid rebate for branded prescription drugs from 15.1% to 23.1% and requires pharmaceutical manufacturers to pay states rebates on prescription drugs dispensed to Medicaid managed care enrollees. In addition, the Affordable Care Act increased the additional Medicaid rebate on "line extensions" (such as extended-release formulations) of solid oral dosage forms of branded products, revised the definition of average manufacturer price by changing the classes of purchasers included in the calculation, and expanded the entities eligible for discounted pricing under the federal 340B drug pricing program. Current orphan drugs are excluded from the expanded 340B hospitals eligible for discounts.

The Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products. The fee (which is not deductible for federal income tax purposes) is based on the manufacturer's market share of sales of branded drugs and biologics (excluding orphan drugs) to, or pursuant to coverage under, specified U. S. government programs. The Affordable Care Act also contains a number of provisions, including provisions governing the way that health care is financed by both governmental and private insurers, enrollment in federal health care programs, reimbursement changes, the increased use of comparative effectiveness research in health care decision-making, and enhancements to fraud and abuse requirements and enforcement, that are affecting existing government health care programs and will result in the development of new programs. The Affordable Care Act also contains requirements for manufacturers to publicly report certain payments or other transfers of value made to physicians and teaching hospitals. We are unable to predict the future course of federal or state health care legislation and regulations, including regulations that will be issued to implement provisions of the Affordable Care Act. The Affordable Care Act and further changes in the law or regulatory framework that reduce our revenues or increase our costs could also have a material adverse effect on our business, financial condition and results of operations and cash flows.

Public and private health care payers control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through the use of tiered formularies and other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payers also set other criteria to govern the uses of a drug that will be deemed medically appropriate and therefore reimbursed or otherwise covered. Payers may require physicians to seek approval from them before a product will be reimbursed or covered, commonly referred to as prior authorization. In particular, many public and private health care payers limit reimbursement and coverage to the uses of a drug that are either approved by the FDA or appear in a recognized drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are supported or not supported by the available evidence, whether or not such uses have been approved by the FDA. For example, in the case of Medicare Part D coverage for oncology drugs, the Medicare Modernization Act, with certain exceptions, provides for Medicare coverage of unapproved uses of an FDA-approved drug if the unapproved use is reasonable and necessary and is supported by one or more citations in CMS-approved compendia, such as the National Comprehensive Cancer Network Drugs and Biologics Compendium. Different pricing and reimbursement schemes exist in other countries. For example, in the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive or negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits and may limit or restrict reimbursement. The downward pressure on health care costs in general, and prescription drugs in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the actions of the National Institute for Clinical Excellence in the United Kingdom, which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries cross-border imports from low-priced markets (parallel imports) exert a commercial pressure on pricing within a country.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of our drug candidate to currently available therapies (so called health technology assessment) in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. E.U. member states may approve a specific price for a drug product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various E.U. member states, and parallel distribution (arbitrage between low-priced and high-priced member states), can further reduce prices. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

An increasing number of states have enacted legislation requiring pharmaceutical and biotechnology companies to file periodic reports of expenses relating to the marketing and promotion of drug products and gifts and payments to individual healthcare practitioners in these states; to make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities; to report information pertaining to and justifying price increases; or to register their sales representatives. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals; price gouging; or pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing. In addition, states such as California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Brexit and the Regulatory Framework in the United Kingdom

In June 2016, the United Kingdom (the "UK") electorate voted in a referendum to leave the European Union (the "EU"), which is commonly referred to as "Brexit". In March 2017, the UK government formally notified the European Council of its intention to leave the EU after it triggered Article 50 of the Lisbon Treaty to begin the two-year negotiation process establishing the terms of the exit and outlining the future relationship between the UK and the EU. Formal negotiations officially started in June 2017. On December 24, 2020 the EU and the UK reached an agreement on a new partnership. The Trade and Cooperation Agreement (the "TCA") sets out the rules that apply between the EU and UK as of January 1, 2021. The UK withdrew from the EU on January 31, 2020. We will review the TCA to determine what impact, if any, the TCA will have on the regulatory, research, manufacturing and supply chain areas.

Environmental, Health and Safety Matters

The manufacturing facilities of the third-parties that develop our product candidates are subject to extensive environmental, health and safety laws and regulations in a number of jurisdictions, governing, among other things: the use, storage, registration, handling, emission and disposal of chemicals, waste materials and sewage; chemicals, air, water and ground contamination; air emissions and the cleanup of contaminated sites, including any contamination that results from spills due to our failure to properly dispose of chemicals, waste materials and sewage.

These laws, regulations and permits could potentially require the expenditure by us of significant amounts for compliance or remediation. If the third-party manufacturers fail to comply with such laws, regulations or permits, we may be subject to fines and other civil, administrative or criminal sanctions, including the revocation of permits and licenses necessary to continue our business activities. In addition, we may be required to pay damages or civil judgments in respect of third-party claims, including those relating to personal injury (including exposure to hazardous substances we use, store, handle, transport, manufacture or dispose of), property damage or contribution claims. Some environmental, health and safety laws allow for strict, joint and several liability for remediation costs, regardless of comparative fault. We may be identified as a responsible party under such laws. Such developments could have a material adverse effect on our business, financial condition and results of operations.

In addition, laws and regulations relating to environmental, health and safety matters are often subject to change. In the event of any changes or new laws or regulations, we could be subject to new compliance measures or to penalties for activities that were previously permitted.

Competition

Our industry is subject to rapid and intense technological change. Competition is intense among manufacturers of nutritional, non-prescription, and prescription pharmaceuticals. We face, and will continue to face, competition from nutraceutical, pharmaceutical, biopharmaceutical, medical device and biotechnology companies developing similar products and technologies both in the United States and abroad, as well as numerous academic and research institutions, governmental agencies and private organizations engaged in drug funding or research and discovery activities both in the United States and abroad. Academic institutions, government agencies and other public and private research organizations may also conduct research, seek patent protection and establish collaborative arrangements for discovery, research and clinical development of technologies and products similar to ours. We also face competition from entities and healthcare providers using more traditional methods. We believe there are a substantial number of products under development by numerous nutraceutical, pharmaceutical, biopharmaceutical, medical device and biotechnology companies, and it is likely that other competitors will emerge.

Many of our existing and potential competitors are large, well established pharmaceutical, chemical or healthcare companies with considerably greater research and product development capabilities and financial, scientific, marketing and human resources than we have. As a result, these competitors may succeed in developing competing products earlier than we do; obtain patents that block or otherwise inhibit our ability to further develop and commercialize our product candidates; obtain approvals from the FDA or other regulatory agencies for products more rapidly than we do; or develop treatments or cures that are safer or more effective than those we propose to develop. These competitors may also devote greater resources to marketing or selling their products and may be better able to withstand price competition. In addition, these competitors may introduce or adapt more quickly to new technologies or scientific advances, which could render our technologies obsolete, and may introduce products or technologies that make the continued development, production, or marketing of our product candidates uneconomical. These competitors may also be more successful in negotiating third-party licensing or collaborative arrangements and may be able to take advantage of acquisitions or other strategic opportunities more readily than we can. These actions by competitors or potential competitors could materially affect our business, financial condition and results of operations. We cannot assure you that we will be able to compete successfully.

We have a limited ability to predict how competitive our products and product candidates will be in the market place. The competition we believe currently exists with respect to each of our products is as follows:

Terra CoV-2 Vaccine

The COVID-19 vaccine market is intensely competitive, characterized by rapid technological progress. As the SARS-CoV-2 pandemic has evolved the status of both the pandemic, with the generation of virus variants and the advancement of our competitor's vaccines and therapeutics along with subsequent regulatory actions, the status of the vaccine candidates is routinely changing. Our competitors include other worldwide research-based biopharmaceutical companies, smaller research companies with more limited therapeutic focus and generic and biosimilar drug manufacturers. We compete with other companies that manufacture and sell products that treat diseases or indications similar to those treated by our vaccine candidate. In December 2020, Pfizer and Moderna both received Emergency Use Authorization ("EUA") to begin distributing their vaccines. The federal government has recently announced it has purchased an aggregate of 600 million doses of these vaccines to inoculate 300 million people in the United States. Johnson & Johnson has developed a single dose vaccine and is expected to seek EUA for the same in late February. In mid-February, the World Health Organization ("WHO") granted emergency use approval for two versions of the AstraZeneca-Oxford COVID-19 vaccine for emergency use, which will target mid and low-income countries.

According to the WHO, there are 69 vaccines currently in clinical development, of which 21 are currently in Phase 3 clinical trials, and there are currently 181 vaccines which are in the pre-clinical development phase. Our Terra CoV-2 vaccine candidate is in pre-clinical development.

Additionally, several companies are working on antiviral drugs, some of which are already in use against other illnesses, to treat people who have COVID-19. On October 22, 2020, the FDA gave the go-ahead under an EUA to Veklury (remdesivir), the first drug approved for the treatment of COVID-19, which is intended for use in adults and children 12 years and older. The FDA has also issued EUAs for several other treatments, including convalescent plasma therapy, a drug used to sedate people placed on a ventilator, and two drugs for people undergoing a type of blood purification known as continuous renal replacement therapy. Other potential treatments include antivirals, monoclonal antibodies, convalescent plasma therapy, immune modulators and stem cell therapy. To the extent these drug treatments are effective there can reduce demand for vaccines against the disease and the potential market for our vaccine product candidate.

Our vaccine development will depend on our ability to identify key points of product differentiation relative to our competitors and conduct pre-clinical testing and file an IND followed by proceeding to a Phase 1 clinical trial. If the Phase 1 trial findings supports further development, a Phase 2 clinical trial may be initiated and/or a partnership to advance further development may be sought. The competition we face with the development of our vaccines is extensive, and could adversely affect us in many ways including the increased numbers of vaccines currently being administered under emergency use authorizations, supplies of raw materials including adjuvants for clinical testing, timing of manufacturers to make our vaccine for testing, available government funding and other funding through partnerships.

MU1140 Homologs and Other Lantibiotics

MU1140 will likely compete directly with antibiotic drugs such as vancomycin and newer drugs, including Cubicin® (daptomycin) and Zyvox® (linezolid). Given the growing resistance of target pathogens to even new antibiotics, we believe that there is ample room in the marketplace for additional antibiotics. Many of our competitors are taking approaches to drug development differing from our approach, including using traditional screening of natural products; genomics to identify new targets, and combinatorial chemistry to generate new chemical structures. Competition in the pharmaceutical industry is based on drug safety, efficacy, ease of use, patient compliance, price, marketing, and distribution. Our lantibiotic development will depend on our success in developing MU1140 homologs and to the point of commercialization or partnership and in the process securing and protecting our intellectual property.

Our Intellectual Property

We rely upon a combination of licenses, patents, trade secrets, know-how, and licensing opportunities to develop our business. Our future prospects depend on our ability to protect our intellectual property. We also need to operate without infringing the proprietary rights of third parties.

Patents

We attempt to protect our technology and products through patents and patent applications pursuant to the terms of our license agreements. We have a worldwide, nonexclusive intellectual property and biological materials license agreement with the National Institute of Allergy and Infectious Diseases ("NIAID"), an institute within the National Institutes of Health ("NIH"), relating to certain research, patent applications and biological materials involving prefusion coronavirus spike proteins and their use in the development and commercialization of vaccine to provide specific, lifetime immunity from SARS-CoV-2. We have an exclusive, worldwide license from EGI (as an assignee of Precigen) to use its technology to develop lantibiotics.

We co-own the intellectual property for certain homologs of our MU1140 product candidate with the Texas A&M University System.

The effect of issued patents is that they provide patent protection for the claims covered by the patents. While the expiration of a product patent normally results in a loss of market exclusivity for the covered product or product candidate, commercial benefits may continue to be derived from: (i) later-granted patents on processes and intermediates related to the most economical method of manufacture of the active ingredient of such product; (ii) patents relating to the use of such product; (iii) patents relating to novel compositions and formulations; and (iv) in the United States and certain other countries, market exclusivity that may be available under relevant law. The effect of patent expiration on products or product candidates also depends upon many other factors such as the nature of the market and the position of the product in it, the growth of the market, the complexities and economics of the process for manufacture of the active ingredient of the product and the requirements of new drug provisions of the Federal Food, Drug and Cosmetic Act or similar laws and regulations in other countries.

We believe that the protection of discoveries in connection with our development activities, our proprietary products, technologies, processes and know-how and all of our intellectual property are important to our business. To achieve a competitive position, we rely on trade secrets, non-patented proprietary know-how and continuing technological innovation, where patent protection is not believed to be appropriate or attainable. In addition, as outlined above, we have a number of patent licenses from third parties, some of which may be important to our business. There can be no assurance that any of our patents, licenses or other intellectual property rights will afford us any protection from competition.

Trademarks

Our trademarks are important to our business. We currently use the following unregistered trademarks: SMaRT Replacement Therapy™, MU1140™, and LPT3-04™. We currently have pending with the USPTO, an application for registration of the mark of ORAGENICS™ (therapeutic products; anti-infectives and vaccine products). We also have rights to use other names essential to our business. Federally registered trademarks have a perpetual life, as long as they are maintained and renewed on a timely basis and used properly as trademarks, subject to the rights of third parties to seek cancellation of the trademarks if they claim priority or confusion of usage. We regard our trademarks and other proprietary rights as valuable assets and believe they have significant value to us.

Protection of Trade Secrets

We attempt to protect our trade secrets, including the processes, concepts, ideas and documentation associated with our technologies, through the use of confidentiality agreements and non-competition agreements with our current employees and with other parties to whom we have divulged such trade secrets. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that other third parties will not otherwise gain access to our trade secrets and other intellectual property. If our employees or other parties breach our confidentiality agreements and non-competition agreements or if these agreements are not sufficient to protect our technology or are found to be unenforceable, our competitors could acquire and use information that we consider to be our trade secrets and we may not be able to compete effectively. Most of our competitors have substantially greater financial, marketing, technical and manufacturing resources than we have and we may not be profitable if our competitors are also able to take advantage of our trade secrets.

We may find it necessary to initiate litigation to enforce our patent rights, to protect our intellectual property or to determine the scope and validity of the proprietary rights of others. Litigation is costly and time-consuming, and there can be no assurance that our litigation expenses will not be significant in the future or that we will prevail in any such litigation.

Government Grants

We have previously received funding from government agencies under the National Science Foundation's and National Institute of Health's Small Business Innovation Research, or SBIR, grants. Eligibility of public companies to receive such grants is based on size and ownership criteria which are under review by the Small Business Administration, or SBA. As a result, our eligibility may change in the future and additional funding from this source may not be available. We have also applied for funding pursuant to BARDA but did not receive a grant award. While we continue to pursue BARDA grant and other grants or government funding related to the COVID-19 pandemic it may not be available to us. In addition, although we seek to protect the competitive benefits we derive from our patents, proprietary information, and other intellectual property, we may not have the right to prohibit the U.S. government from using certain technologies developed or acquired by us due to federal research grants or to prohibit third-party companies, including our competitors, from using those technologies in providing products and services to the U.S. government. The U.S. government could have the right to royalty-free use of technologies that we may develop under such grants. We may commercially exploit those government-funded technologies and may assert our intellectual property rights against other non-government users of technology developed by us, but we may not be successful in our efforts to do so.

Human Capital

Employees

We have seven full-time employees. We enjoy good relations with our employees. None of our employees are a member of any labor union, and we are not a party to any collective bargaining agreement.

Consultants

We have consulting agreements with a number of scientists, clinicians and regulatory experts. They serve as important contacts for us throughout the broader scientific and clinical communities. They are distinguished individuals with expertise in numerous fields, including vaccine development and regulatory matters.

We retain each consultant according to the terms of a consulting agreement. Under such agreements, we pay them a consulting fee and reimburse them for out-of-pocket expenses incurred in performing their services for us. In addition, some consultants hold options to purchase our common stock, subject to the vesting requirements contained in separate award agreements. Our consultants may be employed by other entities and therefore may have commitments to their employer or may have other consulting or advisory agreements that may limit their availability to us.

Corporate Information

We were incorporated in November 1996 and commenced operations in 1999. We consummated our initial public offering in June 2003. Our corporate office is located at 4902 Eisenhower Boulevard, Suite 125, Tampa, Florida 33634.

Available Information

Our website is www.oragenics.com. On our website we make available at no cost our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished as soon as reasonably practicable after we electronically file such material with, or furnish them to, the United States Securities and Exchange Commission ("SEC"). The information contained on our website is not a part of this annual report on Form 10-K.

ITEM 1A. RISK FACTORS.

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below before making an investment decision in our securities. These risk factors are effective as of the date of this Form 10-K and shall be deemed to be modified or superseded to the extent that a statement contained in our future filings modifies or replaces such statement. All of these risks may impair our business operations. The forward-looking statements in this Form 10-K involve risks and uncertainties and actual results may differ materially from the results we discuss in the forward-looking statements. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected. In that case, the trading price of our stock could decline, and you may lose all or part of your investment.

Risk Factor Summary

The below summary of risk factors provides an overview of many of the risks we are exposed to in the normal course of our business activities. As a result, the below summary risks do not contain all of the information that may be important to you, and you should read the summary risks together with the more detailed discussion of risks set forth following this section as well as elsewhere in this Annual Report. Additional risks, beyond those summarized below or discussed elsewhere in this Annual Report, may apply to our activities or operations as currently conducted or as we may conduct them in the future or in the markets in which we operate or may in the future operate. Consistent with the foregoing, we are exposed to a variety of risks, including risks associated with the following:

Risks Related to Our Business

- We have incurred significant losses since our inception and expect to continue to experience losses for the foreseeable future.

- We will need to raise additional capital in the future to complete the development and commercialization of our product candidates and operate our business.

- We were denied funding from the Biomedical Advanced Research and Development Authority ("BARDA") and we may be unable to win any government contracts, grants, agreement or other funding in the future. Even if we are successful in obtaining such contracts, grants, agreements or other funding, we cannot assure the success of our Terra CoV-2 vaccine product candidate, that it will be approved by the FDA or other public health regulatory authority or that any funding provided will be sufficient to complete development and successful commercialization.

- We may rely on government funding and collaboration with government entities for our vaccine development, which adds uncertainty to our research and development efforts and may impose requirements that increase the costs of development, commercialization and production of any programs developed under those government-funded programs.

- We have limited vaccine-specific research, development, manufacturing, testing, regulatory, commercialization, sales, distribution, and marketing experience, and we may need to invest significant financial and management resources to establish these capabilities. Despite such investments and our best efforts, our strategic acquisition of Noachis Terra may turn out to be unsuccessful.

- We have limited financial resources and we may not be able to maintain our current level of operations or be able to fund the further development of our new Terra CoV-2 vaccine product candidate.

● Our vaccine product candidate is at the preclinical stage and has not been approved for sale. We have not conducted substantial research and development for a vaccine product candidate, and we may be unable to produce a vaccine that successfully prevents the virus in a timely and economical manner, if at all.

●*The market opportunities for our vaccine product candidate may be smaller than we believe them to be. Moreover, any pandemic threat may abate, or alternative vaccines currently being broadly disseminated under the FDA's Emergency Use Authorization could become widely accepted and adopted before our vaccines achieve regulatory approval*.

● If we are unable to successfully develop our product candidates, our operating results and competitive position could be harmed. Research and development involves a lengthy and complex process, and we may not be successful in our efforts to develop and commercialize our product candidates. The further development and ultimate commercialization of product candidates for SARS-CoV-2 and COVID-19, as well as our other product candidates, are keys to our growth strategy.

● If we are successful in producing a vaccine against SARS-CoV-2, we may need to devote significant resources to its scale-up and development, including for use by the U.S. government or other foreign authorities. Moreover, government involvement may limit the commercial success of our vaccine product candidate.

● Our product candidates, if approved, will face significant competition and our failure to compete effectively may prevent us from achieving significant market penetration.

● Because our vaccine product development efforts depend on new and rapidly evolving technologies, we cannot be certain that our efforts will be successful.

● Our SARS-CoV-2 vaccine product candidate may face competition from biosimilars approved through an abbreviated regulatory pathway.

● We may be unable to refine a method to produce MU1140 homologs in large-scale commercial quantities. If we cannot, we will be unable to generate significant revenues from sales of our MU1140 homologs product candidate.

● Our success will depend on our ability to obtain regulatory approval of our product candidate under our Lantibiotics Program and its successful commercialization.

● We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.

● We have limited experience in the conduct of clinical trials. We have never initiated a vaccine-related clinical trial. We have never obtained approval of any product candidates. We may be unable to undertake any of those actions successfully.

● We cannot assure you that the market and consumers will accept our products or product candidates. If they do not, we will be unable to generate significant revenues from our products or product candidates and our business, financial condition and results of operations will be materially adversely affected.

● Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

● We will need to further increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing our growth.

● If our manufacturers and suppliers in general fail to meet our requirements and the requirements of regulatory authorities, our research and development may be materially adversely affected.

● We rely on the significant experience and specialized expertise of our senior management and scientific team and the loss of any of our key personnel or our inability to successfully hire their successors could harm our business.

● We need to hire and retain additional qualified scientists and other highly skilled personnel to maintain and grow our business.

● If any of our product candidates are shown to be ineffective or harmful in humans, we will be unable to generate revenues from these product candidates.

● Because we are new to vaccine development, we must identify vaccines for development with our technologies and establish successful third-party relationships.

● We intend to seek licensing partners to cover a portion of the costs associated with obtaining regulatory approval for, and manufacturing and marketing of, our product candidates. If we are unable to obtain agreements with third parties to fund these costs, we will have to fund such costs ourselves or we may be unable to extract any value from these technologies.

● We might not be successful at acquiring, investing in or integrating businesses, entering into joint ventures or divesting businesses.

● We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

● We may be adversely affected by natural disasters, pandemics and other catastrophic events, and by man-made problems such as terrorism, that could disrupt our business operations and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

● Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited, each of which could harm our business.

● Our auditor has previously expressed substantial doubt about our ability to continue as a going concern and absent additional financing we may be unable to remain a going concern.

Risks Related to Our Licenses, Intellectual Property and Data Security and Privacy

● Our vaccine research and development efforts are to a large extent dependent upon our intellectual property and biologicals materials license with the NIAID and the NIH.

● We may incur additional expenses and obligations in connection our NIH license.

● The intellectual property covered by our NIH license concerns patent applications and provisional applications. We cannot assure investors that any of the currently pending or future patent applications will result in granted patents, nor can we predict how long it will take for such patents to be granted.

● We cannot prevent the NIH or other companies, including our competitors, from licensing the same intellectual property and biological materials that we have licensed or from otherwise duplicating our business model and operations.

● Our Lantibiotic Development program development efforts are to a large extent dependent upon our intellectual property and exclusive channel collaboration agreement with Eleszto Genetika, Inc. ("EGI") and is based on early-stage technology in its field.

● We will incur additional expenses in connection with our exclusive channel collaboration arrangement.

● We may not be able to retain the exclusive rights licensed to us under our Lantibiotic ECC to develop and commercialize lantibiotic products.

● Our Collaboration Partner, EGI, may not devote sufficient time and resources to successfully carry out their contracted duties or meet expected deadlines, we may not be able to advance our product candidates in a timely manner or at all.

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

● Changes in patent law or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

● If we are unable to protect our trademarks or other intellectual property from infringement, our business prospects may be harmed.

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

● If we fail to comply with our obligations under our intellectual property license agreements, we could lose our license rights that are important to our business and development of our product candidates.

● If we are sued for infringing intellectual property rights of third parties, it will be costly and time-consuming and an unfavorable outcome in that litigation could have a material adverse effect on our business.

● We may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time-consuming.

● Our success will depend on our ability to partner or sub-license our product candidates and their subsequent successful commercialization.

● If our intellectual property rights do not adequately protect our products or product candidates, or if third parties claim we are infringing their intellectual property rights, others could compete against us more directly or we could be subject to significant litigation. Such results could prevent us from marketing our products or product candidates and hurt our profitability.

● Our business and operations would suffer in the event of cybersecurity/information systems risk.

● We may incur costs of addressing a cybersecurity incident.

● Our business and operations would suffer in the event of failures in our internal computer systems or those of our collaborators.

Risks Related to Government Regulations

● Our product candidates are subject to substantial government regulation, including the regulation of nonclinical testing and clinical trials. If we are unable to obtain regulatory approval for our product candidates, we will be unable to generate revenues.

● We may be unable to obtain regulatory approval for our SARS-CoV-2 vaccine product candidate, or other early-stage product candidates under applicable regulatory requirements. The FDA and foreign regulatory bodies have substantial discretion in the approval process, including the ability to delay, limit or deny approval of product candidates. The delay, limitation or denial of any regulatory approval would adversely impact commercialization, our potential to generate revenue, our business and our operating results.

● Delays or difficulties in the enrollment of patients in clinical trials may result in additional costs and delays in our ability to generate significant revenues, and may delay or prevent our receipt of any regulatory approvals necessary to commercialize our planned and future products.

● Any product candidates that we commercialize will be subject to ongoing and continued regulatory review.

● Our product candidates may cause serious or undesirable side effects or possess other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of approved labeling or result in post-approval regulatory action.

● If any of our product candidates are approved for marketing and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed.

● We may also be subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition.

● Our employees, independent contractors, principal investigators, consultants, vendors and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

● Even if our current product candidates or any future product candidates obtain regulatory approval, they may fail to achieve the broad degree of health care payers, physician and patient adoption and use necessary for commercial success.

● If we are unable to achieve and maintain coverage and adequate levels of reimbursement for any of our product candidates for which we receive regulatory approval, or any future products we may seek to commercialize, their commercial success may be severely hindered.

● If our products do not receive favorable third-party reimbursement, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not generate significant revenues.

Risks Related to Coronavirus Disease (COVID-19)

● Our business is subject to risks arising from public health crises, epidemic or pandemic diseases, such as the recent global outbreak of the coronavirus disease (COVID-19).

● Our ability to conduct clinical trials may be impeded, delayed, limited or prevented entirely due to the spread of COVID-19, the imposition of government restrictions and the concurrent disruptions to ordinary business activities globally.

● Our business involves international components, and we are exposed to various global and local risks related to the coronavirus disease 2019 (COVID-19) that could have a material adverse effect on our financial condition and results of operations.

● Macroeconomic pressures in the markets in which we operate, including, but not limited to, the effectives of the coronavirus disease (COVID-19) may alter the ways in which we conduct our business operations and manage our financial capacities.

● Economic uncertainty may adversely affect our access to capital, cost of capital and ability to execute our business plan as scheduled.

● Inadequate funding for the FDA, the SEC and other government agencies in light of the coronavirus pandemic 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 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.

Risks Related to Our Common Stock

● The issuance of additional equity securities by us in the future would result in dilution to our existing common shareholders.

● Our financial results could vary significantly from quarter to quarter and are difficult to predict.

● Our Series A and Series B preferred stock, if not converted into common stock, has a distribution and liquidation preference senior to our common stock in liquidation which could negatively affect the value of our common stock and impair our ability to raise additional capital.

● The conversion of our Series A Preferred Stock, and Series B Preferred Stock and the exercise of currently outstanding warrants could result in significant dilution to the holders of our common stock.

● Our stockholders may not realize a benefit from our acquisition of Noachis Terra commensurate with the ownership dilution experienced in connection with the acquisition.

● Certain provisions of our articles of incorporation, bylaws, executive employment agreements and stock option plan may prevent a change of control of our company that a shareholder may consider favorable.

● The price and volume of our common stock has been volatile and fluctuates substantially, which could result in substantial losses for stockholders.

● We may be subject to securities litigation, which is expensive and could divert management attention.

● Future sales or issuances of our common stock in the public markets, or the perception of such sales, could depress the trading price of our common stock.

● The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified members for our Board of Directors.

● If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud which could subject us to regulatory sanctions, harm our business and operating results and cause the trading price of our stock to decline.

● We will continue to incur significant costs as a result of and devote substantial management time to operating as a public company listed on the NYSE American.

● We will continue to incur significant costs as a result of and devote substantial management time to operating as a public company listed on the NYSE American.

● If securities or industry analysts publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

● We may issue debt or debt securities convertible into equity securities, any of which may be senior to our common stock as to distributions and in liquidation, which could negatively affect the value of our common stock.

● We are a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to smaller reporting companies, our common stock may be less attractive to investors.

● We have never paid cash dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

Risks Related to Our Business

We have incurred significant losses since our inception and expect to continue to experience losses for the foreseeable future.

We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of approximately $26.4 million and $15.6 million for the years ended December 31, 2020, and 2019, respectively. As of December 31, 2020, our accumulated deficit was approximately $154.4 million. We have devoted a significant amount of our financial resources to research and development, including our nonclinical development activities and clinical trials, as well as licensing and acquisitions related to our product candidates. We expect that the costs associated with our plans to begin preclinical research, contract manufacturing and file an IND for our Terra CoV-2 vaccine product candidate and the research and development of our product candidates pursuant to our exclusive channel partnerships with Eleszto Genetika, Inc. in the area of lantibiotics ("Lantibiotics Program") will continue to increase the level of our overall expenses significantly going forward. Additionally, our NIH license also requires the payment of certain recurring and performance-based royalties that may negatively impact our financial capabilities. As a result, we expect to continue to incur substantial net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' equity and working capital. Because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to accurately predict the timing or amount of substantial expenses or when, or if, we will be able to generate the revenue necessary to achieve or maintain profitability.

We will need to raise additional capital in the future to complete the development and commercialization of our product candidates and operate our business.

Developing and commercializing biopharmaceutical products, including conducting nonclinical studies and clinical trials and establishing manufacturing capabilities, is expensive, and the progress of our efforts to develop and commercialize our product candidates, including our acquisition of a vaccine product candidate, can cause us to use our limited, available capital resources faster than we currently anticipate. Our actual costs may ultimately vary from our current expectations, which could materially impact our use of capital and our forecast of the period of time through which our financial resources will be adequate to support our operations. Our current cash, cash equivalents and short-term investments are not sufficient to fully implement our business strategy and sustain our operations beyond the second quarter of 2022. Accordingly, we will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate or government collaboration and licensing arrangements. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete existing nonclinical and planned clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure, and research and development activities. Specifically, we need to raise additional capital to, among other things:

- conduct preclinical research for our Terra CoV-2 vaccine product candidate, file an IND with the FDA and, if approved, engage in Phase 1 clinical trial and commence preparation for Phase 2 clinical trials;

- engage in GMP and non-GMP manufacturing for our product candidates at the preclinical research and clinical trial stages;

- expand our clinical laboratory operations;
- fund our clinical validation study activities;
- expand our research and development activities; and
- finance our capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- the current and continued microeconomic impact of the COVID-19 pandemic on our ability, the ability of our third-party contractors and suppliers, and the ability of government regulators to conduct ordinary business operations in a timely and efficient manner, as well as the pandemic's broader, macroeconomic impact on the U.S., foreign and global economic markets;
- the level of research and development investment budgeted to develop our current and future product candidates;
- costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- our need or decision to acquire or license complementary technologies or acquire complementary businesses;
- changes in test development plans needed to address any difficulties in product candidate selection for commercialization;
- competing technological and market developments;
- our interaction and relationship with the FDA, or other, regulatory agencies; and
- changes in regulatory policies or laws that affect our operations.

Additional capital may not be available on satisfactory terms, or at all. Furthermore, if we raise additional funds by issuing equity securities, dilution to our existing stockholders would result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or our products under development, or grant licenses on terms that are not favorable to us, which could lower the economic value of those programs to us. If adequate funds are not available, we may have to scale back our operations or limit our research and development activities, which may cause us to grow at a slower pace, or not at all, and our business could be adversely affected.

In addition, we could be forced to discontinue product development and commercialization of one or more of our product candidates, and/or forego licensing attractive business opportunities.

We were denied funding from the Biomedical Advanced Research and Development Authority ("BARDA") and we may be unable to win any government contracts, grants, agreement or other funding in the future. Even if we are successful in obtaining such contracts, grants, agreements or other funding, we cannot assure the success of our Terra CoV-2 vaccine product candidate, that it will be approved by the FDA or other public health regulatory authority or that any funding provided will be sufficient to complete development and successful commercialization.

From time to time, we may apply for contracts, grants, agreements or other funding from government agencies, academic institutions and non-profit organizations. Such contracts or grants can be highly attractive because they provide capital to fund the ongoing development of our technologies and vaccine candidates without diluting our stockholders. However, significant competition exists for these contracts, grants, agreements or other funding. Entities offering such contracts, grants, agreements or other funding may have requirements to apply for or to otherwise be eligible to receive such contracts, grants, agreements or other funding that our competitors may be able to satisfy that we cannot. In addition, such entities have limited funding available to award and may make arbitrary decisions as to whether to offer contracts or make grants, to whom the contracts or grants will be awarded and the size of the contracts or grants to each awardee. Even if we are able to satisfy the award requirements, we may not be a successful awardee. Therefore, we may not be able to win any contracts or grants in a timely manner, if at all. For example, we applied for BARDA funding in connection with our license with the NIH and received notification that are request for BARDA funding had been denied.

Even if we receive a financing through one of the aforementioned mechanisms, the success of our Terra CoV-2 vaccine product candidate cannot be assured solely by our ability to obtain such financing, nor can it assure that any vaccine product candidate so financed will succeed in clinical trials and receive regulatory approval from the FDA or other public health regulatory authorities. Moreover, we cannot guarantee that our receipt of such financing will obviate the need for future financial resources to support the further development of our Terra CoV-2 vaccine product candidate, as additional development activities may be needed, and the vaccine approval and development process can be costly and unpredictable. We have no control over the resources and funding that government agencies may devote to these agreements, which may be subject to annual renewal and which generally may be terminated by the government agencies at any time. Accordingly, our receipt of such funding cannot be relied upon solely as an indicator or guarantee of the success of our Terra CoV-2 vaccine product candidate.

We may rely on government funding and collaboration with government entities for our vaccine development, which adds uncertainty to our research and development efforts and may impose requirements that increase the costs of development, commercialization and production of any programs developed under those government-funded programs.

Because we anticipate the resources necessary to develop our new Terra CoV-2 vaccine product candidate will be substantial, we may explore funding and development collaboration opportunities with the U.S. government and its agencies. For example, we may continue to apply for certain grant funding from BARDA, the NIH or other government agencies to further the research, development, manufacture, testing, and regulatory approval of our Terra CoV-2 vaccine product candidate. We have no control or input over whether an application for BARDA grant funding or any other funding will be accepted or approved, in full or in part, and we cannot provide investors with any assurances that we will receive such funding.

Similar to the requirements imposed by our new NIH license, contracts and grants funded by the U.S. government and its agencies, contain provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- reduce or modify the government's obligations under such agreements without the consent of the other party;
- claim rights, including IP rights, in products and data developed under such agreements;
- audit contract-related costs and fees, including allocated indirect costs;
- suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations.
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- suspend or debar the contractor or grantee from doing future business with the government;
- control and potentially prohibit the export of products;
- pursue criminal or civil remedies under the False Claims Act, False Statements Act, and similar remedy provisions specific to government agreements; and
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period.

In addition, government contracts and grants, ordinarily contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions, including the following:

- specialized accounting systems unique to government contracts and grants;
- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain contract and grant information, which may enable competitors to gain insights into our research program; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination, and affirmative action programs, and environmental compliance requirements.

If we received such grants or agreements, we may not have the right to prohibit the U.S. government from using certain technologies developed by us, and we may not be able to prohibit third-parties, including our competitors, from using those technologies in providing products and services to the U.S. government. Further, under such agreements we could be subject to obligations to and the rights of the U.S. government set forth in the Bayh-Dole Act of 1980, meaning the U.S. government may have rights in certain inventions developed under these government-funded agreements, including a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government could have the right to require us to grant exclusive, partially exclusive, or nonexclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, also referred to as "march-in rights." Although the U.S. government's historic restraint with respect to these rights indicates they are unlikely to be used, any exercise of the march-in rights could harm our competitive position, business, financial condition, results of operations, and prospects. In the event we would be subject to the U.S. government's exercise such march-in rights, we may receive compensation that is deemed reasonable by the U.S. government in its sole discretion, which may be less than what we might be able to obtain in the open market.

Additionally, as is the case under our new NIH license, the U.S. government requires that any products embodying any invention generated through the use of U.S. government funding be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. manufacturers for products covered by such intellectual property.

Although we will need to comply with some of these obligations in relation to our NIH license, not all of the aforementioned obligations may be applicable to us unless and only to the extent that we receive a government grant, contract or other agreement. However, as an organization, we are relatively new to government contracting and new to the regulatory compliance obligations that such contracting entails. If we were to fail to maintain compliance with those obligations, we may be subject to potential liability and to termination of our contracts, including the NIH license, which may have a materially adverse effect on our ability to develop our Terra CoV-2 vaccine product candidate.

We have limited vaccine-specific research, development, manufacturing, testing, regulatory, commercialization, sales, distribution, and marketing experience, and we may need to invest significant financial and management resources to establish these capabilities. Despite such investments and our best efforts, our strategic acquisition of Noachis Terra may turn out to be unsuccessful.

As part of our business strategy, we monitor and analyze strategic acquisition opportunities that we believe will be strategic fits for the Company and beneficial to the Company's shareholders. As demonstrated by our acquisition of Noachis Terra, we may acquire companies, businesses, products and technologies that complement, augment or transform our existing business. However, such acquisitions could involve numerous risks that may prevent us from fully realizing the benefits that we anticipated as a result of such transactions.

Prior to our acquisition of Noachis Terra, we had little-to-no experience in the development and commercialization of vaccines. Although, in connection with the acquisition, we added experienced vaccine researchers and consultants and appointed an experienced vaccine industry professional to our board of directors, given our size and current stage of development, we still have limited vaccine-specific research, development, manufacturing, testing, regulatory, commercialization, sales, distribution, and marketing experience. To successfully develop our Terra CoV-2 vaccine product candidate, we will need to dedicate significant amounts of our limited financial and management resources to bolster our expertise in this area. Our success depends significantly on the continued contributions of our executive officers, financial, scientific and technical personnel and consultants, and on our ability to attract additional personnel.

During our operating history, many essential responsibilities have been assigned to a relatively small number of individuals, and we currently depend heavily upon the efforts and abilities of our management team. However, as we advance into vaccine development, the demands on our key employees will expand and we will need to recruit additional qualified employees for our Company. The competition for such qualified personnel is intense, particularly in light of the demand for a vaccine or other treatment for SARS-CoV-2 and/or COVID-19. The loss of services of any of our existing consultants or our inability to attract additional personnel to fill critical positions could adversely affect our ability to efficiently develop our Terra CoV-2 vaccine product candidate. The loss or unavailability of the services of any of these individuals could have a material adverse effect on our business, prospects, financial condition and results.

Alternatively, or in addition to the above, we may enter into strategic alliances or partnership with other vaccine industry entities to utilize their research, development, manufacturing testing, regulatory or commercialization skills, but we may be unable to enter into such agreements on favorable terms, if at all. If our future strategic collaborators do not commit sufficient resources to our alliances or partnerships and the progress of our vaccine development, if any, and we are unable to develop the necessary capabilities on our own, we may be unable to advance the development of our Terra CoV-2 vaccine product candidate to the point of commercialization, even if we obtain regulatory approval. We will be competing with many companies that currently have existing, extensive and well-funded operations, and without a significant internal team or the support of a third party to perform essential functions related to vaccine research, development, manufacturing, testing, regulatory approval, and commercialization, we may be unable to compete successfully against these more established companies and our Terra CoV-2 vaccine product candidate may fail.

Any failure by us to effectively limit such risks as we implement our strategic acquisition could have a material adverse effect on our business, financial condition or results of operations and cause the price of our securities to fall.

We have limited financial resources and we may not be able to maintain our current level of operations or be able to fund the further development of our new Terra CoV-2 vaccine product candidate.

To date, Oragenics has never developed a vaccine product candidate, and we cannot assure investors that we will be able to successfully develop a vaccine to prevent SARS-CoV-2 or COVID-19 with our current resources and capabilities. Because our new Terra CoV-2 vaccine product candidate is in early stages of development, it will require extensive preclinical and clinical testing, and we will need significant additional funding to conduct such research and testing. We do not expect to generate revenue from product sales, licensing fees, royalties, milestones, contract research or other sources in amounts sufficient to fully fund our operations for the foreseeable future, and we will therefore use our cash resources, and expect to require additional funds, to maintain our existing operations, continue our research and development programs, commence future preclinical studies and clinical trials for our Terra CoV-2 vaccine product candidate, and to seek regulatory approvals.

We anticipate seeking such additional funds through a combination of public or private equity or debt financings, as well as potential collaborations, strategic alliances and marketing, distribution or licensing arrangements and non-dilutive funding from government and nongovernment funding entities, as well as other sources to further the research, development, manufacturing, testing, and regulatory approval of vaccine product candidates. While we may continue to apply for contracts or grants from academic institutions, nonprofit organizations and governmental entities, we may not be successful. Adequate additional funding may not be available to us on acceptable terms, if at all. If we cannot raise the additional funds required for our anticipated operations or to support our development efforts, we may be required to delay significantly, reduce the scope of or eliminate one or more of our research or development programs, downsize our organization, or seek alternative measures to avoid insolvency, including arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies or our vaccine candidate. If we raise additional funds through future offerings of shares of our common stock or other debt or equity securities, such offerings would cause dilution of current stockholders' percentage ownership in the Company, which could be substantial. Additionally, future offerings also could have a material and adverse effect on the price of our common stock.

Our vaccine product candidate is at the preclinical stage and has not been approved for sale. We have not conducted substantial research and development for a vaccine product candidate, and we may be unable to produce a vaccine that successfully prevents the virus in a timely and economical manner, if at all.

Our Terra CoV-2 vaccine development program is in the early stages of research and development, and currently includes only one product candidate, which is in the preclinical stage. Limited data exist regarding the safety and efficacy of our vaccine product candidate, and we must conduct a substantial amount of additional research, development and clinical testing before any regulatory authority will approve our vaccine product candidate. The success of our efforts to develop and commercialize our product candidates could fail for a number of reasons. For example, we could experience delays in product development and clinical trials or unsatisfactory clinical trial results.

In addition, adverse events, or the perception of adverse events, relating to vaccine product candidates and delivery technologies may negatively impact our ability to develop commercially successful products. For example, pharmaceutical companies have been subject to claims that the use of some pediatric vaccines has caused personal injuries, including brain damage, central nervous system damage and other ailments. Regardless of the veracity of or the data supporting these claims, these and other claims may influence public perception of the use of vaccine product candidates and could result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approval of our potential vaccine product candidate. Such greater government regulation could have a material effect on our ability to develop and market our Terra CoV-2 vaccine product candidate.

We have not conducted substantial research on the Terra CoV-2 vaccine product candidate and we lack experience in the research, development, manufacture, regulatory approval, marketing, commercialization and implementation of a vaccine product candidate. Also, uncertainties exist surrounding the longevity and severity of COVID-19 as a global health concern. The success of our efforts to develop and commercialize our product candidates could fail for a number of reasons. Accordingly, we may be unable to produce a vaccine that successfully targets SARS-CoV-2 in a timely and economical manner, if at all.

For example, we expect to commit significant financial resources and personnel to the development of our Terra CoV-2 vaccine product candidate, which may cause delays in or otherwise negatively impact our other product candidate development program. The outcome of any research and development program is highly uncertain. Only a small fraction of biotechnology and vaccine development programs ultimately result in commercial products or even product candidates and a number of events could delay our development efforts and negatively impact our ability to obtain regulatory approval for, and to manufacture, market and sell, a vaccine. Additionally, our ability to develop an effective vaccine will depend on our ability to work on an accelerated timeline, with limited access to financial resources beyond those that we currently possess, and in competition with a significant number of better-funded and more experienced vaccine-development companies. Moreover, if the COVID-19 pandemic is effectively contained or the risk of further spread is diminished or eliminated before we can successfully develop, manufacture and commercialize Terra CoV-2, we may be unable to identify strategic partners willing to work with and support us in our development efforts and, even if we obtain regulatory approval, the market that we anticipate for this product candidate may not exist or may be much smaller than we previously anticipated. Alternatively, even if a market exists, our vaccine product candidate could be found to be ineffective or unsafe, or otherwise fail to receive necessary regulatory clearances. Our vaccine product candidate, even if safe and effective, could be difficult to manufacture on a large scale or uneconomical to market, or our competitors could develop superior products more quickly and efficiently or more effectively market their competing products. Accordingly, our inability to develop a commercially-successful vaccine product will materially harm our business. In addition, other parties are currently producing and administering vaccines for the treatment for SARS-CoV-2 under the FDA's Emergency Use Authorization and other competitive vaccines are expected to seek such authorization as well. Such competitive vaccines already in the market may also lead to the diversion of governmental and nongovernmental resources away from us and toward our competitors.

The market opportunities for our vaccine product candidate may be smaller than we believe them to be. Moreover, any pandemic threat may abate, or alternative vaccines currently being broadly disseminated under the FDA's Emergency Use Authorization could become widely accepted and adopted before our vaccines achieve regulatory approval.

The primary area of focus for our future research and product development activities is the development of a vaccine candidate to prevent SARS-CoV-2 and the disease it principally causes, COVID-19. Our current projections of both the number of people who are or will be affected this disease, as well as the subset of people who may be affected by this disease and who have the potential to benefit from immunity through our Terra CoV-2 vaccine product candidate, are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, because coronaviruses have evolved in recent decades and research on SARS-CoV-2 and COVID-19 are continuously changing due to the complicated nature of the virus, new studies may change the estimated incidence or prevalence of COVID-19. The number of clinical trial participants in the United States, Europe, and elsewhere may turn out to be lower than expected, potential clinical trial participants may not be otherwise amenable to treatment with our products, or new clinical trial participants may become increasingly difficult to identify or gain access to, all of which would adversely affect our ability to conduct the research and development necessary to complete the vaccine product candidate.

Moreover, the threat of the COVID-19 pandemic outbreak may subside before we are able to complete research and development for our Terra CoV-2 vaccine product candidate, obtain regulatory approval for the vaccine product candidate and realize any return on our investment in the research and development. Other organizations some of which are currently broadly administering vaccines under the FDA's Emergency Use Authorization authority, may obtain broad acceptance, or government health organizations may acquire adequate stockpiles of pandemic vaccines or adopt other technologies or strategies to prevent or limit outbreaks before our Terra CoV-2 vaccine product candidate reaches the marketplace, if at all. We may not achieve a return on our investment before the threat of the COVID-19 pandemic subsides or competing products are widely adopted.

If we are unable to successfully develop our product candidates, our operating results and competitive position could be harmed. Research and development involves a lengthy and complex process, and we may not be successful in our efforts to develop and commercialize our product candidates. The further development and ultimate commercialization of product candidates for SARS-CoV-2 and COVID-19, as well as our other product candidates, are keys to our growth strategy.

A key element of our business strategy is to discover, develop, validate and commercialize (i) a vaccine product candidate to provide specific lifetime immunity from SARS-CoV-2, which we aim to market globally to both public and private payers (ii) the development of a portfolio of additional antibiotic product candidates to combat multi drug resistant organism, or MDRO, outbreaks and the associated costs to patients, inpatient facilities and the health care industry. We cannot assure you that we will be able to successfully complete development of, or commercialize any or all of our planned future product candidates, or that they will be clinically usable. For example, we previously attempted to develop an oral mucositis product candidate (or AG013 product candidate) and conducted a Phase 2 clinical trial that was not successful and we ceased further development and terminated our license with a third party to develop such technology. The product development process involves a high degree of risk and may take up to several years or more. Our new product development efforts may fail for many reasons, including:

- our recent entry into the vaccine research and development industry;
- failure of future tests at the research or development stages;
- lack of clinical validation data to support effectiveness;
- delays resulting from the failure of third-party suppliers or contractors to meet their obligations in a timely and cost-effective manner;
- regulatory delays at the FDA or from other independent oversight authorities, particularly in light of the demands placed on public health resources during and following the COVID-19 pandemic;
- failure to obtain or maintain necessary certifications, licenses, clearances or approvals to market or perform the test; or
- lack of commercial acceptance by the health care marketplace.

Few research and development projects result in commercial products, and success in early clinical trials often is not replicated in later trials. At any point, we may abandon development of products (as we did with our oral mucositis product candidate) in favor of the development or acquisition of new products (as we did with our vaccine product candidate), or we may be required to expend considerable resources repeating clinical studies or trials, which would adversely impact the timing for generating potential revenues from those new products. In addition, as we advance the development of new products through to the commercialization stage, we will have to make additional investments in our sales and marketing operations, which may be prematurely or unnecessarily incurred if the commercial launch of a product is abandoned or delayed.

If we are successful in producing a vaccine against SARS-CoV-2, we may need to devote significant resources to its scale-up and development, including for use by the U.S. government or other foreign authorities. Moreover, government involvement may limit the commercial success of our vaccine product candidate.

Because the COVID-19 outbreak has been classified as a pandemic by public health authorities, it is possible that one or more government entities may take actions that directly or indirectly have the effect of abrogating some of our rights or opportunities with respect to the research, development and commercialization of our Terra CoV-2 vaccine product candidate. We have not manufactured a pandemic vaccine to date, but if we were to do so, the economic value of such a vaccine to us could be limited by such government action or inaction. Various government entities, including the U.S. government, are offering, but may not continue to offer, incentives, grants and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against SARS-CoV-2 and/or COVID-19, which may have the effect of increasing the number of competitors and/or providing advantages to known competitors. Accordingly, there can be no assurance that we will be able to successfully establish a competitive market share for our Terra CoV-2 vaccine product candidate.

In the event that any of the preclinical research or, if an IND is accepted by the FDA, the Phase 1 clinical trials for our SARS-CoV-2 vaccine product candidate are perceived to be successful, we may need to work toward the large-scale technical development, manufacturing scale-up and larger scale deployment of this potential vaccine through a variety of U.S. government-sponsored mechanisms, such as an Expanded Access Program or an Emergency Use Authorization program. In this case we may need to divert significant resources to this program, which would require diversion of resources from our other existing product candidate programs. In addition, since the path to licensure of any vaccine against SARS-CoV-2 is unclear, we may have a widely-used vaccine in circulation in the United States or another country prior to our receipt of marketing approval. Unexpected safety issues in these circumstances could lead to significant reputational damage for us and our technology platform going forward and other issues, including delays in our other programs, the need for re-design of our clinical trials and the need for significant additional financial resources.

Our product candidates, if approved, will face significant competition and our failure to compete effectively may prevent us from achieving significant market penetration.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that we are developing. We face competition from a number of sources, such as pharmaceutical companies, including generic drug companies, biotechnology companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical trial expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for product candidates and other resources than us. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. In addition, certain of our product candidates, if approved, may compete with other products, for a share of some patients' discretionary budgets and for physicians' attention within their clinical practices.

We anticipate that, if we obtain regulatory approval of our product candidates, we will face significant competition from other approved therapies and may need to compete with unregulated, unapproved and off-label treatments. Certain of our product candidates, if approved, will present novel therapeutic approaches for the approved indications and will have to compete with existing therapies, some of which are widely known and accepted by physicians and patients. To compete successfully in this market, we will have to demonstrate that the relative cost, safety and efficacy of our approved products, if any, provide an attractive alternative to existing and other new therapies. Such competition could lead to reduced market share for our product candidates and contribute to downward pressure on the pricing of our product candidates, which could harm our business, financial condition, operating results and prospects.

Due to less stringent regulatory requirements in certain foreign countries, there are many more products and procedures available for use in those international markets than are approved for use in the United States. In certain international markets, there are also fewer limitations on the claims that our competitors can make about the effectiveness of their products and the manner in which they can market them. As a result, we expect to face more competition in these markets than in the United States.

Because our vaccine product development efforts depend on new and rapidly evolving technologies, we cannot be certain that our efforts will be successful.

Currently, neither the FDA has given Emergency Use Authorization authority to Moderna and Pfizer for their vaccines. A number of other vaccine manufacturers, academic institutions and other organizations currently have programs to develop such a vaccine. While we are not aware of all of our competitors' efforts, we believe that Sanofi, Janssen, Inovio, Novavax, AIM ImmunoTech Inc. and several others are in the early stages of developing vaccine candidates. These companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products. These companies may also partner or collaborate with large and established companies, such as Merck & Co., Inc., GlaxoSmithKline plc, CSL Ltd, Pfizer Inc. and AstraZeneca, among others, or they may partner or collaborate with or obtain funding from governments, academic institutions or other nongovernmental organizations. In order to effectively compete, we will have to make substantial investments in development, testing, manufacturing and sales and marketing or partner with one or more established companies and establish differentiation from existing vaccines in the market place.

Moreover, our new vaccine development efforts depend on new, rapidly evolving technologies. Our development efforts and, if those are successful, commercialization of our Terra CoV-2 vaccine product candidate could fail for a variety of reasons, and include the possibility that:

- Our SARS-CoV-2 vaccine product candidate or technologies, any or all of the products based on such technologies or any manufacturing process will be ineffective or unsafe, or otherwise fail to receive necessary regulatory approvals or achieve commercial viability;
- third-party supplier or manufacturer facilities will be unable or unwilling to provide necessary supplies, including adjuvants, or scale-up manufacturing capabilities for our products in a cost-effective manner or at all;
- the products, if safe and effective, may be difficult to manufacture on a large-scale or uneconomical to market;
- third-party manufacturing facilities will fail to continue to pass regulatory inspections;
- proprietary rights of third-parties will prevent us or our collaborators from exploiting technologies, and manufacturing or marketing products; and
- Third-party competitors with Emergency Use Authorization from the FDA and use of vaccines will gain greater market share and limit or impair our development efforts.

Our SARS-CoV-2 vaccine product candidate may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first approved. During this twelve-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that, to the extent we are able to reach the BLA stage, our Terra CoV-2 vaccine product candidate should qualify for the twelve-year period of exclusivity. However, risks exist that we may not so qualify, that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our vaccine product candidate to be a reference product for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for a reference product in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

We may be unable to refine a method to produce MU1140 homologs in large-scale commercial quantities. If we cannot, we will be unable to generate significant revenues from sales of our MU1140 homologs product candidate.

Our antibiotic product candidates, all homologs of MU1140, are produced by our strain of *S. mutans* and variants thereof. In March 2005 we successfully developed a methodology for producing MU1140 in quantities sufficient to undertake its nonclinical testing. In June of 2012 we entered into an exclusive collaboration agreement with Precigen Corporation to use its advanced transgene and cell engineering platforms to achieve sufficient production quantities of MU1140. In 2016 we were able to transition manufacturing of OG716 to a third-party manufacturer capable of fermenting quantities sufficient to conduct nonclinical studies. If we are not able to further adequately scale up fermentation and purification methodologies for large-scale manufacture, we will be unable to partner and generate revenues from this product candidate and our business, financial condition and results of operations will be materially adversely affected. The manufacturing of MU1140 homologs, including OG716 or any other possible antibiotic product candidates based on lantibiotics, is a highly exacting and complex process. Manufacturing MU1140 homologs, including OG716, or any other antibiotic candidates derived from lantibiotics on a commercial scale has not yet been achieved to our knowledge, so there are additional risks that such efforts will not be successful. The Precigen technology may not be feasible to efficiently develop methodologies to enable large scale manufacturing of a MU1140 homolog or other antibiotic product candidates. Third-party manufacturers must have additional technical skills and must take multiple steps to attempt to control the manufacturing processes. If we are unable to produce MU1140 homologs in large-scale commercial quantities, we will be unable to generate significant revenues from sales of our MU1140 product candidate and our financial condition and results of operations will be materially adversely affected.

Our success will depend on our ability to obtain regulatory approval of our product candidate under our Lantibiotics Program and its successful commercialization.

Our product candidate under our Lantibiotics Program has not received regulatory approval in any jurisdiction and it may never receive approval or, if approvals are obtained, may never be commercialized successfully. We have incurred and will continue to incur significant costs relating to the nonclinical and clinical development of our antibiotic product candidates (including MU1140 homologs we may develop). We have performed extensive nonclinical testing using native MU1140 and entered into an Exclusive Channel Collaboration Agreement with Precigen (which was assigned to ILH Holdings, Inc. and is n/k/a Eleszto Genetika, Inc.). We began nonclinical activities on homologs of MU1140 in the second half of 2014. Those activities include toxicity results, physicochemical characterizations, and efficacy studies in animals. This work will be done solely by us through the use of outside contractors. If our nonclinical work is successful, we would expect the IND for a first-in-human clinical trial of OG716 to be filed with the FDA based on our ability to complete the requisite studies, contingent on sufficient funding.

Even if we are able to conduct successful clinical trials or the required regulatory approvals are obtained, we may never be able to generate significant revenues from our product candidates. If our product candidates are unsuccessful, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, financial condition and results of operations will be materially adversely affected.

We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.

At any time, we may decide to discontinue the development or commercialization of any of our products or product candidates for a variety of reasons, including inadequate financial resources the appearance of new technologies that render our product obsolete, competition from competing products, inability or limitations to moving forward with development, the economic viability of moving forward with development due to competition, or changes in or failure to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to allocate those resources to potentially more productive uses.

We have limited experience in the conduct of clinical trials. We have never initiated a vaccine-related clinical trial. We have never obtained approval of any product candidates. We may be unable to undertake any of those actions successfully.

As a company, we have limited experience and capacity for the conduct of preclinical research and clinical trials, as well as the progression of a product candidate through to regulatory approval. Because we are in the early stages of development for Terra CoV-2 and because the SARS-CoV-2 vaccine landscape continues to evolve, our clinical trials may require more time and incur greater costs than we anticipate. We cannot be certain that planned clinical trials will begin or conclude on time, if at all. Large-scale trials would require significant additional financial and management resources, and reliance on third-party clinical investigators, CROs and/or consultants. Any performance failure on the part of such third parties could delay clinical development or delay or prevent us from obtaining regulatory approval or commercializing our current or future product candidates, depriving us of potential product revenue and resulting in additional losses. By contrast, larger pharmaceutical and biopharmaceutical companies often have substantial staff or departments with extensive experience in conducting clinical trials with multiple product candidates across multiple indications and obtaining regulatory approval in various countries. In addition, these companies may have greater financial resources to compete for the same clinical investigators, sites and patients that we may attempt to recruit or retain for our preclinical research and clinical trials. As a result, we may be at a competitive disadvantage that could delay the initiation, recruitment, timing and completion of our preclinical research and clinical trials and obtaining regulatory, marketing and related approvals, if achieved at all, for our Terra CoV-2 vaccine product candidate.

We cannot assure you that the market and consumers will accept our products or product candidates. If they do not, we will be unable to generate significant revenues from our products or product candidates and our business, financial condition and results of operations will be materially adversely affected.

The commercial success of our Terra CoV-2 vaccine product candidate, our MU1140 homologs antibiotic product candidates, and any of our other product candidates and technologies, will depend in part on market acceptance by consumers. Biopharmaceutical companies have received substantial support from the scientific community, regulatory agencies and many governmental officials in the United States and internationally. Future scientific developments, media coverage and political events may diminish such support. Public attitudes may be influenced by claims that health products are unsafe for consumption or pose unknown risks to the environment or to traditional social or economic practices. Securing governmental approvals for, and consumer confidence in, such products poses numerous challenges, particularly outside the United States. The market success of product candidates developed by biopharmaceutical companies could be delayed or impaired in certain geographical areas as a result. Products based on our product candidates may compete with a number of traditional dental therapies and drugs manufactured and marketed by major pharmaceutical companies and biotechnology companies. Market acceptance of products based on our product candidates will depend on a number of factors including potential advantage over alternative treatment methods. We can offer you no assurance that physicians, patients or the medical communities in general will accept and utilize products developed from our product candidates. If they do not, we may be unable to generate significant revenues from our product candidates and our business, financial condition and results of operations will be materially adversely affected.

Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products in the European Union and many other jurisdictions, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

We will need to further increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing our growth.

Our current management, personnel, systems and facilities are not adequate to support our future growth plans. We will need to further expand our scientific, sales and marketing, operational, financial and other resources to support our planned research, development, clinical trial work, and commercialization activities.

To manage our operations, growth and various projects effectively, we must:

- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;
- attract and retain sufficient numbers of talented employees;
- develop a marketing, sales, and distribution capability;
- manage our commercialization activities for our product candidates effectively;
- establish and maintain relationships with development and commercialization partners;

- manage our preclinical and clinical trials effectively;

- manage our third-party supply and manufacturing operations effectively and in a cost-effective manner, while increasing production capabilities for our current product candidates to commercial levels; and

- manage our development efforts effectively while carrying out our contractual obligations to partners and other third parties.

In addition, we have utilized and continue to utilize the services of part-time outside consultants to perform a number of tasks for us, including tasks related to preclinical and clinical testing. Our growth strategy may also entail expanding our use of consultants to implement these and other tasks going forward. We rely on consultants for certain functions of our business and will need to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. There can be no assurance that we will be able to manage our existing consultants or find other competent outside consultants, as needed, on economically reasonable terms, or at all. If we are not able to manage our growth effectively and expand our organization by hiring new employees and expanding our use of consultants, we might be unable to implement successfully the tasks necessary to execute effectively on our planned research, development and commercialization activities and, accordingly, might fail to achieve our research, development and commercialization goals.

If our manufacturers and suppliers in general fail to meet our requirements and the requirements of regulatory authorities, our research and development may be materially adversely affected.

We do not have the internal capability to manufacture our SARS-CoV-2 vaccine, MU1140 homologs, or any other product candidates and all of their constituent parts under GMPs, as required by the FDA and other regulatory agencies. In order to continue to develop and commercialize our product candidates and to apply for regulatory approvals for our product candidates, we will need to contract with third parties that have, or otherwise develop, the necessary manufacturing capabilities in full compliance with applicable regulatory requirements.

There are a limited number of manufacturers that operate under GMPs that are capable of manufacturing our product candidates. Due to the early-stage development of our SARS-CoV-2 vaccine product candidate, we cannot at this time accurately predict the numbers and capabilities of manufacturers that will be required and capable of manufacturing the vaccine product candidate and any of its components. Manufacturing on a commercial scale has not yet been undertaken and there are additional technical skills needed for the manufacture of MU1140 homologs that will further limit the number of potential manufacturers. As such, if we are unable to enter into supply and processing contracts with any of these manufacturers or processors for our Terra CoV-2 vaccine product candidate, our MU1140 product candidates, or our other product candidates for the conduct of clinical trials on such product candidate we may incur additional costs and delays in development and commercialization.

Problems with these manufacturing processes such as equipment malfunctions, facility contamination, labor problems, raw material shortages or contamination, natural disasters, power outages, terrorist activities, or disruptions in the operations of our suppliers and even minor deviations from normal procedures, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims and insufficient inventory or supply of product for the conduct of clinical trials. For example, the COVID-19 pandemic and government shutdowns in response have interrupted supply chains, the manufacture and transmission of goods and the regularity with which manufacturers ordinarily operate. Such interruptions, unless remedied entirely, can disrupt our research and development efforts and our clinical trials, and even if remedied, could create delays that materially impact our business.

If we are required to find an additional or alternative source of supply, for example with respect to our ability to obtain an adjuvant, there may be additional costs and delays in the development, clinical trial timing, or commercialization of our product candidates. Additionally, the FDA and other regulatory agencies routinely inspect manufacturing facilities before approving a New Drug Application, or NDA, or Biologic License Application, or BLA, for a drug or biologic manufactured at those sites. If any of our manufacturers or processors fails to satisfy regulatory requirements, the approval and eventual commercialization of our commercial products and product candidates may be delayed.

All of our contract manufacturers must comply with the applicable GMPs, which include quality control and quality assurance requirements as well as the corresponding maintenance of records and documentation. If our contract manufacturers do not comply with the applicable GMPs and other FDA regulatory requirements, we may be subject to product liability claims, the availability of marketed products for sale could be reduced, our product commercialization could be delayed or subject to restrictions, we may be unable to meet demand for our products and may lose potential revenues and we could suffer delays in the progress of nonclinical testing and clinical trials for products under development. We do not have control over our third-party manufacturers' compliance with these regulations and standards. Moreover, while we may choose to manufacture our products ourselves in the future, we have no experience in the manufacture of pharmaceutical or biological products for clinical trials or commercial purposes. If we decide to manufacture products, we would be subject to the regulatory requirements described above. In addition, we would require substantial additional capital and would be subject to delays or difficulties encountered in manufacturing pharmaceutical or biological products. Regardless of the manufacturer of our products, we will be subject to continuing obligations regarding the submission of safety reports and other post-market information.

We rely on the significant experience and specialized expertise of our senior management and scientific team and the loss of any of our key personnel or our inability to successfully hire their successors could harm our business.

Our performance is substantially dependent on the continued services and on the performance of our senior management and scientific team, who have extensive experience and specialized expertise in our business. Our performance also depends on our ability to retain and motivate our other key employees. In June 2016, we hired Dr. Alan Joslyn as President and Chief Executive Officer and in February 2012 we hired Mr. Michael Sullivan, Certified Public Accountant as our Chief Financial Officer, Mr. Sullivan also served as our Interim Principal Executive Officer from October of 2014 through June of 2016. The loss of the services of senior management or any key employees could harm our ability to develop and commercialize our product candidates. We have no key man life insurance policies.

In connection with our acquisition of Noachis Terra, we added vaccine consultants and advisors, who were engaged in various capacities related to the research and development of a SARS-CoV-2 vaccine product candidate. Our ability to successfully continue the vaccine development depends in large part on our ability to retain certain consultants. Despite our efforts to retain these consultants, one or more may terminate their engagement with us on short notice. The loss of the services of any of these consultants could have substantial negative effects on our research and development efforts, which are necessary to further development of our Terra CoV-2 vaccine product candidate.

We need to hire and retain additional qualified scientists and other highly skilled personnel to maintain and grow our business.

Our future success depends on our ability to identify, attract, hire, train, retain and motivate highly skilled technical, managerial and research personnel in all areas within our organization. We plan to continue to grow our business and will need to hire additional personnel to support this growth. We believe that there are only a limited number of individuals with the requisite skills to serve in many of our key positions, and we compete for key personnel with other biotechnology companies, as well as universities and research institutions. It is often difficult to hire and retain these persons, and we may be unable to replace key persons if they leave or be unable to fill new positions requiring key persons with appropriate experience. If we fail to attract, integrate and retain the necessary personnel, our ability to maintain and grow our business could suffer significantly.

If any of our product candidates are shown to be ineffective or harmful in humans, we will be unable to generate revenues from these product candidates.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through nonclinical testing and clinical trials that our products are safe and effective for use in humans. To date the testing of the antibiotic substance MU1140 homologs has been undertaken solely in the laboratory and in animals. We have not yet conducted human trials with any MU1140 homolog nor have we initiated clinical trials for our Terra CoV-2 vaccine product candidate. To date, available clinical data for our AG013 product candidate has been limited to a Phase 1b clinical trial and top-line results from our Phase 2 clinical trial, the latter of which did not demonstrate statistical significance on the primary endpoint of severe oral mucositis when compared to placebo and we ceased further development of such product candidate and terminated our license with our collaboration partner concerning the development of such product candidate. It is possible that when and if future lantibiotic trials and/or our Terra CoV-2 vaccine product candidate trials are conducted in humans, they will show that our antibiotic or vaccine candidates are ineffective or harmful in humans. If MU1140 homologs are shown to be ineffective or harmful in humans, we will be unable to commercialize and generate revenues from sales of this compound. If we are unable to generate revenues from the first generation of MU1140 and homologs, or any other product candidates, our business, financial condition and results of operations will be materially adversely affected.

Because we are new to vaccine development, we must identify vaccines for development with our technologies and establish successful third-party relationships.

Because we are new to vaccine development and lack substantial experience in the research and development of vaccines, the near and long-term viability of our SARS-CoV-2 vaccine product candidate will depend in part on our ability to successfully establish new strategic collaborations with biotechnology companies, non-profit organizations, governmental agencies and other vaccine industry entities. Establishing strategic collaborations and obtaining government funding is difficult and time-consuming. Potential collaborators may reject collaborations based upon their assessment of our financial, regulatory or intellectual property position or based on their internal pipeline; government agencies may reject contract or grant applications based on their assessment of public need, the public interest, our products' ability to address these areas, or other reasons beyond our expectations or control. If we fail to establish a strategic collaborations or government relationships on acceptable terms, we may not be able to develop and commercialize our Terra CoV-2 vaccine product candidate or generate sufficient revenue to fund further research and development efforts.

Additionally, we do not have our own clinical research and development facilities dedicated to vaccine development and manufacture. We have in the past and may in the future engage consultants and independent contract research organizations, subject to regulatory considerations, to design and conduct its clinical trials in connection with the development of our SARS-CoV-2 vaccine product candidate. As a result, these important aspects of a product's development will be outside of our direct control. Even if we establish new collaborations or obtain government funding, these relationships may never result in the successful development or commercialization of our vaccine product candidate for several reasons, including the fact that:

- we may not have the ability to control the activities of our partners and cannot provide assurance that they will fulfill their obligations to us, including with respect to the license, development and commercialization of our vaccine product candidate, in a timely manner or at all;
- such partners may not devote sufficient resources to our vaccine product candidate or properly maintain or defend our intellectual property rights;
- any failure on the part of our partners to perform or satisfy their obligations to us could lead to delays in the development or commercialization of our vaccine product candidate and affect our ability to realize product revenue; and
- disagreements, including disputes over the ownership of technology developed with such collaborators, could result in litigation, which would be time consuming and expensive, and may delay or terminate research and development efforts, regulatory approvals and commercialization activities.

Our collaborators will be subject to the same regulatory approval of their manufacturing facility and process as us. Before we could begin commercial manufacturing of any of our vaccine candidates, we and our collaborators must pass a pre-approval inspection before FDA approval and comply with the FDA's GMP regulations. If our collaborators fail to comply with these requirements, our vaccine candidate may not be approved. If our collaborators fail to comply with these requirements after approval, we could be subject to possible regulatory action and may be limited in the jurisdictions in which we are permitted to sell our products. If we or our collaborators fail to establish agreements as necessary, we could be required to undertake research, development, manufacturing and commercialization activities solely at our own expense. These activities would significantly increase our capital requirements and, given our lack of sales, marketing and distribution capabilities, significantly delay the commercialization of our vaccine product candidate.

We intend to seek licensing partners to cover a portion of the costs associated with obtaining regulatory approval for, and manufacturing and marketing of, our product candidates. If we are unable to obtain agreements with third parties to fund these costs, we will have to fund such costs ourselves or we may be unable to extract any value from these technologies.

As we continue our development of product candidates, we intend to either license these product candidates to, or partner with, one or more major pharmaceutical companies at the earliest possible time in their product development. If we do so, we intend for these licensees or partners to pay the costs associated with any remaining development work, regulatory submissions, clinical trials and the manufacturing and marketing of our product candidates. If we are unable to license our product candidates or otherwise partner with third parties, we will have to fund the costs of our clinical trials ourselves or we will be unable to extract any value from these technologies. We may also have to establish our own manufacturing facilities and find our own distribution channels. This would greatly increase our future capital requirements and we cannot assure you that we would be able to obtain the necessary financing to pay these costs. If we are unable to cover the associated costs or we cannot obtain financing on acceptable terms or at all, our business, financial condition and results of operations will be materially adversely affected.

Our dependence on collaborative arrangements with third parties subjects us to a number of risks. These collaborative arrangements may not be on terms favorable to us. Agreements with collaborative partners typically allow partners significant discretion in electing whether or not to pursue any of the planned activities. We cannot control the amount and timing of resources our collaborative partners may devote to products based on the collaboration, and our partners may choose to pursue alternative products. Our partners may not perform their obligations as expected. Business combinations or significant changes in a collaborative partner's business strategy may adversely affect a partner's willingness or ability to complete its obligations under the arrangement. Moreover, we could become involved in disputes with our partners, which could lead to delays or termination of the collaborations and time-consuming and expensive litigation or arbitration. Even if we fulfill our obligations under a collaborative agreement, our partner may be able to terminate the agreement under certain circumstances. If any collaborative partner were to terminate or breach our agreement with it, or otherwise fail to complete its obligations in a timely manner, our chances of successfully commercializing our product candidates would be materially and adversely affected.

We might not be successful at acquiring, investing in or integrating businesses, entering into joint ventures or divesting businesses.

We expect to continue pursuing strategic acquisitions, investments and joint ventures to enhance or add to our skills and capabilities or offerings of services and solutions, or to enable us to expand in certain geographic and other markets. Depending on the opportunities available, we may increase the amount of capital invested in such opportunities. We may not succeed in completing targeted transactions, including as a result of the market becoming increasingly competitive, or achieve desired results of operations. Furthermore, we face risks in successfully integrating any businesses we might acquire or create through a joint venture. Ongoing business may be disrupted, and our management's attention may be diverted by acquisition, investment, transition or integration activities. In addition, we might need to dedicate additional management and other resources, and our organizational structure could make it difficult for us to efficiently integrate acquired businesses into our ongoing operations and assimilate and retain employees of those businesses into our culture and operations. The loss of key executives, employees, customers, suppliers, vendors and other business partners of businesses we acquire may adversely impact the value of the assets, operations or businesses. Furthermore, acquisitions or joint ventures may result in significant costs and expenses, including those related to retention payments, equity compensation, severance pay, early retirement costs, intangible asset amortization and asset impairment charges, assumed litigation and other liabilities, and legal, accounting and financial advisory fees, which could negatively affect our profitability. We may have difficulties as a result of entering into new markets where we have limited or no direct prior experience or where competitors may have stronger market positions. We might fail to realize the expected benefits or strategic objectives of any acquisition, investment or joint venture we undertake. We might not achieve our expected return on investment or may lose money. We may be adversely impacted by liabilities that we assume from a company we acquire or in which we invest, including from that company's known and unknown obligations, intellectual property or other assets, terminated employees, current or former clients or other third parties. In addition, we may fail to identify or adequately assess the magnitude of certain liabilities, shortcomings or other circumstances prior to acquiring, investing in or partnering with a company, including potential exposure to regulatory sanctions or liabilities resulting from an acquisition target's previous activities, internal controls and security environment. If any of these circumstances occurs, they could result in unexpected legal or regulatory exposure, unfavorable accounting treatment, unexpected increases in taxes or other adverse effects on our business. In addition, we have a lesser degree of control over the business operations of the joint ventures and businesses in which we have made minority investments or in which we have acquired less than 100% of the equity. This lesser degree of control may expose us to additional reputational, financial, legal, compliance or operational risks. Litigation, indemnification claims and other unforeseen claims and liabilities may arise from the acquisition or operation of acquired businesses. For example, we may face litigation or other claims as a result of certain terms and conditions of the acquisition agreement, such as earnout payments or closing net asset adjustments. Alternatively, shareholder litigation may arise as a result of proposed acquisitions. If we are unable to complete the number and kind of investments for which we plan, or if we are inefficient or unsuccessful at integrating any acquired businesses into our operations, we may not be able to achieve our planned rates of growth or improve our market share, profitability or competitive position in specific markets or services. We also periodically evaluate, and have engaged in, the disposition of assets and businesses. Divestitures could involve difficulties in the separation of operations, services, products and personnel, the diversion of management's attention, the disruption of our business and the potential loss of key employees. After reaching an agreement with a buyer for the disposition of a business, the transaction may be subject to the satisfaction of pre-closing conditions, including obtaining necessary regulatory and government approvals, which, if not satisfied or obtained, may prevent us from completing the transaction. Divestitures may also involve continued financial involvement in or liability with respect to the divested assets and businesses, such as indemnities or other financial obligations, in which the performance of the divested assets or businesses could impact our results of operations. Any divestiture we undertake could adversely affect our results of operations.

We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities regulated by the FDA or an applicable foreign regulatory authority. Our products and product candidates are designed to affect bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our product candidates could result in injury and possibly death to a patient. An inability to obtain sufficient insurance coverage on commercially reasonable terms or otherwise to protect against potential product liability claims could inhibit our business.

In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates, among others. If we cannot successfully defend ourselves against product liability claims we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates;
- impairment of our brand and/or reputation;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distraction of management's attention and other resources from our primary business;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance; or
- loss of revenue.

Although we maintain product liability insurance coverage for clinical trials, our insurance coverage may not be sufficient to cover all of our product liability-related expenses or losses and may not cover us for any expenses or losses we suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability, particularly if any of our product candidates receive regulatory approval. Further, a successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and harm our business, financial condition, operating results and prospects.

We may be adversely affected by natural disasters, pandemics and other catastrophic events, and by man-made problems such as terrorism, that could disrupt our business operations and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters are located in Tampa, Florida, a hurricane zone. If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as enterprise financial systems, manufacturing resource planning or enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Our contract manufacturers' and suppliers' facilities are located in multiple locations, where other natural disasters or similar events, such as blizzards, tornadoes, fires, explosions or large-scale accidents or power outages, and other public health emergencies could severely disrupt our operations and have a material adverse effect on our business, financial condition, operating results and prospects. For example, the recent COVID-19 pandemic may cause significant disruption to our business operations, the operations of our third-party contractors and suppliers and the operations of our clinical trials, including as a result of significant restrictions or bans on travel into and within the geographic areas in which our manufacturers product our product candidates or where we conduct our clinical trials. A public health emergency could also affect the operations of the FDA and other regulatory or public health authorities, resulting in delays to meetings related to planned or completed clinical trials and ultimately of reviews and approvals of our product candidates. Such disruption could impede, delay, limit or prevent our employees and third-party contractors from beginning or continuing research and development or clinical trial-related activities, which may impede, delay, limit or prevent initiation or completion of our ongoing clinical trials and preclinical research and ultimately lead to the delay or denial of regulatory approval of our product candidates, which could seriously harm our operations and financial condition.

In addition, acts of terrorism and other geo-political unrest could cause disruptions in our business or the businesses of our partners, manufacturers or the economy as a whole. All of the aforementioned risks may be further increased if we do not implement a disaster recovery plan or our partners' or manufacturers' disaster recovery plans prove to be inadequate. To the extent that any of the above should result in delays in the regulatory approval, manufacture, distribution or commercialization of our product candidates, our business, financial condition, operating results and prospects would suffer.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited, each of which could harm our business.

As of December 31, 2020, we had U.S. federal and state net operating loss carryforwards of approximately $142,893,000. We also accumulated U.S. federal and state research tax credits of approximately $4,043,000 as of December 31, 2020 Under Sections 382 and 383 of the Internal Revenue Code (the "Code"), if a corporation undergoes an "ownership change," the corporation's ability to use its pre-ownership change net operating loss carryforwards and other pre-ownership change tax attributes, such as research tax credits, to offset its post-ownership change income and taxes may be limited. In general, an ownership change will occur when the percentage of the Corporation's ownership (by value) of one or more "5-percent shareholders" (as defined in the Code) has increased by more than 50 percent over the lowest percentage owned by such shareholders at any time during the prior three years (calculated on a rolling basis). Similar rules may apply under state tax laws. An entity that experiences an ownership change generally will be subject to an annual limitation on its pre-ownership change tax loss and credit carryforwards equal to the equity value of the corporation immediately before the ownership change, multiplied by the long-term, tax-exempt rate posted monthly by the IRS (subject to certain adjustments). The annual limitation would be increased each year to the extent that there is an unused limitation in a prior year. In the event that it is determined that we have in the past experienced an ownership change as a result of transactions in our stock, or if we experience one or more ownership changes as a result of future transactions in our stock, then we may be limited in our ability to use our net operating loss carryforwards and other tax assets to reduce taxes owed on the net taxable income that we earn. Any limitations on the ability to use our net operating loss carryforwards and other tax assets could harm our business.

Our auditor has previously expressed substantial doubt about our ability to continue as a going concern and absent additional financing we may be unable to remain a going concern.

In light of our recurring losses, accumulated deficit and negative cash flow as described in our notes to our audited financial statements, the report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2017 contained an explanatory paragraph raising substantial doubt about our ability to continue as a going concern. Our financial statements did not include any adjustments that may have been necessary in the event we were unable to continue as a going concern. Had we been unable to establish to the satisfaction of our independent registered public accounting firm that the net proceeds from our financing efforts will be sufficient to allow for the removal of this going concern qualification, we may need to significantly modify our operational plans for us to continue as a going concern. We believe we can continue our current level of operations with the cash we have on hand inclusive of the proceeds from our ATM facility and warrant exercises, and net of the redemption of the Series C Preferred Stock of approximately $5.6 million, without additional financing through the second quarter of 2022. Absent sufficient additional financing, we may be unable to remain a going concern.

Risks Related to Our Licenses, Intellectual Property and Data Security and Privacy

Our vaccine research and development efforts are to a large extent dependent upon our intellectual property and biologicals materials license with the NIAID and the NIH.

An important element of our intellectual property portfolio is our license with the NIAID and the NIH. Pursuant to the Patent License and Biological Materials License Agreement, we hold a nonexclusive, worldwide license to certain specified patent rights (including patent applications, provisional patent applications and Patent Cooperation Treaty ("PCT") patent applications) and biological materials relating to the use of prefusion coronavirus spike proteins for the purpose of developing and commercializing a vaccine product candidate for SARS-CoV-2. This intellectual property and biological materials license is essential to our operations and our ability to research and develop our Terra CoV-2 vaccine product candidate. The terms of the license agreement will terminate upon the earlier of (a) twenty (20) years from the first commercial sale where no licensed patent rights exist or have ceased to exist or (b) the expiration of the last to expire of any licensed patent rights. Additionally, we must use reasonable commercial efforts to develop, manufacture, and commercialize our vaccine product candidate, to manufacture our vaccine product candidate substantially within the United States and provide the United States public with reasonable access to our vaccine, if approved for commercialization by the FDA. If we breach the terms of the license agreement, including any failure to make minimum royalty payments required thereunder or failure to reach certain developmental milestones, using best efforts to introduce a licensed product or practice a licensed process in certain territories by certain dates, the NIAID has the right to terminate the license.

If we were to lose or otherwise be unable to maintain the NIH license on acceptable terms, or find that it is necessary or appropriate to secure new licenses from other third parties, it would halt our ability to develop and market our Terra CoV-2 vaccine product candidate, which would have an immediate material adverse effect on our business, operating results and financial condition. Thus, our inability to retain the rights and technologies identified by the license, or those that we may in the future identify, could have a material adverse impact on our ability to complete the development of our vaccine product candidate. No assurance can be given that we will be successful in licensing any additional rights or technologies from the NIAID, the NIH or others. If we fail to retain the NIH license or if we fail to obtain additional rights and licenses necessary to further the development and commercialization of our vaccine product candidate, our planned development for our vaccine product candidate may be materially impacted and the costs associated with the development may increase significantly, and we may be entirely unable to complete development of a SARS-CoV-2 vaccine product candidate.

We may incur additional expenses and obligations in connection our NIH license.

We must use reasonable commercial efforts to bring to market a vaccine product candidate covered by the license, which means we must adhere to an existing commercial development plan and existing performance benchmarks. Additionally, we are obliged to pay to the NIAID certain minimum annual royalties, certain benchmark-related royalties and royalties based upon a share of any net sales of our vaccine product candidate, following regulatory approval and the first commercial sale. Additionally, among other obligations, we must provide regular written reports to the NIAID on the development status of our vaccine product candidate and pay for our pro rata share of the NIH's patent prosecution-related expenses and fees. Moreover, we must use reasonable commercial efforts to develop, manufacture, and commercialize the vaccine product candidate, to manufacture the vaccine product candidate substantially within the United States and provide the United States public with reasonable access to the vaccine, if approved for commercialization by the FDA. All of these additional obligations beyond ordinary research and development and regulatory compliance related to the approval of our vaccine product candidate may impose delays or greater costs upon our ability to timely develop our vaccine product candidate.

Although our forecasts for expenses and the sufficiency of our capital resources will take into account the funds available for the research and development of our vaccine product candidate development, our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, changes in the focus and direction of our development programs, competitive and technical advances, costs associated with the development of our product candidates and the our share of the costs of filing, prosecuting, defending and enforcing the intellectual property rights covered by the NIH license. If we exhaust the funds available for the development of Terra CoV-2 more quickly than anticipated, regardless of the reason, and we are unable to obtain additional financing on terms acceptable to us or at all, we may be unable to meet our obligations under the NIH license, which may be terminated, and we will be unable to proceed with development of our product candidates on expected timelines and will be forced to prioritize among them.

The intellectual property covered by our NIH license concerns patent applications and provisional applications. We cannot assure investors that any of the currently pending or future patent applications will result in granted patents, nor can we predict how long it will take for such patents to be granted.

The intellectual property covered by our NIH license concerns certain, specified patent rights (including patent applications, provisional patent applications and PCT patent applications). Although the NIAID has agreed to assume responsibility for the preparation, filing, prosecution and maintenance of all patent applications covered by the licensed patent rights, we cannot be certain as to when or if final patents will be issued for those patent applications covered by the licensed patent rights. However, the NIH may not successfully prosecute certain patent applications, the prosecution of which they control, under which we are only a licensee and on which our business substantially depends. Even if patents issue from these applications, the NIH may fail to maintain these patents, may decide not to pursue litigation against third-party infringers, may fail to prove infringement or may fail to defend against counterclaims of patent invalidity or unenforceability.

Moreover, it is possible that the licensed pending patent applications will not result in granted patents, and even if such pending patent applications grant as patents, they may not provide a basis for intellectual property protection of commercially viable vaccine products or may not provide us with any competitive advantages. Further, it is possible that, for any of the patents that may be granted in the future, others will design around the licensed patent rights or identify methods for preventing or treating SARS-CoV-2 that do not concern the rights covered by our NIH license. Further, we cannot assure investors that other parties will not challenge any patents granted to the NIH or that courts or regulatory agencies will hold NIH's patents to be valid or enforceable. We cannot guarantee investors that, if required to defend the covered patents, we will be successful in defending challenges made against the NIH patents and patent applications. Any successful third-party challenge to the NIH patents could result in the unenforceability or invalidity of such patents, or to such patents being interpreted narrowly or otherwise in a manner adverse to our interests. Our ability to establish or maintain a technological or competitive advantage over our competitors may be diminished because of these uncertainties.

Risks with respect to the NIH and our NIH license may also arise out of circumstances beyond our control. In spite of our best efforts, the NIH may conclude that we have materially breached the license agreement and may therefore terminate the agreement, thereby removing our ability to market vaccine product candidates covered by the agreement. If the NIH license agreement is terminated, or if the underlying patents fail to provide the intended market protection, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to ours. Moreover, if the NIH license agreement is terminated, the NIH may be able to prevent us from utilizing the technology covered by the licensed patent rights. This could have a material adverse effect on our competitive business position and our financial condition, results of operations and our business prospects.

We cannot prevent the NIH or other companies, including our competitors, from licensing the same intellectual property and biological materials that we have licensed or from otherwise duplicating our business model and operations.

Our NIH license is a nonexclusive license and we are not permitted to sublicense the intellectual property or biological materials covered by the license. Therefore, we cannot be certain that the NIH has not previously licensed, or that the NIH will not, in the future, license the intellectual property or biological materials to other biotechnology companies, including those who intend to develop a vaccine product candidate for SARS-CoV-2, some or all of the nonexclusive intellectual property and biological materials available to us under the NIH license. Moreover, we do not currently own any exclusive rights or licenses necessary to fully develop our Terra CoV-2 vaccine product candidate, and such rights or licenses, if in existence, could be held by our competitors or used by other third parties to otherwise directly compete against us. If our competitors or others have or acquire exclusive rights or licenses that they could enforce against us, then we may be required to alter our products, pay licensing fees or cease activities. If our products conflict with rights or licenses of others, third parties could bring legal actions against us or our collaborators, licensees, suppliers or customers, claiming damages and seeking to enjoin manufacturing and marketing of the affected products. If these legal actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to manufacture or market the affected products. We may not prevail in any legal action and a required license under the patent may not be available on acceptable terms or at all. Accordingly, while we may develop, acquire or license the additional technologies necessary to the development of our vaccine candidate we cannot assure you that we will be able to develop, acquire or license such technologies or that alternatives will be sufficient to enable development of our Terra CoV-2 vaccine product candidate or to prevent others from competing with us and developing substantially-similar products.

Our Lantibiotic Development program development efforts are to a large extent dependent upon our intellectual property and exclusive channel collaboration agreement with Eleszto Genetika, Inc. ("EGI") is based on early-stage technology in its field.

Our exclusive channel collaboration agreement contemplates the use of EGI's advanced transgene and cell engineering platforms for the development and production of lantibiotics. Such technologies have a limited history of use in the design and development of active pharmaceutical ingredients and drug products involving direct administration and may therefore involve unanticipated risks or delays.

We will incur additional expenses in connection with our exclusive channel collaboration arrangement.

Pursuant to our exclusive channel collaboration, we are responsible for future research and development expenses of product candidates developed under such collaboration, including those incurred by our collaboration partners for research on our behalf as provided in the lantibiotic exclusive channel collaboration Agreement ("Lantibiotic ECC"). As a result, we expect the level of our overall research and development expenses going forward will increase. The timing and amount of expenses under our Lantibiotic ECC are difficult to predict. Although all manufacturing, nonclinical studies and human clinical trials are expensive and difficult to design and implement, costs associated with the manufacturing, research and development of biologic product candidates are generally greater in comparison to small molecule product candidates. We expect over time to add additional personnel to support our Lantibiotics Program as we progress in our development efforts.

Because our collaborations pursuant to our Lantibiotic ECC is in the early stage, future development costs associated with this program may be difficult to anticipate and exceed our expectations. Our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, unanticipated technical challenges, changes in the focus and direction of our development activities or adjustments necessitated by changes in the competitive landscape in which we operate. If we are unable to continue to financially support such collaborations due to our own working capital constraints, we may be forced to delay our activities. If we are unable to obtain additional financing on terms acceptable to us or at all, we may be forced to seek licensing partners or discontinue development, which in turn could lead to the termination of our Lantibiotic ECC.

We may not be able to retain the exclusive rights licensed to us under our Lantibiotic ECC to develop and commercialize lantibiotic products.

Under our Lantibiotic ECC we are responsible for, among other things, funding the further anticipated development of lantibiotics toward the goal of commercialization, conducting nonclinical and clinical development of product candidates, as well as for other aspects of manufacturing and the commercialization of the product(s). Our collaboration partners may terminate such agreement if we do not perform certain specified requirements, including developing therapies identified to us and considered superior by our collaboration partners. There can be no assurance that we will be able to successfully perform under the Lantibiotic ECC and if the Lantibiotic ECC is terminated it would prevent us from achieving our business objectives.

Our Collaboration Partner, EGI, may not devote sufficient time and resources to successfully carry out their contracted duties or meet expected deadlines, we may not be able to advance our product candidates in a timely manner or at all.

On January 31, 2020, our prior collaboration partner, Intrexon Corporation, pursuant to a restructuring which in part, resulted in a change of Intrexon's name to Precigen, Inc. In addition, pursuant to Precigen's restructuring plan, the Lantibiotic ECC and Lantibiotic Stock Issuance Agreement were assigned to and assumed by ILH Holdings, Inc. ("ILH") (n/k/a Eleszto Genetika, Inc. ("EGI"), a wholly owned subsidiary of Precigen, Precigen subsequently sold the majority of its bioengineering assets, inclusive of EGI, to TS Biotechnology, an entity managed by Third Security. Our success depends, in part, on the performance by our collaborators of their responsibilities under our collaboration arrangements. Our new collaborator may not perform their obligations in a timely fashion or in a manner satisfactory to us or consistent with how previously performed. Typically, we cannot control the amount of resources or time our collaborators may devote to our programs or potential products that may be developed in collaboration with us. We are currently involved in multiple research and development collaborations with academic and research institutions. These collaborators frequently depend on outside sources of funding to conduct or complete research and development, such as grants or other awards. As a result of these uncertainties, we are unable to control the precise timing and execution of any experiments that may be conducted.

Additionally, our current or future corporate collaborators will retain the ability to pursue other research, product development or commercial opportunities that may be directly competitive with our programs. If these collaborators elect to prioritize or pursue other programs in lieu of ours, we may not be able to advance product development programs in an efficient or effective manner, if at all. If a collaborator is pursuing a competitive program and encounters unexpected financial or capability limitations, they may be motivated to reduce the priority placed on our programs or delay certain activities related to our programs or be unwilling to properly fund their share of the development expenses for our programs. Any of these developments could harm our product and technology development efforts, which could seriously harm our business.

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

We or the NIH may be subject to claims that former employees, collaborators or other third parties have an interest in the licensed patents or other intellectual property as an inventor or co-inventor. For example, we or the NIH may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing the intellectual property covered by the NIH license or our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our license or the NIH's ownership, as applicable, of the licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as our right to use intellectual property that is important to our Terra CoV-2 vaccine product candidate. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in patent law or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

The United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, recent United States Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. Moreover, patent law and protection in foreign countries, particularly developing countries, may be insufficient or otherwise unclear in its efficacy to protect our intellectual property. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the scope and value of patents, once obtained.

For our U.S. patent applications containing a priority claim after March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, also known as the America Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is currently developing regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact(s) the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have an adverse effect on our business. One important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party who files a patent application with the USPTO after such date but prior to us may therefore be awarded a patent covering an invention of ours even if we were the first to invent. This "first-inventor-to-file" system will require us both to remain cognizant, going forward, of the timing between invention and filing of a patent application.

Among some of the other changes introduced by the AIA are those that (i) limit where a patentee may file a patent infringement suit and (ii) provide opportunities for third parties to challenge any issued patent in the USPTO. Such changes apply to all of our U.S. patents, even those issued prior to March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings, as compared to the evidentiary standard applied in U.S. federal courts, necessary to invalidate a patent claim, a third party could potentially present evidence in a USPTO proceeding sufficient for the USPTO to find a claim invalid, notwithstanding that the same evidence would be insufficient to invalidate a claim first presented in a district court action. Accordingly, a third party may attempt opportunistically to use USPTO procedures to invalidate our patent claims.

Depending on decisions by the United States Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' abilities to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

If we are unable to protect our trademarks or other intellectual property from infringement, our business prospects may be harmed.

We have applied for trademark protection for trademarks in the United States, the European Union and China. Although we take steps to monitor the possible infringement or misuse of our trademarks, it is possible that third parties may infringe, dilute or otherwise violate our trademark rights. Any unauthorized use of our trademarks or other intellectual property rights could harm our reputation or commercial interests. Moreover, our license with the NIH and NIAID, the NIAID does not commit to defend any declaratory judgment action alleging the invalidity of any of the licensed patent rights covered by the license, nor does the NIAID commit to commence legal actions against third parties alleged to infringe upon those licensed patent rights. Our enforcement against third-party infringers or violators may be unduly expensive and time-consuming, and any remedy obtained may constitute insufficient redress relative to the damages we may suffer.

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

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection insufficient to guard against such infringement. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals. In such instances, we may be unable to enjoin or otherwise prevent infringement of our patents or marketing of competing products in violation of our proprietary rights, generally. Proceedings to enforce our patent rights in foreign jurisdictions could (i) result in substantial costs and divert our efforts and attention from other aspects of our business, (ii) put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and (iii) provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may be unable to seek adequate remedies to address infringement and/or material diminishment of the value of our patents, which could limit our potential revenue opportunities in such jurisdictions. Accordingly, our efforts to establish or enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

If we fail to comply with our obligations under our intellectual property license agreements, we could lose our license rights that are important to our business and development of our product candidates.

In addition to our intellectual property and biological materials license with the NIH, we are a party to an exclusive channel collaboration agreement that impose various royalty and other obligations on us. If we fail to comply with these obligations, our collaboration partners may have the right to terminate the license, in which event we may not be able to develop or market the affected product candidate. Both the NIH license and the Lantibiotic ECC may be terminated in the event of a breach. The loss of such rights could materially adversely affect our business, financial condition, operating results and prospects.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time-consuming and an unfavorable outcome in that litigation could have a material adverse effect on our business.

Our commercial success depends upon our ability to develop, manufacture, market, and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We cannot guarantee that marketing and selling such candidates and using such technologies will not infringe existing or future patents. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents issue, the risk increases that others may assert that our product candidates, technologies or methods of delivery or use infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents cover various drugs, biologics, drug delivery systems or their methods of use, and which of these patents may be valid and enforceable. Thus, due to the large number of patents issued and patent applications filed in our fields, third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

In addition, our product candidates or proprietary technologies may infringe patents owned and/or filed by third parties, or third parties may allege such infringement. Because (i) some patent applications in the United States may be maintained in secrecy until the patents are issued, (ii) patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing and (iii) publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our own and in-licensed issued patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to ours. Any such patent application may have priority over our own and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate, in the United States, in an interference proceeding to determine priority of invention.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates or proprietary technologies infringe such third parties' intellectual property rights, including litigation resulting from filing under Paragraph IV of the Hatch-Waxman Act. Such lawsuits can be costly and could adversely affect our operating results and divert the attention of managerial and technical personnel, even if we do not infringe such patents or the patents asserted against us are later invalidated. A court may, however, decide that we are infringing the third party's patents and order us to cease the activities covered by the patents. In addition, there is a risk that a court will order us to pay to such third-party damages for having violated the other party's patents.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek licenses from third parties. These licenses may not be available on commercially acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property, or such rights might be restrictive and limit our present and future activities. Ultimately, we or a licensee could be prevented from commercializing a product, or forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

In addition to possible infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation, re-examination or other post-grant proceedings declared or granted by the USPTO, and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, generally. To date, no litigation asserting infringement claims has ever been brought against us. If a third-party claim that we infringe its intellectual property rights, we may face a number of issues, including:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;

- substantial damages for infringement, which we may have to pay if a court decides that the product or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;

- a court prohibiting us from selling or licensing the product or using the technology unless the third party licenses its intellectual property rights to us, which it is not required to do;

- if a license is available from a third party, we may have to pay substantial royalties or upfront fees or grant cross-licenses to intellectual property rights for our products or technologies; and

- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could harm our ability to raise additional funds or otherwise adversely affect our business, financial condition, operating results and prospects.

Because we rely on certain third-party licensors and partners, and will continue to do so in the future, if one of our licensors or partners is sued for infringing a third party's intellectual property rights, our business, financial condition, operating results and prospects could suffer in the same manner as if we were sued directly. In addition to facing litigation risks, we have agreed to indemnify certain third-party licensors and partners against claims of infringement caused by our proprietary technologies, and we have entered or may enter into cost-sharing agreements with some our licensors and partners that could require us to pay some of the costs of patent litigation brought against those third parties whether or not the alleged infringement is caused by our proprietary technologies. In certain instances, these cost-sharing agreements could also require us to assume greater responsibility for infringement damages than our technology alone would otherwise suggest.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time-consuming.

Competitors may infringe our intellectual property, including our patent applications or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. Such proceedings and/or litigation can be expensive – particularly for a company of our size – and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to enjoin the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction are not satisfied. An adverse determination in such case could put one or more of our patents at risk of being invalidated, interpreted narrowly or amended such that they fail to cover or otherwise protect our product candidates. Moreover, such adverse determinations could subject our patent applications to the risk that they will not issue, or issue with limited and potentially inadequate scope to cover our product candidates.

Interference, derivation or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or potential partners. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful, domestic or foreign litigation, or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential partners, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that we may, intentionally or incidentally, disclose some of our confidential results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

Our success will depend on our ability to partner or sub-license our product candidates and their subsequent successful commercialization.

Our MU1140 homologs product candidate and vaccine candidate are in early-stage development and is expected to require partners with substantial financial resources to continue the development of the product to commercialization. In addition, these product candidates have not received regulatory approval in any jurisdiction and they may never receive approval or, if approvals are obtained, may never be commercialized successfully. In addition, we do not know whether any of our clinical trials will be successful or can be completed within our current expected budget. For our MU1140 homologs and other antibiotic product candidates, we have performed nonclinical testing using native MU1140 and expect to continue to pursue the nonclinical testing of our MU1140 homologs and other antibiotic product candidates during 2021 we would expect the IND for a first-in-human clinical trial of OG716 to be filed with the FDA based on our ability to complete the requisite studies, contingent on sufficient funding. Even if we are able to partner and conduct successful clinical trials or the required regulatory approvals are obtained, we may never be able to generate significant revenues from our MU1140 homologs or other antibiotic product candidates or other product candidates. If our MU1140 homologs product candidate or our other product candidates under the Lantibiotics Program or our vaccine development are unsuccessful, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, financial condition and results of operations will be materially adversely affected.

If our intellectual property rights do not adequately protect our products or product candidates, or if third parties claim we are infringing their intellectual property rights, others could compete against us more directly or we could be subject to significant litigation. Such results could prevent us from marketing our products or product candidates and hurt our profitability.

Our product and product candidates are protected by patents and patent applications. Our success depends in part on our ability to obtain patents or rights to patents, protect trade secrets, operate without infringing upon the proprietary rights of others, and prevent others from infringing on our patents, trademarks and other intellectual property rights. We will be able to protect our intellectual property from unauthorized use by third parties only to the extent that it is covered by valid and enforceable patents, trademarks and licenses. Patent protection generally involves complex legal and factual questions and, therefore, enforceability of patent rights cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from others may not provide adequate protection against competitors. In addition, any future patent applications may fail to result in patents being issued. Also, those patents that are issued may not provide us with adequate proprietary protection or competitive advantages against competitors with similar product candidates. Moreover, the laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States.

In addition to patents and trademarks, we rely on trade secrets and proprietary know-how. We seek protection of these rights, in part, through confidentiality and proprietary information agreements. These agreements may not provide meaningful protection or adequate remedies for violation of our rights in the event of unauthorized use or disclosure of confidential and proprietary information. Failure to protect our proprietary rights could seriously impair our competitive position.

In the event of an infringement or violation, we may face litigation and may be prevented from pursuing product development or commercialization. We may receive in the future, notice of claims of infringement of other parties' proprietary rights. We may not have the financial resources to defend against claims of infringement by other parties or to prosecute third parties for infringement of our intellectual property. Infringement or other claims could be asserted or prosecuted against us in the future and it is possible that past or future assertions or prosecutions could harm our business.

Our business and operations would suffer in the event of cybersecurity/information systems risk.

Despite the implementation of security measures, our internal computer systems, and those of our manufacturers and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, ransomware, unauthorized access, natural disasters, fire, explosions or large-scale accidents, power outages or surges, terrorism, successful breaches, employee malfeasance, or human or technological error, war and telecommunication and electrical failures. In addition, our systems safeguard important confidential personal data regarding our subjects. If a disruption event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

We may incur costs of addressing a cybersecurity incident.

Cybersecurity incidents have increased in number and severity recently and it is expected that these trends will continue. Should we be affected by such an incident, we may incur substantial costs and suffer other negative consequences, which may include:

- investigation costs and costs to engage specialized consultants;
- remediation costs, such as liability for stolen assets or information, repairs of system damage, and incentives to customers or business partners in an effort to maintain relationships after an attack; and
- litigation and legal risks, including regulatory actions by state and federal regulators.

Our business and operations would suffer in the event of failures in our internal computer systems or those of our collaborators.

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

Risks Related to Government Regulations

Our product candidates are subject to substantial government regulation, including the regulation of nonclinical testing and clinical trials. If we are unable to obtain regulatory approval for our product candidates, we will be unable to generate revenues.

The production and marketing of products which may be developed from our Terra CoV-2 vaccine product candidate, and our MU1140 homologs, or otherwise and our research and development, nonclinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities. Most of the product candidates we are developing must undergo rigorous nonclinical testing and clinical trials and an extensive regulatory approval process before they can be marketed in the United States or internationally.

If we fail to obtain regulatory approval for our product candidates, we may have to cease further development. Clinical trials on our product candidates are expected to take several years to fully complete. The commencement or completion of nonclinical studies or clinical trials can be delayed or prevented for a number of reasons, including:

- limitations directly caused by, or restrictions imposed in response to, the COVID-19 pandemic, including our ability to conduct research and development and clinical trials, to engage or continue to engage with third-party contractors and suppliers or to comply with regulatory obligations relating to our business;
- an inability to raise sufficient capital to commence, conduct, or complete clinical trials;
- difficulties in finding a partner with the resources to support large and expensive clinical development and commercialization costs;

- findings in nonclinical trials;
- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;
- difficulties obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;
- challenges recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including the size and nature of patient population, proximity of patients to clinical sites, eligibility criteria for the trial, nature of the trial protocol, the availability of approved effective treatments for the relevant condition and competition from other clinical trial programs for similar indications;
- severe or unexpected drug or biologic-related side effects experienced by patients in a clinical trial; and
- difficulties retaining patients who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the trial, lack of efficacy, side effects, or personal issues, or who are lost to further follow up.

Clinical trials also may be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a trial, or a data safety monitoring board, or DSMB, overseeing the clinical trial at issue, or other regulatory authorities 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 sites by the FDA or other regulatory authorities;
- inspection of manufacturing and drug packaging operations by regulatory authorities;
- unforeseen safety issues or lack of effectiveness; and
- lack of adequate funding to continue the clinical trial.

We cannot assure you that clinical trials will demonstrate the safety or effectiveness of any of our product candidates, or will otherwise satisfy regulatory requirements. Our nonclinical studies or clinical trials may produce negative or inconclusive results, there may be inconsistencies between early clinical trial results and results obtained in later clinical trials, and we may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical studies and clinical trials have nonetheless failed to obtain FDA approval for their products. If we are unable to resolve the FDA's concerns, we will not be able to obtain regulatory approval for these product candidates.

The pre-marketing approval process can be particularly expensive, uncertain and lengthy, and a number of products for which FDA or other governmental regulatory approval has been sought by other companies have never been approved for marketing. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling, and record-keeping procedures. If we do not comply with applicable regulatory requirements, such violations could result in warning letters, non-approval, suspensions of regulatory approvals or ongoing clinical trials, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

We may encounter such delays and rejection of our product candidates by the FDA or other regulatory authority may also adversely affect our business. Such delays or rejection may be encountered due to, among other reasons, government or regulatory delays, lack of efficacy during clinical trials, unforeseen safety issues, or changes in regulatory policy during the period of product development. More stringent regulatory approval processes in product clearance and enforcement activities could result in our experiencing longer approval cycles, more uncertainty, greater risk, and higher expenses. Even if regulatory approval of a product is granted, this approval may entail limitations on uses for which the product may be labeled and promoted. It is possible, for example, that we may not receive FDA approval to market products based on our licensed, patented product candidates for different indications or to market updated products that represent extensions of our basic product candidates. In addition, we may not receive FDA approval to export our products based on our licensed, patented product candidates in the future, and countries to which products are to be exported may not approve them for import.

From time to time, legislative or regulatory proposals are introduced that could alter the review and approval process relating to our product candidates. It is possible that the applicable regulatory authority will issue additional regulations further restricting the sale of our product candidates. Any change in legislation or regulations that govern the review and approval process relating to our future product candidates could make it more difficult and costlier to obtain approval for new products based on our product candidates, or to produce, market, and distribute such products if approved.

We may be unable to obtain regulatory approval for our SARS-CoV-2 vaccine product candidate, or other early-stage product candidates under applicable regulatory requirements. The FDA and foreign regulatory bodies have substantial discretion in the approval process, including the ability to delay, limit or deny approval of product candidates. The delay, limitation or denial of any regulatory approval would adversely impact commercialization, our potential to generate revenue, our business and our operating results.

We are not permitted to market any of our current product candidates in the United States until we receive approval of an NDA or BLA from the FDA. We are also not permitted to market any of our current product candidates in any foreign countries until we receive the requisite approval from the applicable regulatory authorities of such countries. Failure to obtain such regulatory approvals will delay or prevent us from commercializing any of our current or future product candidates.

To gain approval to market a new drug such as OG716, or a new biological product such as our SARS-CoV-2 vaccine product candidate or AG013, we must provide the FDA and/or foreign regulatory authorities with, among other things, extensive preclinical and clinical data that adequately demonstrates the safety and efficacy of the drug in its intended indication and information to demonstrate the adequacy of the manufacturing methods to assure the drug's identity, strength, quality and purity. The development and approval of new drug product candidates involves a long, expensive and uncertain process, and delay or failure can occur at any stage. A number of companies in the pharmaceutical and biopharmaceutical industries have suffered significant setbacks in clinical trials, including in Phase 3 clinical development, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, observations during clinical trials regarding safety or efficacy, such as previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure success in later clinical trials, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct. Further, different results may be achieved depending upon whether the "per protocol", or PP, analysis is used to report data results or whether the "modified intent-to-treat," or MITT, approach is used. Accordingly, regardless of the outcome of any Phase 2 trials, our Phase 3 trials may not be successful.

The FDA and foreign regulatory bodies have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of product candidates for many reasons. The FDA or the applicable foreign regulatory body may:

- disagree with the design or implementation of one or more clinical trials;
- decline to deem a product candidate safe and effective for its proposed indication, or deem a product candidate's safety or other perceived risks to outweigh its clinical or other benefits.
- find the data from preclinical studies and clinical trials does not sufficiently support approval, or the results of clinical trials may not meet the level of statistical or clinical significance required for approval;
- disagree with our interpretation of data from preclinical studies or clinical trials performed by us or third parties;
- determine the data collected from clinical trials are insufficient to support the submission or approval of an NDA or other applicable regulatory filing.
- require additional preclinical studies or clinical trials;

- identify deficiencies in the formulation, quality control, labeling or specifications of our current or future product candidates;
- grant approval contingent on the performance of costly additional post-approval clinical trials;
- approve our current or any future product candidates for a more limited indication or a narrower patient population than we originally requested or with strong warnings that may affect marketability;
- decline to approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates;
- require a Risk Evaluation and Mitigation Strategy, or REMS, with monitoring requirements or distribution limitations. For example, it is possible that the FDA could require distribution controls in the approval, if any, of our product candidates to prevent inadvertent exposure to pregnant women;
- decline to approve of the manufacturing processes, controls or facilities of third-party manufacturers or testing labs with whom we contract; or
- change its approval policies or adopt new regulations in a manner rendering our clinical data or regulatory filings insufficient for approval.

Any delay, limitation or denial of any regulatory approval would adversely impact commercialization, our potential to generate revenue, our business and our operating results.

Delays or difficulties in the enrollment of patients in clinical trials may result in additional costs and delays in our ability to generate significant revenues, and may delay or prevent our receipt of any regulatory approvals necessary to commercialize our planned and future products.

We may not be able to initiate or continue, or complete in a timely fashion clinical trials for Terra CoV-2 or our other product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Many companies are currently or will soon be researching, developing and testing therapeutic and vaccine product candidates specifically for or with potential application to SARS-CoV-2 or COVID-19, which may reduce our ability to conduct clinical trials for our SARS-CoV-2 vaccine product candidate. For example, even if we are able to identify potential patients or eligibility criteria for a Terra CoV-2 clinical trial, patients who are otherwise eligible for such clinical trials may instead enroll in the clinical trials of our competitors' SARS-CoV-2 product candidates or opt not to enroll due to other competitive vaccines being administered by competitors based upon emergency use authorization.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and impede our ability to obtain additional financing.

Any product candidates that we commercialize will be subject to ongoing and continued regulatory review.

Even after we achieve U.S. regulatory approval for a product candidate, if any, we will be subject to continued regulatory review and compliance obligations. For example, the FDA may impose significant restrictions on the approved indicated uses for which our product candidates may be marketed or on the conditions of approval. A product candidate's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials or a REMS to monitor the safety and efficacy of the product. We will also be subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our product candidates. These requirements include submissions of safety and other post-marketing information and reports, registration, continued compliance with the FDA's good clinical practice, or GCP, requirements and good laboratory practice requirements, which are regulations and guidelines the FDA would apply to all of our product candidates in clinical and preclinical development, along with any clinical trials that we conduct post-approval, and continued compliance with the FDA's cGMP requirements pursuant to which manufacturing facilities are subject to continual review and periodic inspections by the FDA. To the extent that a product candidate is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the marketing or manufacturing of the product, suspend or withdraw product approvals or revoke necessary licenses;
- issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance; commence criminal investigations and prosecutions;
- impose injunctions;
- impose other civil or criminal penalties;
- suspend any ongoing clinical trials;
- delay or refuse to approve pending applications or supplements to approved applications filed by us;
- refuse to permit drugs or active ingredients to be imported or exported to or from the United States;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us to initiate a product recall.

The regulations, policies or guidance of the FDA and other applicable government agencies may change and new or additional statutes or government regulations may prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our product candidates, which would materially and adversely affect our ability to generate revenue and achieve or maintain profitability.

Our product candidates may cause serious or undesirable side effects or possess other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of approved labeling or result in post-approval regulatory action.

Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after marketing such product. Undesirable side effects caused by product candidates could cause us or regulatory authorities to interrupt, modify, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities. Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may harm our business, financial condition, operating results and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our product candidates after obtaining U.S. or foreign regulatory approval or other products with the same or related active ingredients, a number of potentially negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require a recall of the product or we may voluntarily recall a product;
- regulatory authorities may require the addition of warnings or contraindications in the product labeling, narrowing of the indication in the product label or issuance of field alerts to physicians and pharmacies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or institute a REMS;
- we may be subject to limitations as to how we promote the product;
- we may be required to change the way the product is administered or modify the product in some other way;
- the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- sales of the product may decrease significantly;
- we could be sued and held liable for harm caused to patients; and
- our brand and reputation may suffer.

Any of the above events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

If any of our product candidates are approved for marketing and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed.

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted off-label uses of any of our product candidates, we may receive warning or untitled letters and become subject to significant liability, which would materially harm our business. Both federal and state governments have levied large civil and criminal fines against companies for alleged improper promotion and have enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred and our brand and reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they determine our business activities constitute promotion of an off-label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations.

We cannot, however, prevent a physician from using our product candidates in ways that fall outside the scope of the approved indications, as he or she may deem appropriate in his or her medical judgment. Physicians may also misuse our product candidates or use improper techniques, which may lead to adverse results, side effects or injury and, potentially, subsequent product liability claims. Furthermore, the use of our product candidates for indications other than those cleared by the FDA and/or other regulatory agencies may not effectively treat such conditions, which could harm our brand and reputation among both physicians and patients.

We may also be subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we conduct our business. The laws and regulations that may affect our ability to operate include:

- the federal healthcare program anti-kickback statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual or in return for the purchase, lease, or order of any good, facility item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, including, for example, the United States False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA, which prohibits knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (i.e., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA and related implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act, or ACA, which require manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members, with such information published on a searchable website on an annual basis; 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 payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be provided to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the recently enacted ACA, among other things, amended the intent requirement of the federal anti-kickback statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, 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 our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment or the curtailment or restructuring of our operations, any of which could materially and adversely affect our ability to operate our business and our financial results.

Our employees, independent contractors, principal investigators, consultants, vendors and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors and CROs may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless or negligent conduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions or other actions or lawsuits stemming from a failure to comply with such laws or regulations, and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. If any such actions are instituted against us, we may have to terminate employees or others involved and the impact of such termination can result in our experiencing delays and additional costs associated with replacing the services being provided. If we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, FDA debarment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our operating results.

Even if our current product candidates or any future product candidates obtain regulatory approval, they may fail to achieve the broad degree of health care payers, physician and patient adoption and use necessary for commercial success.

The commercial success of any of our current or future product candidates, if approved, will depend significantly on the broad adoption and use of the resulting product by health care payers, physicians and patients for approved indications, and may not be commercially successful. The degree and rate of physician and patient adoption of our current or future product candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the effectiveness of our product as compared to other available therapies;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors for any of our product candidates that may be approved;
- the cost of treatment with our product candidates in relation to alternative treatments and willingness to pay for the product, if approved, on the part of patients;

- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- proper training and administration of our product candidates by physicians and medical staff;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience;
- the willingness of patients to pay for certain of our product candidates relative to other discretionary items, especially during economically challenging times;
- the revenue and profitability that our product candidate may offer a physician as compared to alternative therapies;
- the prevalence and severity of side effects;
- limitations or warnings contained in the FDA-approved labeling for our product candidates;
- any FDA requirement to undertake a REMS;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our product candidates or favorable publicity about competitive products; and
- potential product liability claims.

If any of our current or future product candidates are approved for use but fail to achieve the broad degree of physician and patient adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our operations.

If we are unable to achieve and maintain coverage and adequate levels of reimbursement for any of our product candidates for which we receive regulatory approval, or any future products we may seek to commercialize, their commercial success may be severely hindered.

As to any of our product candidates that become available by prescription only, our success will depend on the availability of coverage and adequate reimbursement for our product from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private third-party payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If any of our product candidates fail to demonstrate attractive efficacy profiles, they may not qualify for coverage and reimbursement. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our prescription-only products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for certain of our product candidates will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or another alternative is available.

Moreover, third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, although private third-party payors tend to follow Medicare, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions in both the United States and in international markets. Third-party coverage and reimbursement for any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could harm our business, financial condition, operating results and prospects.

If our products do not receive favorable third-party reimbursement, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not generate significant revenues.

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our proposed formulations and products and related treatments are obtained by governmental authorities, private health insurers and other organizations, such as Health Maintenance Organizations, or HMOs. Reimbursement from third parties depends greatly on our ability to present data which demonstrate positive outcomes and reduced utilization of other products or services as well as cost data which show that treatment costs using the new product are equal to or less than what is currently covered for other products. If our products do not receive favorable third-party reimbursement and patients are unwilling or unable to pay for our products out-of-pocket, it could limit our revenues and harm our business.

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, recent federal and state government initiatives have been directed at lowering the total cost of health care. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, 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. Federal and state legislatures will likely continue to focus on health care reform, controlling the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

Risks Related to Coronavirus Disease (COVID-19)

Our business is subject to risks arising from public health crises, epidemic or pandemic diseases, such as the recent global outbreak of the coronavirus disease (COVID-19).

Our business operations expose us to risks associated with public health crises, epidemics and pandemics. An epidemic or pandemic disease outbreak, including the recent COVID-19 outbreak, could cause significant disruption to our business operations or the operations of our third-party manufacturers and CROs upon whom we rely, as well as to our clinical trials, including as a result of significant restrictions or bans on travel into and within the countries in which our manufacturers produce our product candidates or where we conduct our clinical trials. Such disruption could impede, delay, limit or prevent our employees and CROs from continuing research and development activities, the production, delivery or release of our product candidates to our clinical trial sites, as well as clinical trial investigators, patients or other critical staff from traveling to or otherwise continuing to participate in our clinical trials, and delay data collection and analysis and other related activities, any of which could impede, delay, limit or prevent completion of our ongoing clinical trials and preclinical studies or commencement of new clinical trials, and ultimately lead to the delay or denial of regulatory approval of our product candidates, which would seriously harm our operations and financial condition and increase our costs and expenses.

The COVID-19 outbreak could also potentially affect the business of the FDA, EMA or other health authorities, which could result in delays in meetings related to planned or completed clinical trials and ultimately of reviews and approvals of our product candidates. The COVID-19 outbreak and mitigation measures also have had and may continue to have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 outbreak impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact. The severity of the coronavirus disease could also make access to our existing supply chain difficult or impossible and could materially impact our business. Any one or a combination of the aforementioned events could have an adverse effect on our business.

Our ability to conduct clinical trials may be impeded, delayed, limited or prevented entirely due to the spread of COVID-19, the imposition of government restrictions and the concurrent disruptions to ordinary business activities globally.

As the U.S. and foreign governments and nongovernmental organizations continue to respond to the COVID-19 public health crisis, our ability to conduct clinical trials may impeded, delayed, limited or prevented entirely by a number of factors, including, but not limited to, the following:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 coronavirus outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

The global outbreak of the COVID-19 coronavirus continues to rapidly evolve. The extent to which the COVID-19 coronavirus may impact our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread and density of the disease, the duration of the outbreak, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

Our business involves international components, and we are exposed to various global and local risks related to the coronavirus disease 2019 (COVID-19) that could have a material adverse effect on our financial condition and results of operations.

Our business may involve international components such as clinical trial enrollment. Consequently, we may be exposed to, or our third-party contractors, suppliers or manufacturers may be exposed to, certain global events beyond our control, including war, public health crises, epidemics, pandemics, trade disputes, geopolitical conflicts and other international events, including, for example, the global impact of COVID-19 and the various responses taken by foreign authorities, such as government-imposed quarantines and other public health safety measures.

The extent to which the coronavirus impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. Moreover, the coronavirus outbreak has indeterminable adverse effects on general commercial activity and the world economy, and our business and results of operations could be adversely affected to the extent that this coronavirus or any other epidemic harms the global economy generally. The international components of our business may be directly subject to, and the domestic components may be indirectly impacted by, a variety of risks, including:

- foreign currency exchange rate fluctuations;
- greater difficulty in staffing and managing foreign operations;
- greater risk of uncollectible accounts;
- longer collection cycles;
- logistical and communications challenges;
- potential adverse changes in laws and regulatory practices, including export license requirements, trade barriers, tariffs and tax laws;
- changes in labor conditions;
- burdens and costs of compliance with a variety of foreign laws;
- political and economic instability;
- increases in duties and taxation;
- foreign tax laws and potential increased costs associated with overlapping tax structures;
- greater difficulty in protecting intellectual property;
- the risk of third-party disputes over ownership of intellectual property and infringement of third-party intellectual property by our products; and
- general economic and political conditions in these foreign markets.

International markets are also affected by economic pressure to contain reimbursement levels and healthcare costs. Profitability from international operations may be limited by risks and uncertainties related to regional economic conditions, regulatory and reimbursement approvals, competing products, infrastructure development, intellectual property rights protection and our ability to implement our overall business strategy. We expect these risks will increase as we pursue our strategy to expand operations into new geographic markets. We may not succeed in developing and implementing effective policies and strategies in each location where we conduct business. Any failure to do so may harm our business, results of operations and financial condition.

Macroeconomic pressures in the markets in which we operate, including, but not limited to, the effectives of the coronavirus disease (COVID-19) may alter the ways in which we conduct our business operations and manage our financial capacities.

To varying degrees, the ways in which we conduct our business operations and manage our financial capacities are influenced by macroeconomic conditions that affect companies directly involved in or providing services related to the drug and biological product development. For example, real GDP growth, business and investor confidence, the COVID-19 pandemic, inflation, employment levels, oil prices, interest rates, tax rates, availability of consumer and business financing, housing market conditions, foreign currency exchange rate fluctuations, costs for items such as fuel and food and other macroeconomic trends can adversely affect not only our decisions and ability to engage in research and development and clinical trials, but also those of our management, employees, third-party contractors, manufacturers and suppliers, competitors, shareholders and regulatory authorities. In addition, geopolitical issues around the world and how our markets are positioned can also impact the macroeconomic conditions and could have a material adverse impact on our financial results.

Economic uncertainty may adversely affect our access to capital, cost of capital and ability to execute our business plan as scheduled.

Generally, worldwide economic conditions remain uncertain. Access to capital markets is critical to our ability to operate. Traditionally, biotechnology companies have funded their research and development expenditures through raising capital in the equity markets. Declines and uncertainties in these markets in the past have severely restricted raising new capital and have affected companies' ability to continue to expand or fund existing research and development efforts. We require significant capital for research and development for our vaccine candidates and clinical trials. The general economic and capital market conditions, both in the U.S. and worldwide, have been volatile in the past and at times have adversely affected our access to capital and increased the cost of capital. There is no certainty that the capital and credit markets will be available to raise additional capital on favorable terms. If economic conditions become worse, our future cost of equity or debt capital and access to the capital markets could be adversely affected. In addition, if we are unable to access the capital markets on favorable terms, our ability to execute our business plan as scheduled would be compromised. Moreover, we rely and intend to rely on third-parties, including clinical research organizations, contract manufacturing organizations and other important vendors and consultants. Global economic conditions may result in a disruption or delay in the performance of our third-party contractors and suppliers. If such third-parties are unable to adequately satisfy their contractual commitments to us in a timely manner, our business could be adversely affected.

Inadequate funding for the FDA, the SEC and other government agencies in light of the coronavirus pandemic 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 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 products 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 agency 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 to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, 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. Moreover, at this time, we cannot predict the extent to which the COVID-19 pandemic outbreak will impact the resources of such government agencies, including, in particular, the public health resources available to the FDA. 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.

Risks Related to Our Common Stock

The issuance of additional equity securities by us in the future would result in dilution to our existing common shareholders.

Our board of directors has authority, without action or vote of our shareholders, to issue all or a part of our authorized but unissued shares, except where shareholder approval is required by law. Any issuance of additional equity securities by us in the future could result in dilution to our existing common shareholders. Such issuances could be made at a price that reflects a discount or a premium to the then-current trading price of our common stock. In addition, our business strategy may include expansion through internal growth by acquiring complementary businesses, acquiring or licensing additional products or brands, or establishing strategic relationships with targeted customers and suppliers. In order to do so, or to finance the cost of our other activities, we may issue additional equity securities that could result in further dilution to our existing common shareholders. These issuances would dilute the percentage ownership interest of our existing common shareholders, which would have the effect of reducing their influence on matters on which our shareholders vote, and might dilute the book value of our common stock. For example, we issued 16,666,668 shares of common stock, short-term warrants to purchase up to 9,583,334 shares of common stock, and long-term warrants to purchase up to 9,583,334 shares of common stock, as part of our March 25, 2019 underwritten public offering. In November and December of 2020, we issued 16,317,567 and 14,444,444 shares of common stock, respectively, in connection with an underwritten public offering and a registered direct offering. In connection with an at-the-market sale of shares of our common stock between February 2 and February 11, 2021 we issued an additional 15,406,618 shares of our common stock and issued 2,472,573 shares pursuant to warrant exercises. As a result, our outstanding shares of common stock has increased significantly from 29,433,135 shares as of December 31, 2018 to 91,766,928 shares as of December 31, 2020 and 109,646,119 as of February 25, 2021.

Our financial results could vary significantly from quarter to quarter and are difficult to predict.

Our operating results could vary significantly from quarter to quarter due to a variety of factors, many of which are outside of our control. As a result, comparing our operating results on a period-to-period basis may not be meaningful. In addition, we may not be able to predict our future revenues or results of operations. We base our current and future expense levels on our internal operating plans and sales forecasts, and our operating costs vary to the extent of our research and development and the candidate of clinical trials. As a result, we may incur significant or unanticipated expenses associated with our research and development efforts of our product candidates under development. In addition to other risk factors discussed in this section, factors that may contribute to the variability of our quarterly results include:

- the timing of release of pre-clinical and clinical trial results and new products and services by our competitors, particularly those that may represent a significant portion of revenues in any given period;
- the popularity of new vaccine products, and products released in prior periods;
- changes in pricing policies by us or our competitors;
- our success in entering new geographic markets;
- decisions by us to incur additional expenses, such as commencing a clinical trial or increases in research and development or cessation of development of any of our product candidates under development;
- the level of expenses associated with our regulatory applications or compliance and clinical trials; and
- the timing of compensation expense associated with equity compensation grants.

As a result of these and other factors, our quarterly and annual operating results could be materially adversely affected. Moreover, our operating results may not meet the expectations of research analysts or investors, in which case the price of our common stock could decrease significantly.

Our Series A and Series B preferred stock, if not converted into common stock, has a distribution and liquidation preference senior to our common stock in liquidation which could negatively affect the value of our common stock and impair our ability to raise additional capital.

On February 11, 2021, we provided a redemption notice to the holder of all our outstanding shares of our Series C Preferred Stock. Shares of our Series C Preferred Stock will be redeemed on March 13, 2021 and no longer be outstanding.

Our Series A and Series B Preferred Stock, if not converted into Common Stock, have distribution and liquidation preferences senior to our common stock.

On November 8, 2017, we issued $3.3 million of Series B Non-Voting, Convertible Preferred Stock (the "Series B Preferred Stock") pursuant to which upon Liquidation each holder of shares of Series B Preferred Stock shall be entitled to receive, after payment to the Series C Preferred Stock, but on par with Series A Convertible Preferred Stock and in preference to the holders of Common Stock, an amount of cash equal to the greater of (i) the product of the number of shares of Series B Preferred Stock then held by such holder, multiplied by the Series B Original Issue Price; and (ii) the amount that would be payable to such holder in the Liquidation in respect of Common Stock issuable upon conversion of such shares of Series B Preferred Stock if all outstanding shares of Series B Preferred Stock were converted into Common Stock immediately prior to the Liquidation.

In May and July of 2017, we issued an aggregate of $3.0 million of Series A Non-Voting, Convertible Preferred Stock (the "Series A Preferred Stock") pursuant to which upon Liquidation each holder of shares of Series A Preferred Stock shall be entitled to receive, after payment to the Series C Preferred Stock, but on par with Series B Convertible Preferred Stock and in preference to the holders of Common Stock, an amount of cash equal to the greater of (i) the product of the number of shares of Series A Preferred Stock then held by such holder, multiplied by the Series B Original Issue Price; and (ii) the amount that would be payable to such holder in the Liquidation in respect of Common Stock issuable upon conversion of such shares of Series A Preferred Stock if all outstanding shares of Series A Preferred Stock were converted into Common Stock immediately prior to the Liquidation.

As such, our Series C preferred stock is senior to all other classes of stock in distribution and liquidation and our Series A and Series B preferred stock, if not converted into common stock, will also be senior to our common stock in distribution and liquidation if such shares are not converted into common stock, which could negatively affect the value of our common stock and impair our ability to raise additional capital.

The conversion of our Series A Preferred Stock, and Series B Preferred Stock and the exercise of currently outstanding warrants could result in significant dilution to the holders of our common stock.

The holders of our Series A Preferred Stock and Series B Preferred Stock may convert their shares of preferred stock into shares of common stock. As of December 31, 2020, we had outstanding: (i) 9,417,000 shares of Series A Preferred Stock outstanding, which are convertible into 941,701 shares of common stock and (ii) 6,600,000 shares of Series B Preferred Stock, which are convertible into 1,320,002 shares of common stock. In addition to our outstanding shares of preferred stock, as of December 31, 2020, there were currently outstanding warrants to purchase 20,513,145 shares of our common stock. The conversion of our Series A Preferred Stock and Series B Preferred Stock, as well as the exercise of our outstanding warrants could result in significant dilution to existing common shareholders, adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities.

Our stockholders may not realize a benefit from our acquisition of Noachis Terra commensurate with the ownership dilution experienced in connection with the acquisition.

In May 2020, in connection with our acquisition of Noachis Terra, the former sole shareholder received the following: (i) cash consideration of approximately $1,925,000; (ii) 9,200,000 restricted shares of the Company's common stock; and (iii) warrants to purchase 9,200,000 shares of the Company's common stock, which warrants and may not be exercised until May 1, 2021. In addition to the above consideration, the former sole shareholder also received the right to receive contingent consideration based upon the exercise of certain of the Company's outstanding warrants.

Certain provisions of our articles of incorporation, bylaws, executive employment agreements and stock option plan may prevent a change of control of our company that a shareholder may consider favorable.

Provisions of our articles of incorporation, bylaws, executive employment agreements and stock option plan may discourage, delay or prevent a change of control of our company that a shareholder may consider favorable. These provisions include:

- authorization of the issuance of "blank check" preferred stock that could be issued by our Board of Directors without shareholder approval and that may be substantially dilutive or contain preferences or rights objectionable to an acquirer;
- the ability of our Board of Directors to amend the bylaws without shareholder approval;
- vacancies on our Board may only be filled by the remaining directors and not our shareholders;
- requirements that only our Board, our President or holders of more than 10% of our shares can call a special meeting of shareholders;
- obligations to make certain payments under executive employment agreements in the event of a change of control and termination of employment; and
- immediate vesting of all outstanding stock options.

As a result, these provisions could discourage bids for our common stock at a premium and limit the price that investors are willing to pay in the future for shares of our common stock. However, in our articles of incorporation we expressly elected not to be governed by Sections 607.0901 and 607.0902 of the Florida Business Corporation Act, which are statutory anti-takeover provisions relating to affiliated transactions and control share acquisitions, respectively. As such, we do not have the protection of these statutes in connection with any unwanted takeover attempts which could have the effect of encouraging an attempted change of control without first negotiating with our Board of Directors.

The price and volume of our common stock has been volatile and fluctuates substantially, which could result in substantial losses for stockholders.

The trading price of our common stock has historically been, and may in the future be, subject to wide fluctuations in response to a number of factors, many of which are beyond our control. These factors include:

- announcements by us of the results of our pending COVID-19 vaccine development program or our competitors or their COVID-19 development programs;
- our level of, and expected future use of, working capital;
- the additional sale of common stock by us in capital raising transactions.
- quarter-to-quarter variations in our operating results;
- our perceived funding needs;
- the results of testing, technological innovations, or new commercial products by us or our competitors;
- governmental regulations, rules, and orders;
- general conditions in the health care, biotechnology or biopharmaceutical industries;
- changes in market or trading conditions in light of economic uncertainty due to the COVID-19 pandemic;
- comments, research reports and/or earnings estimates by securities analysts;
- developments concerning patents or other intellectual property rights;
- litigation or public concern about the safety of our products;

- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments or vaccines being brought to the market under the FDA's Emergency Use Authorization;

- additions or departures of directors, officers and key personnel;

- release of transfer restrictions on our outstanding shares of common stock or sales of additional shares of common stock;

- potential litigation initiated against us.

Our stock price has been, and in the future may be, subject to substantial volatility. For example, our stock traded within a range of a high volume of 112,665,800 and a low volume of 254,900 per share for the period of January 1, 2020, through December 31, 2020. As a result of this volatility, our stockholders could incur substantial losses.

The stock market in general, and the market for biopharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above your initial purchase price. Broad market factors may seriously harm the market price of our common stock, regardless of our operating performance.

If our quarterly or annual results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our results may, in turn, cause the price of our stock to fluctuate substantially. We believe that period-to-period comparisons of our results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

In addition, public statements by us, government agencies, the media or others relating to the coronavirus outbreak (including regarding efforts to develop a coronavirus vaccine) have in the past resulted, and may in the future result, in significant fluctuations in our stock price. Given the global focus on the coronavirus outbreak, any information in the public arena on this topic, whether or not accurate, could have an outsized impact (either positive or negative) on our stock price. Information related to our development, manufacturing and distribution efforts with respect to Terra CoV-2, or information regarding such efforts by competitors with respect to their vaccines, may also impact our stock price.

Our stock price is likely to continue to be volatile and subject to significant volume fluctuations in response to market and other factors, including the other factors discussed in our filings incorporated by reference herein or in future periodic reports; variations in our quarterly operating results from our expectations or those of securities analysts or investors; downward revisions in securities analysts' estimates; and announcement by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock has been in the past and may continue to be volatile. In the past, other publicly-traded companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of securities law-related litigation in the future, and such litigation against us could result in substantial costs and divert management's attention from other business concerns, which could seriously harm our business, financial condition and results of operations and prospects.

Future sales or issuances of our common stock in the public markets, or the perception of such sales, could depress the trading price of our common stock.

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur. In addition, these factors could make it more difficult for us to raise funds through future offerings of common stock. We may sell large quantities of our common stock at any time pursuant to in one or more separate offerings. We cannot predict the effect that future sales of common stock or other equity-related securities would have on the market price of our common stock. We have recently issued a significant number of shares of common stock and the number of outstanding shares has increased from 29,433,135 shares as of December 31, 2018 to 91,766,928, shares as of December 31, 2020, and inclusive of the shares of our common stock issued in connection with our acquisition of Noachis Terra, 109,646,119 outstanding shares of our common stock as of February 25, 2021. In addition, there were 16,017,000 shares of our Preferred stock outstanding which are convertible into 2,261,703 shares of our common stock and, as of December 31, 2020, warrants to purchase an additional 20,513,145 shares of our common stock issuable upon exercise of warrants to investors, inclusive of the warrants to purchase 9,200,000 shares of our common stock issued in connection with our acquisition of Noachis Terra which will be exercisable on May 1, 2021. There were also 5,801,349 shares issuable upon exercise of options outstanding and an additional 2,207,901 shares available for option grants under our 2012 Equity Incentive Plan.

The issuance of shares of our common stock under our 2012 Equity Incentive Plan is covered by Form S-8 registration statements we filed with the Securities and Exchange Commission, or SEC, and upon exercise of the options, such shares may be resold into the market. We have also issued shares of common stock and warrants in connection with previous private placements. Such shares are available for resale as well as certain of the shares of common stock issuable upon exercise of the warrants. We have also issued shares of our common stock in the private placement and financing transaction, which are deemed to be "restricted securities," as that term is defined in Rule 144 promulgated under the Securities Act of 1933, as amended, or Securities Act, and such shares may be resold pursuant to the provisions of Rule 144. In general, pursuant to Rule 144, after satisfying a six-month holding period: (i) affiliated shareholders, or shareholders whose shares are aggregated, may, under certain circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then-outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale and (ii) non-affiliated shareholders may sell without such limitations, in each case provided we are current in our public reporting obligations. Rule 144 also permits the sale of securities by non-affiliates that have satisfied a one-year holding period without any limitation or restriction. We are unable to estimate the number of shares that may be sold because this will depend on the market price for our common stock, the personal or business circumstances of sellers and other factors.

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified members for our Board of Directors.

As a public company, we are already subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Sarbanes-Oxley Act. The requirements of these rules and regulations may increase our legal, accounting and financial compliance costs; may make some activities more difficult, time-consuming and costly; and may also place undue strain on our personnel, systems and resources. Our management and other personnel need to devote a substantial amount of time to comply with these requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costlier. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors and Board committees or as executive officers.

As a public company we are also required to assess our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act and file periodic reports with the SEC. If we are unable to comply with these requirements in a timely manner, or if material weaknesses or significant deficiencies persist, the market price of our stock could decline and we could be subject to sanctions or regulatory investigations, which could harm our business. We must perform an assessment of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. If we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act or the SEC reporting requirements in a timely manner, or if we note or identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. As a smaller reporting company, we do not have to have our independent registered public accounting firm report on the effectiveness of our internal control over financial reporting. If in the future we no longer meet the requirements of a smaller reporting company, our independent registered public accounting firm will have to report on our internal controls over financial reporting. There can be no assurance that our independent registered public accounting firm will not identify material weaknesses which could have an adverse effect on our stock price.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud which could subject us to regulatory sanctions, harm our business and operating results and cause the trading price of our stock to decline.

Effective internal controls required under Section 404 of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our business, reputation and operating results could be harmed. We have discovered, and may in the future discover, areas of our internal controls that need improvement. We cannot be certain that the measures we have taken or intend to take will ensure that we maintain adequate controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls or difficulties encountered in their implementation could subject us to regulatory sanctions, harm our business and operating results or cause us to fail to meet our reporting obligations. Inferior internal controls could also harm our reputation and cause investors to lose confidence in our reported financial information, which could have a negative impact on the trading price of our stock.

We cannot assure you that we will continue to be listed on the NYSE American.

Our common stock commenced trading on the NYSE American (formerly the NYSE MKT) on April 10, 2013, and we are subject to certain NYSE American continued listing requirements and standards. We may also incur costs that we have not previously incurred for expenses for compliance with the rules and requirements of the NYSE American. We cannot provide any assurance that we will be able to continue to satisfy the requirements of the NYSE American's continued listing standards. A delisting of our common stock could negatively affect the price and liquidity of our common stock and could impair our ability to raise capital in the future.

We will continue to incur significant costs as a result of and devote substantial management time to operating as a public company listed on the NYSE American.

As a public company listed on the NYSE American, we incurred and will continue to incur significant legal, accounting and other expenses that we did not incur before when trading on the OTCQB Marketplace. For example, we are subject to the rules and regulations required by the NYSE American, including changes in corporate governance practices and minimum listing requirements. These requirements have increased our legal and financial compliance costs and have and will continue to render some activities more time-consuming and costlier. In addition, our management and other personnel have diverted and will continue to divert attention from operational and other business matters to devote substantial time to these listing requirements and failure to meet these requirements could lead to an adverse effect on the listing of our common stock on the NYSE American.

If securities or industry analysts publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part upon the research and reports that securities or industry analysts publish about us or our business from time to time. If one or more of the analysts who seek to cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage, once commenced, or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

We may issue debt or debt securities convertible into equity securities, any of which may be senior to our common stock as to distributions and in liquidation, which could negatively affect the value of our common stock.

In the future, we may attempt to increase our capital resources by entering into debt or debt-like financing that is unsecured or secured by up to all of our assets, or by issuing additional debt or equity securities, which could include issuances of secured or unsecured commercial paper, medium-term notes, senior notes, subordinated notes, guarantees, preferred stock, hybrid securities, or securities convertible into or exchangeable for equity securities. In the event of our liquidation, our lenders and holders of our debt and securities would receive distributions of our available assets before distributions to the holders of our common stock. Because our decision to incur debt and issue securities in future offerings may be influenced by market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings or debt financings. Further, market conditions could require us to accept less favorable terms for the issuance of our securities in the future.

We are a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to smaller reporting companies, our common stock may be less attractive to investors.

We are a "smaller reporting company," meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a "smaller reporting company," have a public float of less than $250 million and have annual revenues of less than $100 million during the most recently completed fiscal year. As a "smaller reporting company," we are subject to lesser disclosure obligations in our SEC filings compared to other issuers. Specifically, "smaller reporting companies" are able to provide simplified executive compensation disclosures in their filings, are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. Decreased disclosures in our SEC filings due to our status a "smaller reporting company" may make it harder for investors to analyze our operating results and financial prospects.

We have never paid cash dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have never paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any cash dividends in the foreseeable future. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None

ITEM 2. PROPERTIES.

We lease approximately 2,207 square feet for our corporate offices located at 4902 Eisenhower Boulevard, Suite 125, Tampa, Florida 33634. Lease payments range from $4,138 per month to $4,392 per month inclusive of insurance, taxes and utilities. The lease costs for the year ended December 31, 2020 were approximately $61,000 which includes insurance, taxes and utilities. In November of 2019, the Company entered into an amendment for the office space in Tampa to extend the term for an additional three years beginning in March of 2020. Under the amended lease agreement, the rental payments are expected to range from $4,524 per month to $4,800 per month.

In addition to our Tampa location, we continue to lease our research facility located at 13700 Progress Boulevard, Alachua, Florida 32615. The facility is approximately 5,300 square feet of which approximately 60% is laboratory space and the remainder is office space and common areas. The lease costs for the year ended December 31, 2020 were approximately $165,000 which includes insurance, taxes and utilities. Lease payments are capped during the term. In June of 2019, the Company entered into an amendment to our lease for the Alachua facility to provide for a term of five years beginning at the end of the existing lease term in December of 2019. Under the amended lease agreement, the rental payments range from $12,870 per month to $13,338 per month.

ITEM 3. LEGAL PROCEEDINGS.

We are not a party to any material legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Our common stock is quoted on the NYSE American under the ticker symbol "OGEN". The last price of our common stock as reported on the NYSE American on February 25, 2021 was $1.05 per share. As of February 25, 2021, there were approximately 29 stockholders of record of our common stock. This number does not include beneficial owners from whom shares are held by nominees in street name such as banks and brokerage firms.

Dividends

To date, we have neither declared nor paid any dividends on our common stock nor do we anticipate that such dividends will be paid in the foreseeable future. Rather, we intend to retain any earnings to finance the growth and development of our business. Any payment of cash dividends on our common stock in the future will be dependent, among other things, upon our earnings, financial condition, capital requirements and other factors which the board of directors deems relevant. In addition, restrictive covenants contained in any financing agreements entered into in the future may preclude us from paying any dividends.

We issued 100 shares of Series C, Non-Voting, Non-Convertible, Preferred Stock ("Series C Preferred Stock") with a stated value of $33,847 per share to Precigen in exchange for obligations we owed to Precigen Inc. ("Precigen"). These shares have an accruing dividend of 12% per year payable in additional shares of Series C Preferred Stock. The accruing dividend increased to 20% per year after May 10, 2019. In January of 2018 we paid a dividend on our Series C Preferred Stock to Precigen of 1.733 shares for the portion of the 2017 fiscal year that the Series C Preferred Stock was outstanding and in January of 2019, we paid a dividend on our Series C Preferred Stock to Precigen of 12.208 shares. On January 27, 2020 we issued 19.542 shares of additional Series C Preferred Stock to Precigen as a dividend on our Series C Preferred Stock. As a result of the recent sale by Precigen of its equity interest in Oragenics to TS Biotechnology LLC, future dividend payments will be paid to TS Biotechnology. On January 28, 2021 we issued 26.697 shares of additional Series C Preferred Stock to TS Biotechnology as a dividend on our Series C Preferred Stock. On February 11, 2021, we provided notice of redemption, of approximately $5.6 million, for all of our outstanding shares of Series C Preferred Stock. See Note 14 Subsequent Events.

Unregistered Sale Of Equity Securities And Use Of Proceeds

None.

Stock Repurchases in the Fourth Quarter

There were no purchases of our common stock during the three months ended December 31, 2020. The Company has no publicly announced share repurchase programs.

ITEM 6. SELECTED FINANCIAL DATA.

Not applicable.

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

The following information should be read in conjunction with the Consolidated Financial Statements, including the notes thereto, included elsewhere in this Form 10-K. This discussion contains certain forward-looking statements that involve risks and uncertainties. Our actual results and the timing of certain events could differ materially from those discussed in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth herein and elsewhere in this Form 10-K.

Overview

We are focused on the creation of the Terra CoV-2 immunization product candidate to combat the novel coronavirus pandemic and the further development of novel antibiotics against infectious disease.

Our SARS-CoV-2 Vaccine Product Candidate— Terra CoV-2

As a result of our acquisition of one hundred percent (100%) of the total issued and outstanding common stock of Noachis Terra, Inc. ("Noachis Terra") we are now focused on the development and commercialization of a vaccine product candidate to provide long lasting immunity from the novel Severe Acute Respiratory Syndrome coronavirus ("SARS-CoV-2"), which causes the coronavirus disease 2019 ("COVID-19"). Noachis Terra is a party to a worldwide, nonexclusive intellectual property and biological materials license agreement with the National Institute of Allergy and Infectious Diseases ("NIAID"), an institute within the National Institutes of Health ("NIH"), relating to certain research, patent applications and biological materials involving pre-fusion stabilized coronavirus spike proteins and their use in the development and commercialization of a vaccine to provide specific, long lasting immunity from SARS-CoV-2.

Coronaviruses are a family of viruses that can lead to upper-respiratory infections in humans. Recent clinical reports also suggest that the SARS-CoV-2 virus can affect other body-systems, including the nervous, cardiovascular, gastrointestinal and renal systems. Among the recent iterations of coronaviruses to move from animal to human carriers is SARS-CoV-2 (often referred to as COVID-19), which, beginning in Wuhan, China, in late 2019, caused a global pandemic due to its rapid spread and the relatively high mortality rate (as compared to the seasonal influenza). In late January of 2021, the World Health Organization's estimates indicate the number of worldwide COVID-19 infections have exceeded 100,000,000 and the number of deaths directly attributed to COVID-19 have exceeded 2,000,000. Both Pfizer and Moderna have announced preliminary safety and efficacy data from their Phase 3 COVID-19 vaccine studies and recent Emergency Use Authorization by the FDA. We believe given the size of the worldwide pandemic that even with multiple vaccines projected to be available in the coming months, there will be demand for the Terra CoV-2 vaccine, once development is successfully completed. We intend to combine the research, patent applications and biological materials covered by our NIAID license with our existing clinical research and manufacturing capabilities to respond rapidly to this ongoing, global, public health crisis. We believe our Terra CoV-2 vaccine holds the possibility of playing an important role in addressing this crisis.

Coronaviruses, such as SARS -CoV-2, possess signature protein spikes on their outer capsule. The NIAID license covers patents and data on a vaccine candidate that were created based on a stabilized pre-fusion spike trimeric protein. By stabilizing the spike protein in the pre-fusion state, the number of immunogenic centers is increased thereby allowing for a greater likelihood of successful antibody binding, resulting in an improved immunogenic response. The genetic code, acquired from the NIH, for the stabilized pre-fusion spike protein was provided to Aragen Bioscience, Inc. ("Aragen") for the purpose of insertion of the spike protein gene sequence into a Chinese Hamster Ovary ("CHO") cell line. Aragen is a leading contract research organization focused on accelerating preclinical biologics product development, has extensive experience building CHO cell lines for recombinant proteins, such as monoclonal antibodies. Aragen has successfully inserted the NIH pre-fusion spike protein gene sequence into a CHO cell line and is currently developing both the analytical tests and identifying preliminary cell line growth conditions to optimize the spike protein titers. Currently, "mini-pool" production and analytical development is underway. The process to transfer to full-scale manufacture has begun.

The NIH's preclinical study shows that this spike protein, adjuvanted with the mouse specific TLR-4-agonist Sigma Adjuvant System ("SAS", a TLR-4 agonists) that induces T cell activation), generates neutralizing antibody titers in both a pseudovirus neutralization assay and a plaque reduction neutralization titer (PRNT) assay. Recently released information indicated that pretreatment of mice with the NIH-created COVID-19 spike protein in combination with an adjuvant (TLR-4 agonist Sigma Adjuvant System) completely inhibited viral growth in the nasal cavities and lungs of infected animals compared to unvaccinated control animals. In October 2020, we received feedback to our Type B Pre-IND Meeting Request from the FDA. The response indicated that the FDA broadly supported our planned approach to the pre-clinical program that will support the clinical development of the Terra CoV-2, vaccine. As a result, we anticipate filing the Investigational New Drug ("IND") application in the fourth quarter of 2021 and immediately upon the receipt of approval from the FDA, commencing the Phase 1 clinical study, the protocol for which is currently under development.

We recently announced we had entered into an agreement with Adjuvance Technologies Inc. for the use of TQL1055, a novel, rationally designed semi-synthetic analogue of the saponin adjuvant QS-21 with potential improved attributes, including stability and manufacturing efficiency. We also anticipate that our Terra CoV-2 vaccine will provide long lasting protection from the SARS-CoV-2 virus with only one or two doses, with a more rapid immune response compared to vaccines developed without the inclusion of an adjuvant.

As presently designed, we believe the Terra CoV-2 vaccine is expected to permit cost effective storage and distribution at refrigerated temperatures, which should facilitate the distribution and thereby avoid challenges facing the two mRNA vaccines currently available under the FDA's Emergency Use Authorization in the U.S.

We expect to use our currently available cash resources to continue to advance the development of Terra CoV-2 through IND-enabling studies, including immunogenicity, viral challenge studies, toxicology studies, and the Phase 1 trial with further clinical development being contingent upon the receipt of additional funding, including non-dilutive government grant funding which we continue to pursue or partnering or out-licensing opportunities.

Our Antibiotic Product Candidate-OG716

Members of our scientific team discovered that a certain bacterial strain. *Streptococcus mutans,* produces MU1140, a molecule belonging to the novel class of antibiotics known as lantibiotics. Lantibiotics, such as MU1140, are highly modified peptide antibiotics made by a small group of Gram-positive bacterial species. Approximately 60 lantibiotics have been discovered, to date. We believe lantibiotics are generally recognized by the scientific community to be potent antibiotic agents.

In nonclinical testing, MU1140 has shown activity against all Gram-positive bacteria against which it has been tested, including those responsible for a number of healthcare associated infections, or HAIs. A high percentage of hospital-acquired infections are caused by highly antibiotic-resistant bacteria such as methicillin-resistant Staphylococcus aureus (MRSA) or multidrug-resistant Gram-negative bacteria. We believe the need for novel antibiotics is increasing as a result of the growing resistance of target pathogens to existing FDA approved antibiotics on the market along with the increased use of currently available antibiotics due to secondary infections in SARS-CoV-2 infected patients.

Lantibiotics have been difficult to investigate for their clinical usefulness as therapeutic agents in the treatment of infectious diseases due to a general inability to produce or synthesize sufficient quantities of pure amounts of these molecules. Traditional fermentation methods can only produce minute amounts of the lantibiotic.

In June 2012, we entered into a worldwide exclusive channel collaboration agreement with Precigen (formerly known as Intrexon Corporation) for the development and commercialization of the native strain of MU1140 and related homologs to use its advanced transgene and cell engineering platforms. At that time we also entered into a stock issuance agreement with Precigen. Through our work pursuant to the collaboration agreement, we have been able to produce a significant increase in the fermentation titer of MU1140 compared to standard fermentation methods and have discovered a new purification process for MU1140. Our work generated a substantial number of homologs of MU1140 and the exclusive channel collaboration was thereafter amended to clarify the applicable field and to adjust the milestone payments and provide that they will be paid in cash. In January 2020 Precigen consummated a reorganization of its ongoing active pharmaceutical ingredients (API) fermentation operations and assets which included transfer of the exclusive collaboration agreement and related stock issuance agreement. Following such reorganization, Precigen divested certain of its assets to TS Biotechnology Holdings, LLC which included shares of Oragenics securities and the subsidiary Eleszto Genetika, Inc. ("EGI" formerly known as ILH Holdings, Inc.) that held the collaboration agreement and stock issuance agreements with us, and. On March 1, 2021, due to such prior amendments, assignments and transfers we entered into an amended and restated exclusive channel collaboration agreement with EGI which (i) included the prior amendments, (ii) updated the names of the parties, and (iii) incorporated any remaining applicable terms from the stock issuance agreement and thereafter terminated the stock issuance agreement (the "Lantibiotic ECC"). We expect to continue our research and development and collaboration efforts with EGI to develop potential derivatives of the MU1140 molecule using genetically modified bacteria.

In our pre-clinical studies to support a potential IND filing with the FDA, we tested a total of six homologs of MU1140 for certain compound characteristics, including but not limited to: drug activity (based on minimum inhibitory concentration or "MIC") equal or better than "standard of care" drugs against certain drug-resistant bacteria, safety, toxicity, stability, and manufacturability. An animal study specifically evaluated homolog efficacy in relation to survival, measurable amounts of *Clostridium difficile ("C. diff")* colony forming units, and toxin levels. Three homologs demonstrated promising results with one homolog, OG253 achieving a 100% survival rate throughout the entire study in contrast to an approximately 30% survival rate for the vancomycin positive control.

Based on these early results, we selected a lead candidate, OG253, for which we had a pre-IND meeting with the FDA in November of 2015 regarding the pursuit of an IND for OG253. Following additional research and development on second generation lantibiotics, in August of 2016, we opted to select a second generation lantibiotic, OG716, for treatment of *C. diff* as our new lead candidate. OG716 is a new, orally-active homolog, that has exhibited positive results in an animal model for potential treatment of *C. diff*. Generated from our MU1140 platform, this new lantibiotic showed promising efficacy in reducing clinically relevant *C. diff* infections as measured by increased animal survival and decreased relapse as well as reduced production of toxins A & B and *C. diff* spores.

The timing of the filing of an IND regarding OG716 is subject to our having sufficient available human, material and financing capital, which includes research subjects, both animal and human, given all of our anticipated needs and expected requirements in connection with our ongoing research and development initiatives. We will continue to advance the OG716 program to the IND filing based on the availability of both human and financial capital. Based upon the current funding available we will continue to conduct some of the requisite studies. While we commenced certain of these studies at the end of 2019, we expect to focus on efficient and cost-effective improvements in the manufacturing process of the product as we move to complete the pre-clinical studies required to support our first in man Phase 1 clinical study.

Product Candidates.

Through our wholly-owned subsidiary, Noachis Terra, we began the research and development stage for our new Terra CoV-2 vaccine product candidate. We hold a nonexclusive, worldwide intellectual property license agreement for certain research, patent applications and biological materials relating to the use of pre-fusion coronavirus spike proteins for the development and commercialization of a vaccine against SARS-CoV-2.

Additionally, we are developing our lead lantibiotic candidate, OG716, to treat *Clostridium difficile* while also creating semi-synthetic lantibiotic analogs that may be effective against systemic gram (+) multidrug infections, and analogs that may be effective in treating gram (-) infections. We seek to protect our product candidates through patents and patent applications pursuant to the terms of our license agreements.

Product/Candidate	Description	Application	Status
Terra CoV-2	Vaccine candidate (plasmid + adjuvant) to provide long lasting immunity against SARS-CoV-2	Broad, community-based vaccine immunity against SARS-CoV-2	Pre-clinical
OG716	A homolog of MU1140: Member of lantibiotic class of antibiotics	*Clostridium difficile* associated diarrhea	Pre-clinical

Our Business Development Strategy

Success in the biopharmaceutical and product development industry relies on the continuous development of novel product candidates. The large majority of product candidates do not make it past all clinical trials which forces companies to look externally for innovation. Accordingly, we expect from, time to time, to seek strategic opportunities through various forms of business development, which can include strategic alliances, licensing deals, joint ventures, collaborations, equity-or debt-based investments, dispositions, mergers and acquisitions. We view these business development activities as a necessary component of our strategies, and we seek to enhance shareholder value by evaluating business development opportunities both within and complementary to our current business as well as opportunities that may be new and separate from the development of our existing product candidates.

Recent Developments

ATM Offering-Sales Agreement. On February 1, 2021, the Company entered into a Sales Agreement (the "Sales Agreement") with A.G.P./Alliance Global Partners, as sales agent (the "Sales Agent"), pursuant to which the Company may offer and sell through or to the Sales Agent (the "Offering") up to $20.0 million in shares of its common stock (the "Shares") at-the-market. Through February 12, 2021, the Company sold an aggregate of 15,406,618 shares of its common stock at-the-market pursuant to the Sales Agreement for aggregate net proceeds to the Company of approximately $19.3 million. Shares offered and sold in the Offering were issued pursuant to the Company's universal shelf registration statement on Form S-3 (the "Shelf Registration Statement") and the prospectus supplement relating to the Offering filed with the Securities and Exchange Commission (the "SEC") on February 1, 2021. The Offering will terminate upon (a) the election of the Agent upon the occurrence of certain adverse events, (b) 10 days' advance notice from one party to the other, or (c) the sale of the Shares equating to $20 million. Under the terms of the Sales Agreement, the Sales Agent is entitled to a commission at a fixed rate of 3.0% of the gross proceeds from each sale of shares under the Sales Agreement.

Series C Preferred Stock Redemption. On February 11, 2021, we provided a notice of redemption, for approximately $5.6 million, to the holder of our Series C Preferred Stock, with a redemption date of March 13, 2021 (which included the dividend of 26.697 shares paid on January 28, 2021 and any accrued dividends due through the redemption date), after which time the Series C Preferred Stock will be cancelled and no further dividends will accrue. The applicable portion of the net proceeds received from the above referenced ATM Offering are being utilized for the redemption.

Warrant Exercises. Between February 9, 2021 and February 25, 2021 the Company issued an additional 2,472,573 shares of common stock as a result of the exercise of certain outstanding warrants as follows: (i) warrants to acquire 360,000 shares of Common Stock at an exercise price of $1.00 per share issued in connection with its July 2018 public offering were exercised and (ii) warrants to acquire 2,112,573 shares of Common Stock at an exercise price of $0.90 per share issued in connection with its March 2019 public offering were exercised (the "Warrant Exercises"). The Warrant Exercises provided aggregate gross proceeds to the Company of $2,261,315.

Additional Consideration Payment – Noachis Terra Acquisition. As a result of the Warrant Exercises, the Company paid $542,263 of additional consideration to the sole former shareholder of Noachis Terra. The additional consideration payment will be included in operating expenses.

Financial Overview

Net Revenues

We did not generate any revenue for the years ended December 31, 2020 and 2019, respectively from the sales or licensing of our product candidates.

Research and Development Expenses

Research and development consist of expenses incurred in connection with the discovery and development of our product candidates. These expenses consist primarily of employee-related expenses, which include salaries and benefits and attending science conferences; expenses incurred under our license agreements with third parties and under other agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our nonclinical studies; the cost of acquiring and manufacturing clinical trial materials; facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, and depreciation of fixed assets; license fees, for and milestone payments related to, in-licensed products and technology; stock-based compensation expense; and costs associated with nonclinical activities and regulatory approvals. We expense research and development costs as incurred.

Our research and development expenses can be divided into (i) clinical research, and (ii) nonclinical research and development activities and (iii) manufacturing process development and analytical testing procedure development. Clinical research costs consist of clinical trials, manufacturing services, regulatory activities and related personnel costs, and other costs such as rent, utilities, depreciation and stock-based compensation. Nonclinical research and development costs consist of our research activities, nonclinical studies, related personnel costs and laboratory supplies, and other costs such as rent, utilities, depreciation and stock-based compensation and research expenses we incur associated with the development of our product candidates. While we are currently focused on advancing our product development programs, our future research and development expenses will depend on the clinical success of our product candidates, as well as ongoing assessments of each product candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans, research expenses and capital requirements.

Our research and development expenses were $22,107,563 and $12,120,318 for the years ended December 31, 2020 and 2019, respectively.

Our current product development strategy contemplates an expected increase in our research and development expenses in the future as we continue the advancement of our product development programs for our vaccine and lantibiotic product candidates, with greater near-term emphasis on our vaccine product candidate. The lengthy process of completing clinical trials; seeking regulatory approval for our product candidates; and expanding the potential claims we are able to make, requires expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenues and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Our current product candidates are not expected to be commercially available until we are able to obtain regulatory approval from the FDA.

Our plan is to budget and manage expenditures in research and development such that they are undertaken in a cost-effective manner yet still advance the research and development efforts. While we have some control under our Lantibiotic ECC and NIH license as to the planning and timing of our research and development and therefore the timing of when expenditures may be incurred for various phases of agreed upon projects, actual expenditures can vary from period to period. Subject to available capital, we expect overall research and development expenses to increase as a result of our vaccine product candidate and as our financial resources permit. Our research and development projects are currently expected to be taken to the point where they can be licensed or partnered with larger pharmaceutical companies.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, business development, marketing, information technology, legal and human resources functions. Other general and administrative expenses include facility costs not otherwise included in research and development expenses, patent filing, and professional fees for legal, consulting, auditing and tax services.

We anticipate that our general and administrative expenses may remain flat, but be subject to variability for, among others, the following reasons:

- to support our research and development activities, which, subject to available capital, we expect to expand as we continue the development of our product candidates;
- the efforts we undertake from, time to time, to raise additional capital; and
- the increased payroll, and stock-based compensation, expanded infrastructure and consulting, legal, accounting and investor relations costs associated with being a public company.

Other Income (Expense)

Other income (expense) includes local business taxes, as well as interest income and expense. Interest income consists of interest earned on our cash and cash equivalents. The primary objective of our investment policy is capital preservation. Interest expense consists primarily of interest and costs associated with our indebtedness.

Income Taxes

As of December 31, 2020, and 2019, we have federal and state net operating loss carryforwards of approximately $142,893,000 and $117,963,000, respectively, to offset future federal and state income taxes. Federal and state of Florida tax net operating loss carryforwards generated prior to December 31, 2017 will expire through 2037. Federal and state of Florida tax net operating loss carryforwards generated subsequent to December 31, 2017, do not expire and are no longer subject to taxable income limitation pursuant to the Coronavirus Aid, Relief, and Economic Security Act, passed on March 27, 2020. State of Pennsylvania tax net operating loss carryforwards will expire through 2036. We also have research and development tax credit carryforwards of approximately $4,043,000 and $2,805,000 as of December 31, 2020, and 2019, respectively, to offset future federal and state income taxes. The federal tax credit carryforward will expire beginning in 2021 and continuing through 2040, unless previously utilized.

Utilization of net operating loss carryforwards and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or, could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986 ("IRC Section 382") and with Section 383 of the Internal Revenue Code of 1986, as well as similar state provisions. These ownership changes may limit the amount of net operating loss carryforwards and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change, as defined by IRC Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. The Company has completed several financings since its inception, as well as the recent acquisition of Noachis Terra, which may result in a change in ownership as defined by IRC Section 382, or could result in a change in control in the future. In each period since our inception, we have recorded a 100% valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal tax benefit in our statements of operations.

Critical Accounting Estimates and Policies

Our discussion and analysis of our consolidated financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("US GAAP"). The preparation of consolidated financial statements in accordance with US GAAP requires us to make estimates and assumptions that affect reported amounts and related disclosures. There are certain critical estimates that we believe require significant judgment in the preparation of our consolidated financial statements. We consider an accounting estimate to be critical if:

- It requires us to make an assumption because information was not available at the time or it included matters that were highly uncertain at the time, we were making the estimate; and

- Changes in the estimate or different estimates that we could have selected may have had a material impact on our financial condition or results of operations.

The principal areas of estimation reflected in the consolidated financial statements are stock-based compensation and valuation of warrants.

Stock-Based Payment Arrangements

Generally, all forms of stock-based payments, including stock option grants, and warrants are measured at their fair value on the awards' grant date using a Black-Scholes pricing model. Restricted stock grants are measured at their fair value at the date of the grant. Stock-based compensation awards issued to non-employees for services rendered are recorded at the fair value of the stock-based payment. The expense resulting from stock-based payments are recorded in research and development expense or general and administrative expense in the consolidated statement of operations, depending on the nature of the services provided. Stock-based payment expense is recorded over the requisite service period in which the grantee provides services to us. To the extent the stock option grants, warrants, or restricted stock grants do not vest at the grant date they are subject to forfeiture.

Stock-Based Compensation

U.S. Generally Accepted Accounting Principles ("US GAAP") requires all stock-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values as of the grant date. Stock-based compensation expense is recorded over the requisite service period in which the grantee provides services to us, to the extent the options do not vest at the grant date and are subject to forfeiture. For performance-based awards that do not include market-based conditions, we record share-based compensation expense only when the performance-based milestone is deemed probable of achievement. We utilize both quantitative and qualitative criteria to judge whether milestones are probable of achievement. For awards with market-based performance conditions, we recognize the grant-date fair value of the award over the derived service period regardless of whether the underlying performance condition is met. We account for forfeitures of stock-based awards as a component of compensation expense as the forfeitures occur.

Warrants

The Company used the Black Scholes Option Pricing Model in calculating the relative fair value of any warrants that have been issued.

New Accounting Pronouncements

There are no additional accounting pronouncements issued or effective during the twelve months ended December 31, 2020 that have had or are expected to have an impact on our financial statements.

Income Taxes

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.

Results of Operations:

	Year Ended December 31,			
	2020	2019	Increase/Decrease	Percentage
Revenue, net	$ —	$ —	$ —	—
Operating expenses:				
Research, and development	22,107,563	12,120,318	9,987,245	82.40%
General and administrative	4,533,893	3,757,251	776,642	20.67%
Total operating expenses	26,641,456	15,877,569	10,763,887	67.79%
Loss from continuing operations	(26,641,456)	(15,877,569)	(10,763,887)	67.79%
Other income (expense):				
Interest income	89,294	320,011	(230,717)	-72.10%
Interest expense	(10,685)	(7,300)	(3,385)	46.37%
Local business tax	(2,400)	(1,601)	(799)	49.91%
Other income	1,795	456	1,339	293.64%
Forgiveness of Paycheck Protection Program loan and accrued interest	132,753	—	132,753	N/A
Total other income (expense), net	210,757	311,566	(100,809)	-32.36%
Loss from continuing operations before income taxes	(26,430,699)	(15,566,003)	(10,864,696)	69.80%
Income tax benefit	—	—	—	0.00%
Net loss from continuing operations	$ (26,430,699)	$ (15,566,003)	$ (10,864,696)	69.80%

For the Years Ended December 31, 2020 and 2019

Research and Development. Research and development expenses were $22,107,563 for the year ended December 31, 2020 compared to $12,120,318 for the year ended December 31, 2019; an increase of $9,987,245, or 82.4%. This increase was primarily due to the acquisition of Noachis Terra, Inc. which was accounted for as in-process research and development expenses and an increase in costs associated with the advancement of our Terra CoV-2 vaccine program, employee stock-based compensation, and salaries costs of $11,176,479, $4,122,963, $194,088, and $63,333, respectively. These increases were partially offset by decreases in costs associated with our clinical trial work related to our oral mucositis product candidate under our Lantibiotic ECC and a reduction in costs associated with our Lantibiotic ECC of $4,461,809, and $1,130,103, respectively.

General and Administrative. General and administrative expenses were $4,533,893 for the year ended December 31, 2020 compared to $3,757,251 for the year ended December 31, 2019; an increase of $776,642, or 20.7%. This increase was primarily due to increases in non-employee stock-based compensation, employee stock-based compensation, insurance, and legal costs of $448,231, $295,851, $116,160, and $61,434, respectively. These increases were partially offset by decreases in travel and entertainment, conferences, and consulting costs of $102,554, $27,474, and $25,393, respectively.

Other Income (Expense). Other income (expense) was $210,757 for the year ended December 31, 2020 compared to $311,566 for the year ended December 31, 2019; a net change of $100,809. The decrease was primarily attributable to a decrease in interest income of $230,717, which was offset by the forgiveness of the Paycheck Protection Program loan and accrued interest of $132,753.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through the sale of equity securities in our initial public offering, the sale of equity securities and warrants in private and public offerings, debt financing, warrant exercises and grants. As of December 31, 2020, we had an accumulated deficit of $(154,444,983) and we have yet to achieve profitability. We incurred net losses of $(26,430,699) and $(15,566,003) for the years ended December 31, 2020 and 2019, respectively. We expect to incur significant and increasing operating losses for the foreseeable future as we seek to advance our product candidates through nonclinical testing and clinical trials to ultimately obtain regulatory approval and eventual commercialization. We will need to raise additional capital to fund our operations. We anticipate that our cash resources as of December 31, 2020, together with proceeds from our ATM facility and warrant exercises, and net of the redemption of the Series C Preferred Stock of approximately $5.6 million, will be sufficient to fund our operations as presently structured through the second quarter of 2022. There can be no assurance that additional capital will be available to us on acceptable terms, if at all. Adequate additional funding may not be available to us on acceptable terms, or at all. We expect that research and development expenses will increase along with general and administrative costs, as we grow and operate our business. The following table sets forth the primary sources and uses of cash for each of the periods indicated:

	Years ended December 31,	
	2020	**2019**
Net cash used in operating activities	$ (16,952,864)	$ (13,012,843)
Net cash used by investing activities	—	(25,214)
Net cash provided by financing activities	16,324,445	11,097,750
Net decrease in cash and cash equivalents	$ (628,419)	$ (1,940,307)

During the years ended December 31, 2020 and 2019, our operating cash flows from operations used cash of $(16,952,864) and $(13,012,843), respectively. The use of cash in all periods primarily resulted from our net losses adjusted for non-cash items and changes in operating assets and liabilities. We had working capital surplus of $16,640,534 and $16,987,690 as of December 31, 2020 and 2019, respectively.

Additional details of our financing activities for the periods reflected in this report are provided below:

Financings

The May 2017 Series A Preferred Stock Financing

On May 10, 2017 we entered into a securities purchase agreement with three accredited investors, to purchase up to $3,000,000 of Series A Convertible Preferred Stock (the "Series A Preferred Stock Financing"). The sale of the Preferred Stock took place in two separate closings and at the first closing which occurred on May 10, 2017, we received gross proceeds of approximately $1,302,000. The second closing occurred on July 25, 2017 and we received gross proceeds of approximately $1,698,000, which was the balance of the Preferred Stock Financing. The full $3,000,000 of Preferred Stock, and after giving effect to the reverse stock split, is convertible into one million two hundred thousand shares of our Common Stock, based on a fixed conversion price of $2.50 per share on an as-converted basis. In addition, and after giving effect to the reverse stock split, we issued warrants to purchase an aggregate of 462,106 shares of Common Stock at the first closing and we issued an aggregate of 602,414 shares of Common Stock at the second closing. The warrants have a term of seven years from the date of issuance are non-exercisable until 6 months after issuance, have an exercise price of $3.10 per share. Proceeds from the Series A Preferred Stock Financing (including the exercise of any warrants for cash) was used for general corporate purposes, including working capital.

On July 27, 2017, we entered into an agreement to amend the warrants issued in connection with the Series A Preferred Stock Financing to provide notification and objection requirements with respect to the change of control provisions. The change of control provisions in the warrants had previously caused the warrants to be treated as a derivative liability as opposed to being treated as equity on our balance sheet. The warrants have been replaced by amended and restated warrants containing such notification and objection requirements (the "Amended and Restated Common Stock Purchase Warrants") so that the Amended and Restated Common Stock Purchase Warrants are now treated as equity on our balance sheet. All other terms of the original warrants remain unchanged by the Amended and Restated Common Stock Purchase Warrants.

In connection with the Series A Preferred Financing, we filed a Certificate of Designations of Preferences, Rights and Limitations of Series A Preferred Stock with the Secretary of State of the State of Florida, effective May 10, 2017. The number of shares of Preferred Stock designated as Series A Preferred Stock was 12,000,000.

In connection with the issuance and sale of the Series A Preferred Stock and common stock warrants that were issued commensurate with the issuance of the Series A Preferred Stock, we granted certain demand registration rights and piggyback registration rights with respect to the shares of our Common Stock issuable upon conversion of the Preferred Stock and exercise of the Warrants, pursuant to a Registration Rights Agreement.

Except as otherwise required by law, the Series A Preferred Stock have no voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Certificate of Designation, (b) amend its articles of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series A Preferred Stock, (c) increase the number of authorized shares of Series A Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing. Upon any liquidation, dissolution or winding-up by us, whether voluntary or involuntary that is not a Fundamental Transaction (as defined in the Certificate of Designation), the holders of Series A Preferred Stock shall be entitled to receive out of the assets, the greater of (i) the product of the number of shares of Series A Preferred Stock then held by such holder, multiplied by the Original Issue Price; and (ii) the amount that would be payable to such holder in the Liquidation in respect of Common Stock issuable upon conversion of such shares of Series A Preferred Stock if all outstanding shares of Series A Preferred Stock were converted into Common Stock immediately prior to the Liquidation. The Series A Preferred Stock is classified as permanent equity.

The November 2017 Series B Preferred Stock Financing

On November 8, 2017, we completed a private placement of $3,300,000 of Series B Non-Voting, Convertible Preferred Stock (the "Series B Convertible Preferred Stock") pursuant to a Securities Purchase Agreement with four existing shareholders who are accredited investors including an entity affiliated with a director of the Company (the "Series B Preferred Stock Financing").

The full $3,300,000 of Series B Convertible Preferred Stock is convertible, after giving effect to the reverse stock split into one million three hundred and twenty thousand shares of our Common Stock, based on a conversion of one share of Series B Preferred Stock into two shares of Common Stock. The purchase price per share of the Series B Preferred Stock is represented by $2.50 per share of the Common Stock on an as converted basis. In addition, and after giving effect to the reverse stock split, we issued to the investors in the private placement accompanying common stock purchase warrants to purchase an aggregate of 1,064,518 shares of Common Stock. The warrants have a term of seven years from the date of issuance, and are non-exercisable until six (6) months after issuance, and after giving effect to the reverse stock split, have an exercise price of $3.10 per share.

In connection with the Series B Preferred Financing, we filed a Certificate of Designation and Rights of Series B Convertible Preferred Stock with the Secretary of State of the State of Florida, effective November 8, 2017. The number of shares of Preferred Stock designated as Series B Preferred Stock was 6,600,000.

Except as otherwise required by law, the Series B Preferred Stock have no voting rights. However, as long as any shares of Series B Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series B Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock or alter or amend the Certificate of Designation, (b) amend its articles of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series B Preferred Stock, (c) increase the number of authorized shares of Series B Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing.

The Series B Preferred Stock shall rank (i) on par with the Common Stock and Series A Preferred Stock and junior to Series C Preferred Stock as to dividend rights and (ii) junior to Series C Preferred Stock, on par with Series A Preferred Stock and senior to the Common Stock as to distribution of assets upon liquidation, dissolution or winding-up by us, whether voluntary or involuntary.

Upon any liquidation, dissolution or winding-up by us, whether voluntary or involuntary, the holders of Series B Preferred Stock shall be entitled to receive out of the assets, after payment to the holders of Series C Preferred Stock but on par with the holders of Series A Preferred Stock and in preference to the holders of the Common Stock, an amount of cash equal to the greater of (i) the product of the number of shares of Series B Preferred Stock then held by such holder, multiplied by the Original Issue Price; and (ii) the amount that would be payable to such holder in the Liquidation in respect of Common Stock issuable upon conversion of such shares of Series B Preferred Stock if all outstanding shares of Series B Preferred Stock were converted into Common Stock immediately prior to the Liquidation. The Series B Preferred Stock is classified as permanent equity.

The Series C Preferred Stock Issuance

Concurrently with the Series B Preferred Stock Financing, we also entered into a Debt Conversion Agreement (the "Precigen Debt Conversion Agreement") with Precigen, Inc. (formerly Intrexon Corporation ("Intrexon") pursuant to which we exchanged the amount owed on an unsecured non-convertible promissory note including accrued interest and trade payables owed by us to the noteholder (collectively the "Debt") in the aggregate amount of approximately $3,400,000 for equity in the form of 100 shares of Series C, Non-Voting, Non-Convertible Preferred Stock (the "Series C Preferred Stock") with a stated value equal to the amount of the Debt. In connection therewith, we filed a Certificate of Designation and Rights of Series C Non-Convertible Preferred Stock with the Secretary of State of the State of Florida, to be effective November 8, 2017. The number of shares of Preferred Stock designated as Series C Preferred Stock is 1,000.

In connection with the Precigen Debt Conversion Agreement, we filed a Certificate of Designation and Rights of Series C Non-Convertible Preferred Stock with the Secretary of State of the State of Florida, to be effective November 8, 2017. The number of shares of Preferred Stock designated as Series C Preferred Stock is 1,000.

Each issued and outstanding share of Series C Preferred Stock entitles the holder of record to receive dividends at the annual rate of twelve percent (12%) (the "Initial Rate") of its Stated Value, payable by issuing additional shares of Series C Preferred Stock within thirty days after the end of each calendar year pro-rata for partial years. The Initial Rate increased to twenty percent (20%) automatically after May 10, 2019.

The Series C Preferred Stock ranks senior to the Common Stock, Series A Preferred Stock, Series B Preferred Stock and to any other equity securities issued by us (the "Junior Securities") as to rights upon liquidation, dissolution or winding-up by us, whether voluntary or involuntary.

Upon any liquidation, dissolution or winding-up by us, whether voluntary or involuntary, the holders of Series C Preferred Stock shall be entitled to receive, in preference to the Junior Securities, an amount of cash equal to the product of (i) sum of (a) the number of shares of Series C Preferred Stock then held by such holder plus, (b) the number of shares of Series C Preferred Stock issuable to such holder in connection with any accrued but unpaid dividends, multiplied by (ii) the Stated Value, of $33,847.9874 per share, of Series C Preferred Stock ("the Series C Liquidation Amount") and no distribution or payments shall be made in respect of any Junior Securities unless all Series C Liquidation Amounts, if any, are first paid in full.

On January 25, 2018 we paid a dividend on our Series C Preferred Stock of 1.733 shares of additional Series C Preferred Stock, on January 31, 2019 we paid a dividend on our Series C Preferred Stock of 12.208 shares of additional Series C Preferred Stock and on January 27, 2020 we paid a dividend on our Series C Preferred Stock of 19.542 shares of additional Series C Preferred Stock.

On February 11, 2021, we provided a redemption notice, for approximately $5.6 million, to the holder of all our outstanding shares of our Series C Preferred Stock. Shares of our Series C Preferred Stock will be redeemed on March 13, 2021 and no longer be outstanding.

The April 6, 2018 Registered Direct Offering and Private Placement

On April 6, 2018, we entered into a securities purchase agreement with certain investors pursuant to which issued an aggregate of 900,000 shares of our common stock, par value $0.001 per share, at $2.00 per share. In a concurrent private placement, we issued to the investors who participated in the registered offering, warrants exercisable for one share of common stock for each share purchased in the registered offering for an aggregate of warrants to acquire 900,000 shares of common stock at an exercise price of $2.00 per share. Each warrant is exercisable beginning on the six-month anniversary of the date of its issuance and expires five years from the date of issuance.

The July 17, 2018 Underwritten Public Offering

On July 17, 2018, we closed an underwritten public offering of units for gross proceeds of approximately $13.8 million, which includes the full exercise of the underwriter's over-allotment option to purchase additional shares and warrants, prior to deducting underwriting discounts and commissions and offering expenses payable by us.

The offering was comprised of Class A Units, priced at a public offering price of $1.00 per unit, with each unit consisting of one share of common stock and a seven-year warrant to purchase one share of common stock with an exercise price of $1.00 per share (each, a "Warrant" and collectively, the "Warrants"), and Class B Units, priced at a public offering price of $1.00 per unit, with each unit comprised of one share of series D preferred stock (the "Series D Preferred Stock"), which is convertible into one share of common stock, and a Warrant. The conversion price of the Series D Preferred Stock issued in the transaction as well as the exercise price of the Warrants are fixed and do not contain any variable pricing features or any price based anti-dilutive features. The Series D Preferred Stock issued in this transaction included a beneficial ownership blocker but has no dividend rights (except to the extent that dividends are also paid on the common stock), liquidation preference or other preferences over common stock, and, with certain exceptions, has no voting rights. The securities comprising the units were immediately separable and have been issued separately.

At the closing of our underwritten public offering, a total of 4,436,000 shares of common stock, 9,364,000 shares of Series D Preferred Stock convertible into 9,364,000 shares of common stock, and warrants to acquire 13,800,000 shares of common stock were issued inclusive of the underwriter's exercise of their over-allotment option to purchase 1,800,000 shares of common stock and warrants to acquire 1,800,000 shares of common stock at $1.00 per share.

Since the closing of our underwritten public offering all of the shares of Series D Preferred Stock that were issued have been converted into shares of our common stock in accordance with the terms for conversion and of the warrants issued, an aggregate of 10,265,500 Warrants were exercised for cash. In 2018, 9,505,500 Warrants were exercised and in 2020 an additional 760,000 Warrants were exercised. A total of 10,265,500 shares of Company common stock were issued as a result of the exercise of such Warrants.

The March 25, 2019 Underwritten Public Offering

On March 25, 2019, we announced the closing of an underwritten public offering for gross proceeds of approximately $12.5 million, which included the partial exercise of the underwriter's over-allotment option to purchase additional shares and warrants, prior to deducting underwriting discounts and commissions and offering expenses. The offering was comprised of 16,666,668 shares of common stock, short-term warrants to purchase up to 8,333,334 shares of common stock, and long-term warrants to purchase up to 8,333,334 shares of common stock, at a price to the public of $0.75 per share and accompanying warrants.

In connection with the public offering, we granted the underwriter a 30-day option to purchase up to 2,500,000 additional shares of common stock and/or short-term warrants to purchase 1,250,000 shares of common stock and long-term warrants to purchase 1,250,000 shares of common stock the public offering price, less underwriting discounts and commissions. The underwriter exercised its option to purchase the short-term warrants to purchase 1,250,000 shares of common stock and long-term warrants to purchase 1,250,000 shares of common stock effective as of the closing.

Each short-term warrant had an exercise price of $0.75 per share of common stock, is immediately exercisable, and expired on the earlier of (1) the eighteen-month anniversary of the date of issuance and (2) twenty-one trading days following our release of top-line data related to our Phase 2 double blind, placebo controlled clinical trial of AG013. As a result of our announcement of top-line data on the Phase 2 clinical trial of AG013 on April 15, 2020, the short-term Warrants were subject to expiration on May 14, 2020. On May 14, 2020 9,545,334 of the Company's short-term warrants expired unexercised (exclusive of 38,000 shares previously exercised).

Each long-term warrant has an exercise price of $0.90 per share of common stock, is immediately exercisable and expires five years following the date of issuance. Through December 31, 2020 the Company issued 4,882,114 shares of Common Stock at an exercise price of $0.90 per share issued in connection with the exercise of the long-term warrants. The long-term warrant exercises provided aggregate gross proceeds to the Company of approximately $4.3 million.

November 2020 Public Offering.

On November 24, 2020, we closed an underwritten public offering for gross proceeds of approximately $6.0 million, which included the full exercise of the underwriter's over-allotment option to purchase additional shares, prior to deducting underwriting discounts and commissions and offering expenses. The offering was comprised of 14,189,189 shares of common stock at a price to the public of $0.37 per share. We granted the underwriter a 45-day option to purchase up to 2,128,378 additional shares of our common stock at the public offering price, less underwriting discounts and commissions. The underwriter exercised its option in full to purchase 2,128,378 additional shares of common stock, which the indicated gross proceeds reflect. We intend to use the net proceeds of the offering primarily to continue funding our pre-clinical development of our SARS-CoV-2 vaccine, Terra CoV-2 and our lantibiotics program and for general corporate purposes, including research and development activities, capital expenditures and working capital. Dr. Frederick Telling who is a Director of the Company, participated in the offering through the purchase of 100,000 shares of the Company's common stock. Dr. Telling's participation was approved by the Company's Audit Committee.

December 2020 Registered Direct Offering.

On December 29, 2020, we closed a registered direct offering for gross proceeds of approximately $6.5 million, prior to deducting underwriting discounts and commissions and offering expenses. The offering was comprised of 14,444,444 shares of common stock at a price to the public of $0.45 per share. We intend to use the net proceeds of the offering primarily to continue funding our pre-clinical development of our SARS-CoV-2 vaccine, Terra CoV-2 and our lantibiotics program and for general corporate purposes, including research and development activities, capital expenditures and working capital.

Other Financings

We enter into short term financing arrangements for the payment of our annual insurance premiums for our products liability insurance and directors and officers and employment practices insurance.

Products Liability Insurance

On March 10, 2019, we entered into a short-term note payable for $17,688 bearing interest at 5.69% to finance the product liability insurance. Principal and interest payments on this note began April 10, 2019 and are made evenly based on a straight-line amortization over an 11-month period with the final payment being made on February 14, 2020.

Directors' and Officers' Insurance

On August 24, 2020 we entered into a short-term note payable for $413,784 bearing interest at 5.39% to finance a portion of the directors' and officers' liability insurance and employment practices liability insurance premiums. Principal and interest payments on this note began August 24, 2020 and are made evenly based on a straight-line amortization over an 11-month period with the final payment being due on June 24, 2021.

On August 7, 2019 we entered into a short-term note payable for $254,889 bearing interest at 5.74% to finance a portion of the directors' and officers' liability insurance and employment practices liability insurance premiums. Principal and interest payments on this note began August 24, 2019 and are made evenly based on a straight-line amortization over an 11-month period with the final payment being made on June 22, 2020.

Future Capital Requirements

Our capital requirements for 2021 will depend on numerous factors, including the success of our commercialization efforts and of our research and development, the resources we devote to develop and support our technologies and our success in pursuing strategic licensing and funded product development relationships with external partners. Subject to our ability to raise additional capital including through possible joint ventures and/or partnerships, we expect to incur substantial expenditures to further commercialize or develop our technologies including continued increases in costs related to research, nonclinical testing and clinical trials, as well as costs associated with our capital raising efforts and being a public company. We will require substantial funds to conduct research and development and nonclinical and Phase 1 and Phase 2 clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase 2 and 3 clinical testing and manufacture and marketing of any products that are approved for commercial sale. Our plans include seeking both equity and debt financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to ensure continuation of our operations and research and development programs.

Our current available cash and cash equivalent, provide us with limited liquidity. We believe our existing cash and cash equivalents together with the net proceeds from our ATM facility and warrant exercises, and net of the redemption of the Series C Preferred Stock of approximately $5.6 million, will allow us to fund our operating plan through the second quarter of 2022. We expect to continue to seek additional funding for our operations. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned clinical testing, research and development and commercialization activities, which could harm our business. The sale of additional equity or debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We also will require additional capital beyond our currently forecasted amounts. For example, as we continue to work with EGI under the Lantibiotic ECC for the development of MU1140 homologs we will require additional capital.

Because of the numerous risks and uncertainties associated with research, development and commercialization of our product candidates, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- conduct preclinical research for our Terra CoV-2 vaccine product candidate, file an IND with the FDA and, if approved, engage in Phase 1 clinical trials;
- identifying and securing clinical sites for the conduct of human trials for our product candidates;
- the determination to redeem all or any portion of our outstanding Series C Preferred Stock;
- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting nonclinical and clinical trials including the research and development expenditures we expect to make in connection with our collaboration agreements with Precigen;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;

- our ability to maintain current research and development licensing agreements and to establish new strategic partnerships, licensing or other arrangements and the financial terms of such agreements;

- our ability to achieve our milestones under our Lantibiotic ECC and licensing arrangements and the payment obligations we may have;

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and

- the timing, receipt and amount of sales of, or royalties on, our products and future products, if any.

We have based our estimates on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our shares or debt and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Tax Loss and Credit Carryforwards

At December 31, 2020, we have federal and state tax net operating loss carryforwards of approximately $142,893,000. Federal and state of Florida tax net operating loss carryforwards generated prior to December 31, 2017 will expire through 2037. Federal and state of Florida tax net operating loss carryforwards generated subsequent to December 31, 2017, do not expire and are no longer subject to taxable income limitation pursuant to the Coronavirus Aid, Relief, and Economic Security Act, passed on March 27, 2020. State of Pennsylvania tax net operating loss carryforwards will expire through 2036. The Company also has federal research and development tax credit carryforwards of approximately $4,043,000. The federal tax credit carryforward will expire beginning in 2021 and continuing through 2040, unless previously utilized.

Utilization of net operating loss carryforwards and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or, could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986 (“IRC Section 382”) and with Section 383 of the Internal Revenue Code of 1986, as well as similar state provisions. These ownership changes may limit the amount of net operating loss carryforwards and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change, as defined by IRC Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. The Company has completed several financings since its inception which may result in a change in ownership as defined by IRC Section 382, or could result in a change in control in the future.

At December 31, 2020 and 2019, we recorded a 100% valuation allowance against our deferred tax assets of approximately $36,580,000 and $30,098,000, respectively, as our management believes it is uncertain that they will be fully realized. If we determine in the future that we will be able to realize all or a portion of our net operating loss carryforwards, an adjustment to our net operating loss carryforwards would increase net income in the period in which we make such a determination.

Inflation

Inflation affects the cost of raw materials, goods and services that we use. In recent years, inflation has been modest. However, high energy costs and fluctuations in commodity prices can affect the cost of all raw materials and components. Although we cannot precisely determine the effects of inflation on our business, it is management’s belief that the effects on operating results will not be significant. We do not believe that inflation has had a material impact on our results of operations for the periods presented, except with respect to payroll-related costs and other costs arising from or related to government-imposed regulations.

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

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The Financial Statements are incorporated herein by reference to pages F-1 to F-23 at the end of this report and the supplementary data is not applicable.

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

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

Management's evaluation of the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act was performed under the supervision and participation of our senior management, including our Chief Executive Officer and Chief Financial Officer. The purpose of disclosure controls and procedures is to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of such period, our disclosure controls and procedures were effective as of December 31, 2020 in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported with the time periods specified in the Securities and Exchange Commission's rules and forms. Management believes that, existing controls were effective and operating properly as designed. During 2020, management believes that the Company maintained a consistent and verifiable financial reporting organization and internal control procedures.

Changes in Internal Controls over Financial Reporting

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has concluded there were no other significant changes in our internal controls over financial reporting that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

As a result of the COVID-19 pandemic, certain employees began working remotely in March 2020. Notwithstanding these changes to the working environment, we have not identified any material changes in our internal control over financial reporting. We will continue to monitor and assess the COVID-19 situation to determine any potential impact on the design and operating effectiveness of our internal controls over financial reporting.

Limitations on the Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our Disclosure Controls and internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management or board override of the control.

The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Chief Executive Officer and Chief Financial Officer Certification

Appearing after the Signatures section of this report there is a Certification of the Chief Executive Officer and the Chief Financial Officer. The Certification is required in accordance with Section 302 of the Sarbanes-Oxley Act of 2002 (the Section 302 Certifications). This Item of this report, which you are currently reading is the information concerning the evaluation referred to in the Section 302 Certification and this information should be read in conjunction with the Section 302 Certification for a more complete understanding of the topics presented.

Management's Report on Internal Control over Financial Reporting

The management of Oragenics, Inc. is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in the Securities Exchange Act Rule 13a-15(f). The Company's internal control over financial reporting is a process designed to provide reasonable assurance to the Company's management and board of directors regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

The Company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. All internal control systems, no matter how well designed, have inherent limitations, including the possibility of human error and the circumvention of overriding controls. Accordingly, even effective internal control over financial reporting can provide only reasonable assurance with respect to financial statement preparation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, under the supervision of the Chief Executive Officer and the Chief Financial Officer, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2020. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework (1992)* as updated in May of 2013, (the "2013 COSO Framework"). We integrated the changes prescribed by the 2013 COSO Framework into our internal controls over financial reporting during the year ending December 31, 2015. We also used SEC guidance on conducting such assessments. Based on our assessment, we believe that, as of December 31, 2020, the Company's internal control over financial reporting was effective.

This annual report 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 our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

ITEM 9B. OTHER INFORMATION.

The disclosure set forth below is provided in lieu of a separate Form 8-K filing pursuant to Items 1.01 and 1.02 of Form 8-K.

Amended and Restated Exclusive Channel Collaboration Agreement. On March 1 2021, we amended and restated our exclusive channel collaboration agreement for the development of lantibiotics the amended and restated exclusive channel collaboration agreement (i) incorporated the previous amendments; (ii) updated the name of the counterparty following prior assignments and name changes from Intrexon Corporation to the current counterparty, Eleszto Genetika, Inc.; and (iii) incorporated relevant provisions of the stock issuance agreement, as amended, entered into in connection with the Lantibiotic ECC and terminated the stock issuance agreement, all other terms of the exclusive channel collaboration agreement remained in effect. The foregoing is a summary of the amended and restated exclusive channel collaboration agreement and does not purport to be complete and is qualified in its entirety by reference to the full text of the amended and restated exclusive channel collaboration agreement, a copy of which is filed as **Exhibit 10.1** hereto and is incorporated herein by reference.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Directors and Executive Officers

The following table sets forth the names, ages and titles of the Company's Directors, executive officers, key employees and the position they each hold with the Company.

Name	Age	Position
Dr. Frederick W. Telling, Ph.D.	69	Chairman and Director
Alan Joslyn, Ph.D.	62	President, Chief Executive Officer and Director
Robert C. Koski	62	Director
Charles L. Pope	69	Director
Dr. Alan W. Dunton, M.D.	66	Director
Kimberly M. Murphy	58	Director
Michael Sullivan	64	Chief Financial Officer, Secretary and Treasurer
Dr. Martin Handfield	50	Senior Vice President Discovery Research

Directors of the Company

Dr. Frederick W. Telling. Dr. Telling was elected Chairman of the Board of Directors on February 4, 2011. He has served as a Director since June 2010. Dr. Telling retired from Pfizer Inc. in June 2007 after 30 years of service. At Pfizer Dr. Telling served as its Corporate Vice President and Vice President of Corporate Strategic Planning and Policy. Dr. Telling also serves on the boards of various civic and non-profit organizations. Dr. Telling holds a B.A. degree in History and Economics from Hamilton College and a MA degree in Industrial and Labor Relations and a PhD in Economics and Public Policy from Cornell University.

Dr. Telling brings to our Board an extensive array of business and industry experience as well as experience as a director of public companies.

Alan F. Joslyn, Ph.D. Dr. Joslyn has served as a Director of our company since June 2016. Dr. Joslyn served as Board member of Synergy Pharmaceuticals (NASDAQ: SGYP) from 2009 until 2020. Since 2014, Dr. Joslyn has been a partner in Lazarus Pharmaceuticals, LL. From March 2010 to April 2014, Dr. Joslyn served as CEO and a Director of Sentinella Pharmaceuticals and from August 2009 to October 2012 as CEO and Director of Edusa Pharmaceuticals, both privately held biotechnology companies. From March 2007 to March 2009, Dr. Joslyn served as President and Chief Executive Officer of Mt. Cook Pharma and as Senior Vice President of Research & Development at Penwest Pharmaceuticals from 2004 to 2007. From 1995 to 2004, Dr. Joslyn held a number of leadership positions within Johnson & Johnson focusing on development of gastroenterology products including Propulsid®, Motilium®, Aciphex® and prucalopride. Dr. Joslyn received his B.S. in medicinal chemistry, B.A. in biology and Ph.D. in biochemical pharmacology from the State University of New York at Buffalo.

Dr. Joslyn brings to our Board over two decades of experience in the pharmaceutical industry and extensive expertise in gastroenterology and infectious disease product development.

Charles L. Pope. Mr. Pope has served as a Director since June 2010. Mr. Pope served as the Chief Financial Officer of Palm Bancorp, Inc. from June 2009 to June 2012. From September 2007 through June 2009, Mr. Pope served as the Chief Financial Officer of Aerosonic Inc., a manufacturer of aviation products. Mr. Pope served as the Chief Financial Officer of Reptron Inc., a manufacturer of electronic products, from March 2005 through June 2007. From March 2002 to March 2005, Mr. Pope served as Chief Financial Officer of SRI/Surgical Express, Inc. From February 2001 to March 2002, Mr. Pope served as Chief Financial Officer of Innovaro, Inc. (formerly UTEK Corporation NYSE American: INV) a public company. Mr. Pope served as a director of Innovaro, Inc. from March 2010 to August 2012. Mr. Pope also served as a director of Inuvo, Inc. from July 2008 through July 2018. Prior to this time, Mr. Pope served as a Partner in the Audit and Financial Advisory Consulting Divisions of PricewaterhouseCoopers LLP, and he was also a Partner in the Accounting and SEC Directorate in PricewaterhouseCoopers LLP's New York City office. Mr. Pope holds a B.S. degree in Economics and Accounting from Auburn University and is a Certified Public Accountant in Florida.

Mr. Pope brings to our Board over three decades of experience in the finance and accounting fields. In addition, Mr. Pope also has experience serving as a director of public companies.

Dr. Alan W. Dunton. Dr. Dunton has served as a Director of Oragenics, Inc. since April 2011. He is the principal owner of Danerius, LLC, a biotechnology consulting company which he founded in 2006. In addition to Oragenics, he is currently a Director of the public biotechnology company, Palatin, Inc. (AMEX: PTN), CorMedix (NASDAQ: CRMD) and Regeneus (ASX: RGS). Dr. Dunton is also a member of the Board of Members or Directors of Cytogel Pharma, a privately-held firm in Darien, Connecticut. He previously served as a Director of Sancilio and Company, MediciNova and Targacept, Inc. Dr. Dunton is also a member of the Board of Director of CorMedix, Inc. (CRMD), a publicly traded biotechnology company in Berkeley Heights, New Jersey since March 2019. Dr. Dunton has held significant senior positions in major pharmaceutical companies. Most recent was from November 2015 through March 2018 as the Senior Vice President of Research, Development and Regulatory Affairs of Purdue Pharma L.P., a private pharmaceutical company. From January 2007 until March 2009, Dr. Dunton served as President and Chief Executive Officer of Panacos Pharmaceuticals, Inc. He was the non-Executive Chairman and Director of EpiCept, Inc. (OTC MKTS: EPCT) a public biotechnology company developing products for cancer, pain and inflammatory conditions. In 2005, Dr. Dunton served as the Non-Executive Chairman of the Board of Directors of ActivBiotics, Inc., a private biopharmaceutical company. Previously, he was the President and Chief Executive Officer of Metaphore Pharmaceuticals, Inc. from 2003 until 2006, when it merged with ActivBiotics. From 2004 until 2005, Dr. Dunton served as a member of the board of directors of Vicuron Pharmaceuticals until it was acquired by Pfizer, Inc. In 2002, Dr. Dunton served as President, Chief Operating Officer and a director of Emisphere Technologies, Inc., a biopharmaceutical company. From 1994 to 2001, Dr. Dunton was a senior executive in various capacities in the Pharmaceuticals Group of Johnson & Johnson. From 1999 to 2001, Dr. Dunton was President and Managing Director of The Janssen Research Foundation, a Johnson & Johnson company. From 1998 to 1999, he served as Group Vice President of Global Clinical Research and Development of Janssen. Prior to joining Janssen, Dr. Dunton was Vice President of Global Clinical Research and Development at the R.W. Johnson Pharmaceutical Research Institute, also a Johnson & Johnson company. Prior to joining Johnson & Johnson, Dr. Dunton held positions in clinical research and development at Syntex Corporation, CIBA-GEIGY Corporation and Hoffmann La Roche Inc. Dr. Dunton holds a MD degree from New York University School of Medicine, where he completed his residency in internal medicine. He also was a Fellow in Clinical Pharmacology at the New York Hospital/Cornell University Medical Center.

Dr. Dunton brings to our Board a significant depth of experience in the pharmaceutical industry that will be invaluable to the Company as we continue to develop biotechnology assets.

Robert C. Koski. Mr. Koski has served as a Director since June 2009. Mr. Koski has practiced as an attorney with the Koski Firm, a sole proprietorship located in Atlanta, Georgia since 1992, where his practice includes litigation and tax law. Mr. Koski has also served as a partner in the Koski Family Limited Partnership, which beneficially owns an interest in the Company, and as a director of the Koski Family Foundation since December 1996. Mr. Koski holds a B.A. degree in Philosophy and English from Colgate University, a JD from Emory School of Law and an LLM degree in Taxation and Litigation from Emory University.

Mr. Koski brings to our Board over two decades of experience in the legal field as a practicing attorney. In addition to his legal experience, Mr. Koski's educational background provides a foundation for leadership and consensus-building.

Kimberly M. Murphy. Ms. Murphy has served as a director since May 2020. Before joining the Company, Ms. Murphy served as Vice President of the Influenza Franchise and Global Vaccine Commercialization Leader at GlaxoSmithKline plc (NYSE: GSK) ("GSK"), where she led the global influenza vaccines business, global pandemic preparedness across vaccines and antivirals, lifecycle management, business development, and global P&L management. Ms. Murphy currently serves as a director for Blue Water Acquisition Corp. (NASDAQ: BLUW). Ms. Murphy also served as Vice President and Global Marketing Head for the shingles vaccine, SHINGRIX. From June 2014 to May 2015, Ms. Murphy was Vice President and Lead for the North America Vaccines Integration Planning Team, responsible for the integration planning of GSK's acquisition of Novartis AG's vaccine division. From October 2012 to June 2014, Ms. Murphy served as Vice President of U.S. Vaccines Customer Strategy and from March 2011 to October 2012, she served as the Senior Director of U.S. Influenza Portfolio Strategy. Prior to joining GSK in March 2011, Ms. Murphy worked for Novartis Vaccines and Diagnostics Inc., a division of Novartis AG (NYSE: NVS), as the head of the U.S. Meningococcal Franchise. Before working for Novartis, Ms. Murphy enjoyed a distinguished career at Merck & Co., Inc. (NYSE: MRK). Ms. Murphy has previously served in board and advisory roles for a privately-held vaccine development company, the Biotechnology Industry Organization, the Biodefense Advisory Council, and the Saint Joseph's University Pharmaceutical & Healthcare Marketing MBA Program. Ms. Murphy holds a B.A. degree in English from Old Dominion University and a M.B.A. degree in Marketing from Saint Joseph's University. Ms. Murphy has also completed the Marketing Excellence Program at the Wharton School of the University of Pennsylvania.

Ms. Murphy brings to the Company's Board a wealth of experience in the commercialization and marketing of development-stage vaccine candidates, particularly those created by public companies. Ms. Murphy's skill will be vital to the Company's development of a vaccine candidate for SARS-CoV-2.

Executive Management

Alan F. Joslyn, Ph.D. The biography of Dr. Joslyn is included above.

Michael Sullivan. Mr. Sullivan has served as our Interim Principal Executive Officer from October 30, 2014 until June 5, 2016 and served as our Chief Financial Officer, Secretary and Treasurer since February 6, 2012. Mr. Sullivan has held senior level financial positions for several publicly and privately held businesses including Utek Corporation, eANGLER, and HSN Direct International Limited. Most recently, he was the Group Financial Officer for the Investigative Services and Litigation Consulting Services segment of First Advantage Corporation a firm specializing in talent acquisition solutions where he streamlined the employee recruitment process. Mr. Sullivan is a Florida Certified Public Accountant. He graduated from the Florida State University with a Bachelor of Science in Accounting and a Master of Business Administration.

Key Employee

Dr. Martin Handfield. Dr. Handfield is, the Company's Senior Vice President of Discovery Research and previously has served as our Director of Research and Development. Dr. Handfield has served the Company since January 2009. Prior to joining our Company, Dr. Handfield held a position as Tenured Associate Professor at the Center for Molecular Microbiology and the Department of Oral Biology at the University of Florida College of Dentistry, where he co-invented IVIAT and co-founded *ivi* Gene Corp. and Epicure Corp. to commercialize this and related technologies. Dr. Handfield holds a B.S. degree in Biochemistry, and a MS degree and PhD in Microbiology and Immunology from the Université Laval College of Medicine in Canada, and did postdoctoral training at the University of Florida.

Our executive officers serve at the pleasure of our Board of Directors until their successors are elected or qualified and subject, in certain cases to employment agreements we have entered into with our officers. Our chief Executive Officer and President Dr. Alan Joslyn and Mr. Sullivan, our Chief Financial Officer and Dr. Handfield, our Senior Vice President of Discovery Research, each have employment agreements with us. See "Executive Compensation—Employment Contracts and Change in Control Arrangements."

Board of Directors and Committees

Our property, affairs and business are under the general management of our Board of Directors as provided by the laws of the State of Florida and our Bylaws.

The Board of Directors conducts its business through meetings of the full Board and through committees of the Board. The Board of Directors has appointed standing Audit, Compensation and Nominating and Governance Committees of the Board of Directors.

The Board periodically reviews the size of the Board and recommends any changes it determines to be appropriate given our needs. Under our Bylaws, the number of members on the Board may be increased or decreased by resolution of the Board.

Independence of Directors

Our common stock is listed on a national securities exchange, the NYSE American. Accordingly, in determining whether our Directors are independent, we are required to comply with the rules of the NYSE American. We also expect to continue to comply with securities and other laws and regulations regarding the independence of directors, including those adopted under Section 301 of the Sarbanes-Oxley Act and Rule 10A-3 under the Securities and Exchange Act of 1934 with respect to the independence of Audit Committee members. The NYSE American listing standards define an "independent director" generally as a person, other than an officer of a company, who does not, in the view of the company's Board of Directors, have a relationship with the company that would interfere with the director's exercise of independent judgment. The Board has affirmatively determined that each of the following directors, constituting a majority of the Board, is independent within the meaning of the NYSE American listing standards:

Dr. Frederick W. Telling
Charles L. Pope
Dr. Alan Dunton
Robert Koski
Kimberly W. Murphy

Such independence definition includes a series of objective tests, including that the director is not an executive officer employee of the company and has not engaged in various types of business dealings with the company. In addition, as further required by the NYSE American listing standards, the Board has made a subjective determination as to each independent director that no relationships exist which, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit Committee Financial Expert

The Audit Committee members currently consist of Mr. Charles Pope, Dr. Frederick Telling and Dr. Alan Dunton with Mr. Pope serving as Chairman. The Board has affirmatively determined that each such person met the independence requirements for audit committee purposes based on the more stringent independence standards imposed by applicable NYSE American and SEC rules. In addition, the Board of Directors has determined that Mr. Pope is an "audit committee financial expert" as that term is defined in Item 407(d)(5) of Regulation S-K promulgated under the Securities and Exchange Act of 1934. In March 2004, the Audit Committee adopted a written charter which was modified on April 24, 2007 and on December 29, 2009. The Company believes that its Audit Committee Charter complies with the requirements related to Sarbanes-Oxley and a current copy of the Audit Committee Charter is available on our website http://ir.oragenics.com/governance-docs.

Code of Ethics

We have adopted a code of ethics known as the Company Operating Principles, which is applicable to all of our directors and employees, including our principal executive officer and our principal financial officer. A copy of the Company Operating Principles can be found on our website at www.oragenics.com. Any future amendments to, or waivers from, the Company Operating Principles will be posted on our website.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires the Company's officers and Directors and any persons who beneficially own more than ten percent of the Company's Common Stock to file reports of ownership and changes in ownership of such securities with the Securities and Exchange Commission Officers, Directors and beneficial owners of more than ten percent of the Common Stock are required by applicable regulations to furnish the Company with copies of all Section 16(a) forms they file. Based solely on its review of copies of forms furnished to the Company and written representations from the executive officers and directors, the Company believes, all persons subject to the reporting requirements with regard to the Common Stock complied with the applicable filing requirements during 2020.

ITEM 11. EXECUTIVE COMPENSATION.

Compensation Discussion and Analysis

This section explains the objectives of our named executive officer compensation program, the compensation decisions we made with respect to compensation for our fiscal year ended December 31, 2020, and the factors we considered in making those decisions, and focuses on the compensation of officers who are listed below as our "named executive officers":

- Alan Joslyn, our President and Chief Executive Officer,
- Michael Sullivan, our Chief Financial Officer, and
- Martin Handfield, our Senior Vice President of Discovery Research.

The Compensation Committee of our Board of Directors is responsible for establishing and evaluating our policies governing the compensation of our executive officers, including its named executive officers. The Compensation Committee reviews and proposes recommendations to the Board of Directors regarding the compensation to be paid to the Chief Executive Officer. In addition, the Compensation Committee reviews and approves the compensation to be paid to all other executive officers. The Compensation Committee ensures that the total compensation paid to our executive officers is fair, reasonable and competitive. The Compensation Committee has, in the past, at times included the other members of our Board of Directors in its deliberations regarding the salaries of our named executive officers.

At our 2020 Annual Meeting of Stockholders, on an advisory basis, a majority of the stockholders who voted on this matter approved the compensation of our named executive officers as disclosed in our 2020 Proxy Statement. The Compensation Committee believes the views of our stockholders are an important consideration when making decisions regarding our compensation program and will continue to take the views of our stockholders into consideration when assessing our compensation program and making decisions related to the structure and amount of pay.

Business Highlights

This past year was significant for the Company as we transitioned to the development of the Terra CoV-2 immunization product candidate to combat the novel coronavirus pandemic. Our compensation program in 2020 reflects the challenges associated with designing a compensation program at the beginning of the year in light of the efforts directed at the enrollment in a clinical trial and then transitioning to the development of a vaccine. Despite such challenges, the Compensation Committee remains committed to a philosophy which strongly aligns pay with demonstrated performance, and is confident that the decisions made are reflective of this overarching philosophy.

Compensation Objective

Our named executive compensation programs are designed to achieve the following objectives:

- Attract, motivate and reward named executive officers whose knowledge, skills, performance and business relationships are critical to our success;
- Align the interests of our named executive officers and stockholders by motivating named executive officers to ultimately increase stockholder value as well as facilitate retention;
- Motivate our named executive officers to manage our business to meet our short term and long-range goals and reward accomplishment of these goals;
- Provide a competitive compensation package which includes some pay for performance factors.

Compensation Determination Process

We conduct an annual review of named executive officer compensation, generally in December or January. At the Compensation Committee's direction, our Chief Executive Officer prepares an executive compensation review for each named executive officer, other than himself, which may include recommendations for:

- a proposed year-end bonus, if any, based on the achievement of individual and/or corporate objectives;
- a proposed increase, if any, in base salary and target annual incentive opportunity for the upcoming year; and
- an award, if any, of stock options or stock awards for the year under review.

As part of the compensation review, our Compensation Committee also considers changes to a named executive officer's employment agreement, compensation arrangements, responsibilities or severance arrangements.

In accordance with NYSE American requirements, the Compensation Committee also meets in an executive session without the Chief Executive Officer to consider and make recommendations to our Board of Directors regarding the Chief Executive Officer's compensation, including base salary, cash bonus and year-end annual stock options. The Compensation Committee also grants year-end stock options to other named executive officers based on, among other factors, recommendations by our Chief Executive Officer.

In conjunction with the year-end annual compensation review, or as soon as practicable after the fiscal year-end, our Chief Executive Officer recommends to the Compensation Committee the corporate objectives and other criteria to be utilized for purposes of determining cash bonuses (i) for each named executive officer for the upcoming year (in accordance with that named executive officer's employment agreement), and (ii) for all other employees as a group. The Compensation Committee in its discretion may revise our Chief Executive Officer's recommendations or make its own recommendations to our Board of Directors, which may in turn suggest further revisions. At the end of the year, the Compensation Committee, in consultation with our Chief Executive Officer, reviews performance and determines the extent to which any established goals were achieved.

Setting Compensation for Named Executive Officers - Compensation Committee, Board of Directors and Chief Executive Officer

The Compensation Committee of our Board of Directors has the primary responsibility for determining compensation of our named executive officers. Our Compensation Committee recommends the compensation of our Chief Executive Officer and determines all compensation matters for our named executive officers, including base salary, bonuses, and equity compensation. Our Board of Directors, after considering the recommendations of the Compensation Committee, makes the final determination with respect to the compensation of our Chief Executive Officer. Utilizing input from our Chief Executive Officer, the Compensation Committee makes an independent decision on compensation for each other named executive officers, although our Compensation Committee has, on occasion, submitted its compensation determinations for named executive officers to our full Board of Directors for its approval.

Role of Compensation Consultant

Our Compensation Committee is authorized to engage a compensation consultant or other advisors to review our executive officers' compensation, including a benchmarking analysis against the compensation of executive officers at comparable companies, to ensure that our compensation is market competitive, with the goal of retaining and adequately motivating our senior management. In March 2019 and January of 2020, our Compensation Committee retained Korn Ferry as a compensation consultant ("Korn Ferry") to assess our current compensation programs and provide recommendations for continued improved alignment of the programs with our compensation philosophy and goals and to review and make recommendations regarding our executive and director compensation for 2019 and 2020.

Our Compensation Committee regularly evaluates the performance of its compensation consultant, considers alternative compensation consultants, and has the final authority to engage and terminate such services. The Compensation Committee has assessed the independence of Korn Ferry pursuant to SEC rules and the applicable listing standards of the NYSE American and concluded that no conflict of interest exists that would prevent Korn Ferry from serving as an independent consultant to our Compensation Committee.

During 2019 and 2020, Korn Ferry attended meetings of our Compensation Committee (both with and without management present) and provided the following services:

- consulting with the Compensation Committee chair and other members between committee meetings;
- establishing a compensation comparator peer group for use when making compensation decisions;
- providing competitive market data based on the compensation peer group for our executive officer positions and evaluating how the compensation we pay our executive officers compares both to our performance and to how the companies in our compensation peer group compensate their executives;

- reviewing and analyzing the base salary levels, annual cash bonus opportunities, and equity incentive compensation opportunities of our executive officers;
- assessing executive compensation trends within our industry, and updating on corporate governance and regulatory issues and developments;
- reviewing market equity compensation practices, including burn rate and overhang, and advising on the mix of equity award types; and
- providing competitive market data based on the compensation peer group for the non-employee members of our Board and evaluating the compensation we pay to our non-employee directors.

Benchmarking in the Context of Our Other Executive Compensation Principles

Our Compensation Committee reviews the compensation of similarly-situated executive officers at companies that we consider to be our peers, taking into consideration the experience, position and functional role, level of responsibility and uniqueness of applicable skills of both our executive officers and those of our peers, and the demand and competitiveness for attracting and retaining an individual with each executive officer's specific expertise and experience. While this analysis is helpful in determining market-competitive compensation for senior management, it is only one factor in determining our executive officers' compensation, and our Compensation Committee exercises its judgment in determining the nature and extent of its use.

For purposes of comparing our executive compensation against the competitive market, our Compensation Committee reviews and considers the compensation levels and practices of a group of comparable biotechnology companies. The companies in this compensation peer group for 2019 and 2020 were selected by our Compensation Committee in March 2019 and reviewed in January 2020, in consultation with Korn Ferry, on the basis of their similarity to us in terms of size, market capitalization, stage of development, research and development spend, industry sector, business strategy, and number of employees.

To analyze the compensation practices of the companies in our compensation peer group, Korn Ferry gathered data from public filings (primarily proxy statements) and from other sources. This market data was then used as a reference point for our Compensation Committee to assess our current compensation levels in the course of its deliberations on forms and amounts of compensation. Given our objective of attracting, retaining, motivating, and rewarding a highly-skilled team of executive officers and other employees, we aim to deliver a total compensation package that is within a competitive range around the median as compared to peers, with an emphasis on equity incentive compensation so as to more effectively tie our named executive officers and employees' interests to those of our shareholders. In light of this, when undertaking its competitive analysis, our Compensation Committee reviews data pertaining to the 25th, 50th and 75th percentiles for base salary, total cash compensation (base salary plus annual bonus) and equity compensation. This competitive analysis is one factor, among others, taken into account by our Compensation Committee in assessing current compensation levels and recommending changes to compensation or additional awards of equity. Our Compensation Committee expects to review our compensation peer group at least annually and make adjustments to its composition, taking into account changes in both our business and the businesses of the companies in the peer group.

Our Compensation Committee believes that, given the competitiveness of our industry and our Company culture, our base compensation, annual cash bonuses and equity programs are flexible enough to reward the achievement of clearly defined corporate goals and are sufficient to retain our existing executive officers and to hire new executive officers with the appropriate qualifications and experience.

Elements of Named Executive Compensation

For 2020, the principal components of compensation for our named executive officers consisted of:

- Annual base salary;
- Annual bonus incentives; and
- Equity Incentive Awards/Option Awards.

Annual Base Salary

We provide our named executive officers with base salary to compensate them for services rendered during the year. Generally, the base salaries reflect the experience, skills, knowledge and responsibilities required of each executive officer, and reflect our executive officers' overall performance and contributions to our business.

During its review of base salaries for executives, the Compensation Committee primarily considers:

- the negotiated terms of each named executive officer's employment agreement, if any;
- an internal review of the named executive officer's compensation, both individually and relative to other named executive officers; and
- base salaries paid by comparable companies in the biopharmaceutical industry that have a similar business and financial profile.

Salary levels are considered annually as part of the company's performance review process. Merit-based increases to salaries are based on management's assessment of the individual's performance, the recommendations made by the Chief Executive Officer to the Compensation Committee, and the comparative compensation at peer companies. The factors used in determining increases in base salary include individual performance, changes in role and/or responsibility and changes in the competitive market environment. The Compensation Committee periodically reviews the base salary for each executive officer.

Annual Incentive Bonuses

We provide an opportunity for each of our named executive officers to receive an annual incentive bonus based on the satisfaction of individual and company objectives established by our Board of Directors, or if no objectives are established at the discretion of the Committee. These incentives are paid in cash. For any given year, these objectives may include individualized goals or company-wide goals that relate to operational, strategic or financial factors such as progress in developing our product candidates, achieving certain manufacturing, intellectual property, clinical and regulatory objectives, and raising certain levels of capital.

2020 Bonus Plan

The Company established performance-based bonus targets for its named executive officers in 2020 (the "2020 Bonus Plan"). The percentages were weighted for purposes of determining bonuses, if any, for the Company's executive officers with respect to 2020 performance. Under such cash bonus program, Dr. Joslyn, Mr. Sullivan, and Dr. Handfield were eligible for cash bonuses of up to 50%, 35% and 25% of their respective base salaries, or $183,750, $80,483, and $51,345 respectively, (each a "Bonus Target").

The bonuses payable to Dr. Joslyn were to be based upon the achievement of the following objectives:

(i) Up to 60% of the Bonus Target for objectives related to AG013 clinical trials and development strategy;

(ii) Up to 25% of the Bonus Target for financial performance objectives relating to the Company raising capital; and

(iii) Up to 15% of the Bonus Target for administrative and management matters.

The bonuses payable to Mr. Sullivan were to be based upon the achievement of the following objectives:

(i) Up to 80% of the Bonus Target for financial performance objectives including the Company's raising capital, budgeting and regulatory compliance;

(ii) Up to 10% of the Bonus Target for initiatives regarding Company development opportunities; and

(iii) Up to 10% of the Bonus Target for administrative and management matters.

The bonuses payable to Dr. Handfield were to be based upon the achievement of the following objectives:

(i) Up to 50% of the Bonus Target for objectives related to lantibiotic program developments, including toxicology study and manufacturing;

(ii) Up to 25% of the Bonus Target for strategic initiatives on collaboration development opportunities including diligence; and

(iii) Up to 20% of the Bonus Target for financial performance objectives relating to grant funding; and

(iv) Up to 5% of the Bonus Target for administrative and management matters.

The executive officers' actual bonuses for fiscal year 2020 were eligible to exceed 100% of their 2020 Bonus Target percentage in the event performance exceeded the predetermined goals and/or upon the achievement of other specified goals, including stretch goals. Payment of bonuses to the Company's executive officers under the 2020 Bonus Plan and the actual amount of such bonus, if any, were subject to the discretion of the Committee.

Equity Incentive Compensation

We believe that successful long-term corporate performance is more likely to be achieved with a corporate culture that encourages a long-term focus by our named executive officers and other employees through the use of equity awards, the value of which depends on our stock performance. We established our 2012 Equity Incentive Plan, as amended to provide all of our employees, including our named executive officers, with incentives to help align our employees' interests with the interests of our stockholders and to enable them to participate in the long-term appreciation of our stockholder value. Additionally, equity awards provide an important retention tool for all employees, as the awards generally are subject to vesting over an extended period of time based on continued service with us.

We typically grant equity awards in connection with hiring a new employee. In addition, equity awards may also be granted for performance annually at, or soon after, the end of each year, depending on position, performance and tenure at the Company.

The determination of whether to grant stock options, as well as the size of such grants, to our named executive officers involves assessments by the Compensation Committee and our Board of Directors and, with respect to named executive officers other than himself, our Chief Executive Officer. Generally, annual equity awards are driven by our desire to retain and motivate our named executive officers, and we consider individual performance and contributions during the preceding year to the extent the Compensation Committee and our Board of Directors believe such factors are relevant. As with base salary and cash bonuses, in evaluating and determining stock option grants to our named executive officers, the Compensation Committee and our Board of Directors also considers publicly available data prepared by Korn Ferry at the request of the Compensation Committee from other similar clinical stage companies identified by the Compensation Committee.

We currently grant stock options or stock awards to new employees when they join our Company based upon their position with us and their relevant prior experience. The range of options that can be granted to employees is prescribed in a schedule based on employee's title and position. The awards granted by the Compensation Committee generally vest over time during the ten-year option term (although some previously granted awards vest immediately), or upon the achievement of certain milestones. Unless otherwise agreed to by us with respect to a termination without "cause" or for "good reason," vesting and exercise rights generally cease upon termination of employment, except in the case of death (subject to a one-year limitation), disability or retirement. Prior to the exercise of an option, the holder has no rights as a stockholder with respect to the shares subject to such option, including voting rights or the right to receive dividends or dividend equivalents. In addition to the initial option grants, our Compensation Committee may grant additional options to retain our employees and reward, or provide incentive for, the achievement of corporate goals and strong individual performance. Our Board of Directors has not granted our Chief Executive Officer the discretion to grant options to non-executive employees upon joining our Company, or to make grants during each annual non-executive employee review cycle.

It is our policy to award stock options at an exercise price equal to the closing price on the NYSE American Market of our common stock on the date of the grant. For purposes of determining the exercise price of stock options, the grant date is deemed to be the later of the first day of employment for newly hired employees, or the date on which the Compensation Committee approves the stock option grant.

We have no program, practice or plan to grant stock options, in coordination with the release of material nonpublic information. We also have not timed the release of material nonpublic information for the purpose of affecting the value of stock options or other compensation, and we have no plan to do so. We do, however, have a policy regarding the adjustment or recovery of stock option awards in connection with the restatement of our financial statements, as our stock option awards have not been tied to the achievement of specific financial statement goals.

Other Compensation

Other aspects of compensation applicable to our named executive officers consist of the following:

Retirement Benefits. We maintain a Simple Individual Retirement Arrangement plan in which all full-time employees, including our named executive officers, are eligible to participate. We provide this plan to help its employees save some amount of their cash compensation for retirement in a tax efficient manner. We do not provide an option for its employees to invest in our stock under the 401k plan. We match 100% of the employee's contribution up to a maximum of 3% of the employee's compensation.

Health and Welfare Benefits. All full-time employees, including our named executive officers, may participate in our health and welfare benefit programs, including medical, dental and vision care coverage as may be provided and applicable to all employees.

Perquisites. We do not provide perquisites or other personal benefits to our named executive officers other than those that we provide to our employees.

Employment Agreements. During 2020, we had employment agreements in effect with Dr. Alan Joslyn, Mr. Michael Sullivan, and Dr. Martin Handfield. We entered into employment agreements with these officers to ensure that they would perform their respective roles with us for an extended period of time. In addition, we also considered the critical nature of each of their positions and our need to retain them when we committed to these agreements. In June 2020, we amended Dr. Joslyn's agreement to extend the term for a two-year period. See "Employment Contracts and Change in Control Arrangements."

2020 Named Executive Officer Compensation Decisions

We believe that the total compensation paid to our named executive officers for the fiscal year ended December 31, 2020 achieved the overall objectives of our executive compensation program. In accordance with our overall objectives, we believe executive compensation for 2020 was competitive with other similarly-sized companies. The Compensation Committee took the following key compensation actions in 2020:

Base Salaries

During 2020, we made no changes in the annual base salaries of our named executive officers.

Determination of Cash Bonus-2020

We made performance-based cash bonus awards pursuant to the terms of the 2020 Bonus Plan to Dr. Joslyn, Mr. Sullivan, and Dr. Handfield of $137,813, $60,361, and $38,509, respectively, based upon their performance during 2020. These performance-based cash bonus awards were made in January of 2021.

***Determination of Equity Awards*:**

We made stock option grants to Dr. Joslyn, Mr. Sullivan, and Dr. Handfield, under the Company's 2012 Equity Incentive Plan consisting of (i) an annual grant ("Annual Award"); and (ii) a retention grant (the "Retention Award"). Dr. Joslyn, Mr. Sullivan, and Dr. Handfield, received Annual Awards which vested immediately on the date of grant to purchase 400,000, 250,000 and 220,000 shares of Company common stock, respectively, at an exercise price of $0.48 per share, the closing price of the Company's common stock on the grant date, February 5, 2020. Each of these officers also received a separate Retention Award which is subject to time-based vesting in equal annual installments over a three-year period on the first, second and third anniversaries of the date of grant, to purchase 400,000, 250,000 and 220,000 shares of Company common stock, respectively, at an exercise price of $0.48 per share, the closing price of the Company's common stock on the grant date, February 5, 2020. The stock option awards are subject to the standard terms and conditions of the Company's form of stock option agreement which includes, as applicable, earlier vesting upon a change in control of the Company.

Other Policies and Considerations - Employment Contracts and Change in Control Arrangements

Employment Agreement—Dr. Joslyn

We have entered into an Executive Employment Agreement dated as of June 6, 2016, with Dr. Alan Joslyn pursuant to which Dr. Joslyn serves as our President and Chief Executive. The employment term was a one-year term with an automatic 12-month extension thereafter unless either party provides the other 30 days' prior written notice of its intention not to renew the employment agreement.

Dr. Joslyn received a one-time signing bonus of $25,000 upon execution of the employment agreement and is currently entitled to receive an annual base salary of $350,000 which is subject to annual review and adjustment by the Company's Board of Directors. He is eligible to receive annual performance bonus from the Company of up to fifty percent (50%) of his annual base salary based upon appropriate Company-based and individual-based targets specified by the Compensation Committee of the Board, in its discretion, as approved by the full Board of Directors. Dr. Joslyn is also entitled to participate in our employee benefit plans on terms comparable to other full-time employees as well as four weeks paid vacation annually.

The employment agreement also provided for Dr. Joslyn to be granted equity awards under the Company's 2012 Incentive Plan consisting of (i) stock options to purchase 30,000 shares of the Company's common stock at an exercise price equal to $5.50 per share which stock options shall vest is six installments of 5,000 shares each every six months after June 6, 2016, provided that he has continued his employment with the Company through such dates, and (ii) 3,000 shares of restricted stock of the Company, vesting in two installments on the six month and twelve month anniversaries of June 6, 2016. All of the performance bonuses, as well as any equity awards which are granted to Dr. Joslyn or which become vested as a result of the satisfaction of financial performance goals of the Company, are subject to the Company's policy on recoupment or clawback of executive incentive compensation.

Dr. Joslyn is subject to a covenant not to disclose our confidential information during his employment term and an assignment of intellectual property rights. Also, during his employment term and for a period of 12 months thereafter, Dr. Joslyn covenants not to compete with us and not to solicit any of our customers, vendors or employees. If Dr. Joslyn breaches any of these covenants, the Company will be entitled to injunctive relief.

If Dr. Joslyn's employment is terminated by us for Cause (as defined in his employment agreement) or by Dr. Joslyn during the term of the agreement, he will be entitled to receive his (i) his then-current annual base salary through the date of termination; (ii) any reimbursable expenses for which he has not yet been reimbursed as of the date of termination; and (iii) any other rights and vested benefits (if any) provided under employee benefit plans and programs of the Company, determined in accordance with the applicable terms and provisions of such plans and programs ("Accrued Compensation").

If Dr. Joslyn's employment is terminated by us without "Cause", subject to his execution of a release of claims against us, and in addition to the payment of the Accrued Compensation, the Company is obligated to make payments to Dr. Joslyn within 60 days after his termination date equal to six months of his annual base salary, as in effect at the termination date, plus any earned but unpaid bonus (the "Additional Severance Payments").

The employment agreement also contains change of control provisions providing that if Dr. Joslyn's employment with the Company is terminated by the Company without Cause during the period of ninety (90) days following a Change in Control (as that term is defined below) of the Company, in lieu of the Additional Severance Payments described above, Dr. Joslyn will be entitled to receive a severance payment equal to the sum of (i) six (6) months of his annual base salary, at the higher of the base salary rate in effect on the date of termination or the base salary rate in effect immediately before the effective date of the Change of Control, and (ii) his Performance Bonus for the year which includes the effective date of the Change in Control, payable at the target level of performance, which will be paid in a single lump sum after his execution and non-revocation of the Release. In addition, he will also receive in the same payment the amount of any performance bonus that, as of the date of termination, has been earned by Dr. Joslyn but has not yet been paid by the Company. If Dr. Joslyn holds any stock options or other stock awards granted under the Company's 2012 Incentive Plan which are not fully vested at the time his employment with the Company is terminated by the Company without Cause during the period of ninety (90) days following a Change in Control, such equity awards shall become fully vested as of the termination date. For purposes of the employment agreement, the term "Change in Control" means a transaction or series of transactions which constitutes a sale of control of the Company, a change in effective control of the Company, or a sale of all or substantially all of the assets of the Company, or a transaction which qualifies as a "change in ownership" or "change in effective control" of the Company or a "change in ownership of substantially all of the assets" of the Company under the standards set forth in Treasury Regulation section 1.409A-3(i)(5).

Dr. Joslyn's employment agreement also provides that each of the payments and benefits under the agreement are subject to compliance with Section 409A of the Code and it includes time of payment language intended to comply with Section 409A requirements.

Amendment to Dr. Joslyn's Employment Agreement

On June 8, 2018 we entered into an amendment to Dr. Joslyn's employment agreement which extended the term of his agreement to June 6, 2020. All other terms of his employment agreement remained in full force and effect. On June 5, 2020, we entered into a second amendment that extended the term for another two years.

Employment Agreements—Mr. Sullivan and Dr. Handfield

We have entered into employment agreements with our Chief Financial Officer, Mr. Michael Sullivan and Dr. Martin Handfield, our Senior Vice-President of Research and Development (the "Employment Agreements"). The annual base salaries provided in the Employment Agreements are payable in installments consistent with our normal payroll practices. Mr. Sullivan and Dr. Handfield are also eligible under the Employment Agreements to receive annual bonuses during the term at the discretion of the Compensation Committee and the Board of Directors with Mr. Sullivan's employment agreement providing for such a discretionary bonus of up to 35% of his base salary and with Dr. Handfield's employment agreement providing for a discretionary bonus component, which the Compensation Committee has set as up to 25% of his base salary.

The Employment Agreements are terminable at any time by either party and if the executive officer is involuntarily terminated by us, he shall receive his base salary and vacation pay each accrued through the date of termination, and any nonforfeitable benefits earned and payable to him under the terms of the employee handbook (which applies to all employees) and benefits available under any applicable incentive plan in which the executive participates. In addition, if the executive officer's separation from employment is not voluntary and without cause, we would be obligated to pay the executive officer six months of his annual base salary as severance and the executive shall be entitled to out placement services. If the executive officer is terminated for cause, he shall be entitled to receive his base salary and accrued vacation due through the date of termination and any nonforfeitable benefits already earned and payable to the executive under the terms of the employee handbook or other applicable incentive plans maintained by us. Cause is defined in the Employment Agreements as any action that is illegal, immoral, or improper that reflects on the Company, the employee, or the ability of either to function optimally. If the executive officer voluntarily resigns, he shall be entitled to this base salary and accrued vacation due through the date of termination (including any mutually agreed upon notice period) and any nonforfeitable benefits already earned and payable to the executive officer employee under the terms of the employee handbook or other incentive plans maintained by us.

If the executive officer dies during the term of employment with us, his estate shall be paid his salary as it would have accrued over a period of thirty days after the executive officer's death. We shall also extend the executive officer's right to exercise vested stock options for six months. In the event the executive officer becomes disabled (as defined in the then applicable short and long-term disability insurance policies) we shall pay to the executive officer his salary as it would have accrued over a period of 30 days after the executive became so disabled and we shall extend the executive officer's right to exercise vested stock options for six months.

The Employment Agreements also each include non-disclosure and Company ownership of invention provisions, as well as a provision providing for the Company to defend and indemnify the executive if the executive is named as a defendant in any lawsuit regarding any action taken within the scope of employment. In the event of a change in control, any stock options or other awards granted (other than performance awards) under our 2012 Incentive Plan shall become immediately vested in full and, in the case of stock options, exercisable in full. If the change in control results in an involuntary separation from employment of the executive officer within 180 days following a change in control, the executive officer would be entitled to (i) receive six months of salary and the extension of his benefits (excluding vacation time and paid time off) and (ii) exercise vested options for six months from the date of separation. Under the Employment Agreements, "involuntary separation of employment" means (i) termination without cause, (ii) any reduction in responsibilities of office altering the status of the executive officer as an employee, or (iii) the duplication of the executive officer's position by an equivalent executive in an acquiring entity; and "change in control" means the sale of the entire company, or substantially all of its assets, or the sale of the business unit employing an individual which results in the termination of employment or subsequent transfer of the employment relationship to another legal entity, or entity, or single party acquiring more shares than are owned by the Koski Family Limited Partnership, including its members and their immediate families, including spouses and their children.

On February 20, 2015, we entered into an amended and restated employment agreement, effective January 1, 2015, with Mr. Sullivan. The terms of Mr. Sullivan's amended and restated employment agreement were substantially similar to those of the previous agreement disclosed above except for:

1. The percentage of base salary eligible for bonus awards was set as previously disclosed for Mr. Sullivan at up to 35% of base salary.

2. A provision was added in Mr. Sullivan's agreement to provide for the clawback of bonuses pursuant to the Board's adoption of a clawback policy. In the A&R Employment Agreement Mr. Sullivan acknowledges and agrees that any incentive-based compensation paid to him will be subject to clawback or repayment to the extent such clawback or repayment is required by the terms of the Company's recoupment, clawback or similar policy as may be in effect from time to time, or as required by law.

3. A provision was added whereby Mr. Sullivan would be required to release the Company as a condition to receiving any severance benefit provided by his A&R Employment Agreement with the form of release added and attached as an exhibit to his A&R Employment Agreement.

4. The definition of a change of control in the prior agreement was revised to align it with the definition of a change in control set forth in the Company's 2012 Incentive Plan as follows:

   (i) Any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) becomes the "beneficial owner" (as defined in Rule 13d 3 of the Exchange Act), directly or indirectly, of securities of the Company representing fifty percent (50%) or more of the total voting power represented by the Company's then outstanding voting securities;

   (ii) The consummation of the sale or disposition by the Company of all or substantially all of the Company's assets;

   (iii) A change in the composition of the Board occurring within a two-year period, as a result of which fewer than a majority of the directors are Incumbent Directors. "Incumbent Directors" means directors who either (A) are Directors as of the effective date of this Agreement, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company); or

   (iv) The consummation of a merger or consolidation of the Company with any other corporation, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its parent) at least fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity or its parent outstanding immediately after such merger or consolidation.

Tax and Accounting Implications

Deductibility of Executive Compensation

The Compensation Committee takes into consideration the tax consequences of compensation to the named executive officers, but tax considerations are not a significant part of our Company's compensation policy.

Accounting for Share-Based Compensation

We account for share-based compensation in accordance with the requirements of FASB ASC Topic 718. This accounting treatment has not significantly affected our executive compensation decisions.

Clawbacks

In order to further align management's interests with those of shareholders and to support the Company's governance practices, the Board of Directors adopted a recoupment policy applicable to annual bonuses and other short-term and long-term incentive compensation based on financial targets ("Incentive Compensation") received by current and former executive officers of the Company and such other senior executives/employees of the Company who may from time to time be deemed subject to the policy by the Board of Directors ("Covered Executive"). The policy provides that if, as a result of a restatement of the Company's financial statements due to the Company's material noncompliance with any financial reporting requirement under the securities laws, a Covered Executive received more Incentive Compensation than the Covered Executive would have received absent the incorrect financial statements, the Company shall recover said excess Incentive Compensation (defined as the excess of (i) the actual amount of Incentive Compensation paid to the Covered Executive over (ii) the Incentive Compensation that would have been paid based on the restated financial results during the three-year period preceding the date on which the Company is required to prepare such restatement). The policy also provides that if the Board of Directors makes a determination in its sole discretion that a Covered Executive engaged in Misconduct (as defined below), the Board of Directors may require reimbursement or forfeiture of all or part of the Incentive Compensation received by the Covered Executive. The Board of Directors may use its judgment in determining the amount to be recovered. Misconduct is defined as (i) conviction of a felony, (ii) material breach of any agreement with the Company, (iii) material breach of any Company policy or code, (iv) act of theft, embezzlement or fraud, (v) misrepresentation or misstatement of financial or performance results, and (vi) any other act or event that the Board of Directors has determined that recoupment is appropriate.

Consideration of Stockholder Advisory Vote on Executive Compensation

The Compensation Committee also expects to consider the results of our stockholder advisory vote on executive compensation. At the Company's previous annual meeting, our shareholders voted in favor of the compensation of our named executive officers: approximately 91.7% of the shares represented in person or by proxy having voted in favor of the program. In light of these results, the Compensation Committee decided to substantially continue the executive compensation program in 2020. The Board of Directors determined that stockholder advisory votes on executive compensation will be submitted to our shareholders annually until the next required advisory vote on the frequency of conducting advisory votes on executive compensation.

Summary Compensation Table

The following table sets forth the aggregate compensation in 2020 and 2019 for services in all capacities paid or accrued by the Company to Dr. Alan Joslyn, Mr. Michael Sullivan, and our next most highly compensated officers who earned more than $100,000 in total salary and bonus during the fiscal year ended December 31, 2020 (the "Named Executive Officers").

Name and principal position	Year	Salary	Bonus(1)	Stock Awards (2)	Option Awards (2)	All Other Compensation (3)	Total
Dr. Alan Joslyn	2020	$367,500	$137,813	$ —	$376,000	$ 21,326	$902,639
President and Chief Executive Officer	2019	$367,500	$ 87,282	$ —	$ —	$ 33,612	$488,394
Michael O. Sullivan	2020	$229,950	$ 60,361	$ —	$235,000	$ 6,899	$532,210
Chief Financial Officer	2019	$229,950	$ 76,458	$ —	$ —	$ 6,899	$313,307
Dr. Martin Handfield	2020	$205,380	$ 38,509	$ —	$206,800	$ 6,162	$456,851
Senior Vice President Discovery Research	2019	$205,380	$ 33,374	$ —	$ —	$ 6,162	$244,916

(1) The amounts in this column for 2020 represent a performance-based cash bonus award made pursuant to the terms of the 2020 Bonus Plan which was earned in 2020 and paid in early January 2021.

(2) The amounts in this column represent the aggregate grant date fair value computed in accordance with Financial Accounting Standards Board Accounting Standards Codification, Topic 718, Compensation—Stock Compensation (ASC 718). On February 5, 2020, Dr. Joslyn, Mr. Sullivan, and Dr. Handfield were awarded stock options, under the Company's 2012 Equity Incentive Plan consisting of (i) an annual grant ("Annual Award"); and (ii) a retention grant (the "Retention Award"). Dr. Joslyn, Mr. Sullivan, and Dr. Handfield, received Annual Awards which vested immediately on the date of grant to purchase 400,000, 250,000 and 220,000 shares of Company common stock, respectively, at an exercise price of $0.48 per share, the closing price of the Company's common stock on the grant date, February 5, 2020. Each of these officers also received a separate Retention Award which is subject to time-based vesting in equal annual installments over a three-year period on the first, second and third anniversaries of the date of grant, to purchase 400,000, 250,000 and 220,000 shares of Company common stock, respectively, at an exercise price of $0.48 per share, the closing price of the Company's common stock on the grant date, February 5, 2020. The stock option awards are subject to the standard terms and conditions of the Company's form of stock option agreement which includes, as applicable, earlier vesting upon a change in control of the Company. Under Securities and Exchange Commission rules relating to executive compensation disclosure, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Fair values relating to share grants have been determined under ASC 718 and were calculated using the common stock closing price on the date of grant and multiplying that price by the number of shares subject to the share grant. The equity-based compensation expense relating to the stock grants is recognized over the requisite service period of the grant. For option awards, we utilize the Black-Scholes option pricing model to determine the fair value on the date of the grant multiplied by the number of options subject to the option grants in accordance with ASC 718. The stock-based compensation expense relating to the stock option grants is recognized over the requisite service period of the grant and the amounts included in the Option Awards column do not reflect compensation actually received by the named executive officers. For information on the assumptions used to calculate the fair value of stock option grants, refer to Note 8 - "Stock Compensation Plan" in our financial statements for the year ended December 31, 2020.

(3) Amounts in this column for Dr. Joslyn, Mr. Sullivan and Dr. Handfield represent the Company's matching contributions to our Simple IRA retirement plan. The retirement plan requires us to match employee contributions up to the first 3% of compensation earned. For Dr. Joslyn, the amount reflected also includes $10,301 which represents amounts reimbursed by the Company for Dr. Joslyn's expense in commuting to the Company's headquarters in Tampa, Florida. Such reimbursement amount is included in Dr. Joslyn's compensation.

The Compensation Committee believes that our future success depends, in large part, upon our ability to maintain a competitive position in attracting, retaining and motivating key personnel. The Compensation Committee utilizes the 2012 Equity Incentive Plan to provide incentives to employees. We do not have any separate long-term incentive plans that provide compensation intended to serve as incentives for performance other than awards contemplated under, or pursuant to, our 2012 Equity Incentive Plan.

Outstanding Equity Awards

The following table provides information concerning unexercised options outstanding as of December 31, 2020:

Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date
Dr. Alan Joslyn	400,000	400,000(1)	0.48	2/5/2030
President and Chief Executive Officer	400,000		0.73	9/27/2028
	28,000		1.52	6/22/2028
	14,000		3.70	6/22/2027
	30,000		5.50	6/6/2026
Michael O. Sullivan	250,000	250,000(1)	0.48	2/5/2030
Chief Financial Officer	250,000		0.73	9/27/2028
	18,000		1.52	6/22/2028
	17,500		3.70	6/22/2027
	20,000		13.20	3/16/2025
	4,000		8.80	12/8/2024
	2,500		8.60	10/30/2024
	4,500		12.00	2/10/2022
Dr. Martin Handfield	220,000	220,000(1)	0.48	2/5/2030
Senior Vice President of Discovery Research	220,000		0.73	9/27/2028
	16,000		1.52	6/22/2028
	14,000		3.70	6/27/2027
	15,000		13.20	3/16/2025
	4,000		8.80	12/8/2024

(1) Represents awards that are time vested with each award vesting evenly on an annual basis over three years, subject to earlier vesting upon a change in control as defined in the award agreements.

Director Compensation

The Director Compensation program for 2020 consisted of the following:

Non-employee directors

Cash Compensation. The Director compensation program for 2020 provided that all non-employee Directors would receive an annual base fee for service on the Board of $45,000. In addition, the Chairperson of the Board and of our Audit Committee, Compensation Committee and Nominating Committee would also receive annual fees of $40,000, $20,000, $15,000 and $10,000 respectively. All non-employee Directors serving on our Audit Committee, Compensation Committee and Nominating Committee (other than as the Chairperson) would receive an annual fee of $10,000, $7,500, and $5,000, respectively, in connection with such committee service. In addition, from time to time, the Board may establish special committees and in connection therewith determine the cash compensation that would be paid to the directors serving on a special committee at the time of the establishment of such committee. All fees for Board service are generally paid on or before the last business day of each quarter.

The Board is expecting to meet in-person for a minimum of four meetings each year. To the extent, the Board meets in excess of six in-person meetings an additional per meeting fee would also be considered to be paid to each director by the Board for such additional in-person meeting. To the extent the Board determines to establish a special committee or a special committee was previously established and continues to function, the Board would determine the cash compensation payable to each director serving on any such special committee.

Our Compensation Committee and our Board of Directors use market data as one means of evaluating and establishing Board remuneration. In 2019 and 2020, the Compensation Committee engaged Korn Ferry, as a compensation consultant to advise the Compensation Committee. Korn Ferry advises the Compensation Committee on matters related to executive compensation, board remuneration and related governance matters.

Equity Compensation-New Director. Equity compensation is issued to Directors upon joining our Board. Non-employee Directors receive a stock option for the purchase of shares of Company's Common Stock equating to $60,000 with an exercise price set as the Closing price of the Company's Common Stock on the day immediately prior to the appointment to the Board, which will immediately vest and be exercisable for ten years, subject to early termination under the terms of the 2012 Equity Incentive Plan. If new directors join the Board before July 1 of the calendar year, they would receive 100% of the value; 50% of such total value if they join between July 1 and October 1; 25% of such total value if they join after October in a calendar year.

Annual Equity Compensation Awards. As part of the Director Compensation Program each non-employee director receives equity awards under the 2012 Incentive Plan. In 2020 at the time of determining such annual equity award the Board considered the view of its compensation consultant Korn Ferry and revised its annual equity awards from 4,000 shares of restricted stock and an award of 8,000 stock options to an annual award of stock options which was based upon a value of $75,000 and equated to 156,540 stock options which were awarded under the Company's 2012 Incentive Plan at an exercise price of $0.48 per share, the closing price on February 5, 2020. The options vested immediately. The stock option awards are subject to the standard terms and conditions of the Company's form of stock option agreement which includes earlier vesting upon a change in control of the Company.

Discretionary Awards. As part of the Director Compensation Program, the Board may also make discretionary equity-based awards from time to time under our 2012 Incentive Plan. On February 5, 2020, the Board considered the view of its compensation consultant, Korn Ferry, and made a discretionary retention stock option award in the amount of 156,540 shares which would vest on the first anniversary of the grant date provided that the recipient remains a director of the Company through the vesting date.

Minimum dollar value stock ownership requirements. Each non-employee director receiving the above equity-based awards will be subject to a minimum dollar value stock ownership holding requirement with respect to the awards received as well as all prior equity awards under the 2012 Incentive Plan which requirement is intended to align the ability to sell shares with the performance of the Company's stock price. The non-employee Directors will each be subject to a minimum dollar value stock ownership requirement equal to six times the annual Board retainer ($270,000) which dollar threshold they would be precluded from selling shares of Company stock acquired from the Company under its 2012 Incentive Plan.

Reimbursement of Expenses. Non-employee Directors are also reimbursed for expenses incurred in connection with their attendance at Board or committee meetings and reasonable out-of-pocket business expenses associated with their Board service.

Long-term Incentive Compensation. The Company did not have a Long-Term Incentive Compensation plan in place performance in 2020 for its Non-Employee Directors.

The following table sets forth the compensation of our non-employee Directors in 2020.

Director Compensation Table

Name	Fees earned or paid in cash (1)	Stock Awards	Option awards (2)	All other compensation (3)	Total
Dr. Frederick W. Telling	$ 107,500	—	147,148	—	$ 254,648
Robert C. Koski	$ 45,000	—	147,148	—	$ 192,148
Charles L. Pope	$ 82,500	—	147,148	—	$ 229,648
Dr. Alan W. Dunton	$ 76,687	—	147,148	—	$ 223,835
Kimberley W. Murphy	$ 42,000	—	67,945	—	$ 109,945

(1) Amounts represent cash compensation earned by our Non-employee Directors during 2020 in connection with their Board service including any service on committees.

(2) The amounts in this column represent the aggregate grant date fair value computed in accordance with Financial Accounting Standards Board Accounting Standards Codification, Topic 718, Compensation—Stock Compensation (ASC 718). As part of the Company's non-employee Director Compensation Program, each non-employee Director received an Annual Equity Compensation award of 156,540 stock options under the Company's 2012 Incentive Plan at an exercise price of $0.48 per share, the closing price on February 5, 2020, the date of grant. The options vested immediately. In addition, and as part of the Company's non-employee Director Compensation Program, each non-employee Director received a Discretionary award of 156,540 stock options under the Company's 2012 Incentive Plan at an exercise price of $0.48 per share, the closing price on February 5, 2020, the date of grant, which would vest on the first anniversary of the grant date provided that the recipient remains a director of the Company through the vesting date. The stock option awards are subject to the standard terms and conditions of the Company's form of stock option agreement which includes earlier vesting upon a change in control of the Company. In May of 2020, and as part of the Company's non-employee Director Compensation Program, director Murphy received an award of 138,644 stock options under the Company's 2012 Incentive Plan at an exercise price of $0.43 per share. As of the end of the year non-employee directors, Telling, Koski, Pope, Dunton and Murphy have aggregate options to acquire, 638,620, 638,620, 638,620, 639,120 and 138,664, respectively and there are no stock awards outstanding for any non-employee director.

(3) No other compensation was paid to the non-employee Directors except for reimbursement for travel expenses to Board meetings and other Board related meetings.

Employee Directors

The Director Compensation Program provides that employee Directors receive no additional compensation in connection with their board service. There was one employee Director in 2020, Dr. Joslyn, our Chief Executive Officer, and no separate compensation is paid for his service as a director. For a summary of Dr. Joslyn's compensation see the Summary Compensation Table.

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

The following table sets forth information about beneficial ownership of our Common Stock as of February 25, 2021 (unless otherwise noted) by (i) each shareholder that has indicated in public filings that the shareholder beneficially owns more than five percent of the Common Stock, (ii) each of the Company's directors and named officers and (iii) all directors and officers as a group. Except as otherwise noted, each person listed below, either alone or together with members of the person's family sharing the same household, had, to our knowledge, sole voting and investment power with respect to the shares listed next to the person's name.

Name and address(1)	Number of shares beneficially owned	Percentage of ownership (2)
Directors and officers		
Dr. Frederick W. Telling (3)	1,388,158	1.3%
Alan Joslyn (4)	1,108,333	1.0%
Robert C. Koski (5)	2,382,964	2.1%
Charles L. Pope (6)	826,728	*%
Dr. Alan Dunton (7)	859,881	*%
Kimberly Murphy (8)	298,664	*%
Michael Sullivan (9)	664,088	*%
(All Directors and officers as a group 7 persons)	7,528,816	6.5%
5% shareholders		
Joseph Hernandez (10)	9,200,000	8.4%

* Beneficial ownership percentage is less than 1%.

(1) Except as indicated, the address of the person named in the table is c/o Oragenics, Inc., 4902 Eisenhower Blvd., Suite 125, Tampa, Florida 33634.

(2) In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of the Common Stock subject to options or warrants held by that person that are currently exercisable or will become exercisable within 60 days after February 25, 2021 are deemed outstanding, while the shares are not deemed outstanding for purposes of computing percentage ownership of any other person. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of the Common Stock held by them. Applicable percentage ownership is based on 109,646,119 shares of the Common Stock outstanding as of February 25, 2021. The inclusion in the table above of any shares deemed beneficially owned does not constitute an admission of beneficial ownership of those shares.

(3) Includes: (i) 798,620 shares able to be acquired pursuant to stock options, and (ii) 150,000 shares able to be acquired upon the exercise of warrants.

(4) Includes (i) 1,005,333 shares able to be acquired pursuant to stock options; and (ii) 33,333 shares able to be acquired upon the exercise of warrants. Excludes 666,667 shares subject to options that have not vested.

(5) The share amounts include: (i) 776,483 shares held by the Koski Family Limited Partnership ("KFLP") of which Mr. Koski is a general partner; (ii) 300,000 shares able to be acquired by the KFLP upon conversion of Series B Convertible Preferred Stock; (iii) 241,936 shares able to be acquired by the KFLP upon exercise of warrants; (iv) 212,839 shares owned directly by Mr. Koski; (v) 53,086 shares owned directly by trusts for which Mr. Koski serves as sole trustee as follows: the Robert Clayton Koski Trust for the benefit of Anthony James Hunter (10,760 shares); The Robert Clayton Koski Trust for the benefit of Hunter Buchanan Koski (10,760 shares); The Robert Clayton Koski Trust for the benefit of Clayton Ward Bennett (10,000 shares); and The Robert Clayton Koski Trust for the benefit of Robert Edward Koski (10,760 shares) and the Robert Clayton Koski Trust for the benefit of Elyse Margaux Koski (10,806 shares); and (vi) 798,620 shares able to be acquired pursuant to stock options. The address of the KFLP is 3525 Turtle Creek Boulevard #19B, Dallas, TX 75219.

(6) Includes: 798,620 shares able to be acquired pursuant to stock options.

(7) Includes: (i) 798,620 shares able to be acquired pursuant to stock options and (ii) 20,000 shares able to be acquired upon the exercise of warrants.

(8) Includes 298,664 shares able to be acquired pursuant to stock options

(9) Includes: 649,833 shares able to be acquired pursuant to stock options and excludes 416,667 shares subject to options that have not vested.

(10) Based upon information provided by Mr. Hernandez in his Schedule 13D filing with the SEC on January 26, 2021, Mr. Hernandez is the beneficial owner of 9,200,000 shares of Common Stock issuable upon exercise of warrants that become exercisable on May 1, 2021.

Securities Authorized for Issuance under Equity Compensation Plans

Our 2012 Incentive Plan, which is currently our only equity compensation plan, has been approved by our stockholders. The following table sets forth certain information as of December 31, 2020 with respect to the 2012 Incentive Plan:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options (A)	Weighted-Average Exercise Price of Outstanding Options (B)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A)) (C)
Equity compensation plans approved by stockholders:			
2012 Equity Incentive Plan	5,801,349	$ 0.90	2,207,901
Equity compensation plans not approved by stockholders: (1)			
None	—	$ —	—
Total:	5,801,349	$ 0.90	2,207,901

(1) The Company does not have any equity compensation plans that have not been approved by shareholders.

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

SEC rules require us to disclose any transaction or currently proposed transaction in which we are a participant and in which any related person has or will have a direct or indirect material interest involving an amount that exceeds the lesser of $120,000 or one percent (1%) of the average of the Company's total assets as of the end of last two completed fiscal years. A related person is any executive officer, director, nominee for director, or holder of 5% or more of the Company's common stock, or an immediate family member of any of those persons.

The Audit Committee of the Board of Directors (or, to the extent applicable, our disinterested directors) is responsible for reviewing all transactions between the Company and any officer or Director of the Company or any entity in which an officer of Director has a material interest. Any such transactions must be on terms no less favorable than those that could be obtained on an arms-length basis from independent third parties.

The July 17, 2018 Underwritten Public Offering

On July 17, 2018, we closed an underwritten public offering of units for gross proceeds of approximately $13.8 million, which includes the full exercise of the underwriter's over-allotment option to purchase additional shares and warrants, prior to deducting underwriting discounts and commissions and offering expenses payable by us. The Company's non-employee directors, Frederick Telling and Alan Dunton participated in the Public Offering through the purchase of 100,000 shares and 20,000 shares, respectively, of the Company's common stock and warrants to purchase 100,000 shares and 20,000 shares, respectively, of the Company's common stock. Dr. Telling and Dr. Dunton's participation was approved by our Audit Committee.

The offering was comprised of Class A Units, priced at a public offering price of $1.00 per unit, with each unit consisting of one share of common stock and a seven-year warrant to purchase one share of common stock with an exercise price of $1.00 per share (each, a "Warrant" and collectively, the "Warrants"), and Class B Units, priced at a public offering price of $1.00 per unit, with each unit comprised of one share of series D preferred stock (the "Series D Preferred Stock"), which is convertible into one share of common stock, and a Warrant. The conversion price of the Series D Preferred Stock issued in the transaction as well as the exercise price of the Warrants are fixed and do not contain any variable pricing features or any price based anti-dilutive features. The Series D Preferred Stock issued in this transaction included a beneficial ownership blocker but has no dividend rights (except to the extent that dividends are also paid on the common stock), liquidation preference or other preferences over common stock, and, with certain exceptions, has no voting rights. The securities comprising the units were immediately separable and have been issued separately.

At the closing of our underwritten public offering, a total of 4,436,000 shares of common stock, 9,364,000 shares of Series D Preferred Stock convertible into 9,364,000 shares of common stock, and warrants to acquire 13,800,000 shares of common stock were issued inclusive of the underwriter's exercise of their over-allotment option to purchase 1,800,000 shares of common stock and warrants to acquire 1,800,000 shares of common stock at $1.00 per share.

Since the closing of our underwritten public offering all of the shares of Series D Preferred Stock that were issued have been converted into shares of our common stock in accordance with the terms for conversion and 9,505,500 warrants were exercised for cash generating approximately $9.5 million in proceeds to us.

The March 25, 2019 Underwritten Public Offering

On March 25, 2019 we closed on an underwritten public offering of 16,666,668 shares of our common stock, par value $0.001 per share (the "Common Stock"), together with Series 1 Warrants to purchase up to an aggregate of 8,333,334 shares of our common stock (the "Series 1 Warrants") and Series 2 Warrants to purchase up to an aggregate of 8,333,334 shares of our common stock (the "Series 2 Warrants"), at a price to the public of $0.75 per share and related warrants (the "Public Offering"). We also granted the Underwriter a 30-day option to purchase up to an additional 2,500,000 additional shares of common stock (the "Option Shares") and/or Series 1 Warrants to purchase up to 1,250,000 shares of common stock and Series 2 Warrants to purchase up to 1,250,000 shares of common stock (the "Option Warrants").

Each Series 1 Warrant has an exercise price of $0.75 per share of common stock and will expire on the earlier of (1) the eighteen-month anniversary of the date of issuance and (2) twenty-one trading days following the Company's release of top-line data related to its Phase 2 double blind, placebo controlled clinical trial of AG013. Each Series 2 Warrant has an exercise price of $0.90 per share of common stock and will expire five years following the date of issuance.

Dr. Frederick Telling, Dr. Alan Joslyn, participated in the Public Offering through the purchase of 100,000 shares and 66,667 shares, respectively, of the Company's common stock and Series 1 warrants to purchase 50,000 shares and 33,333 shares, and Series 2 warrants to purchase 50,000 shares and 33,333 shares respectively, of the Company's common stock. Dr. Telling and Dr. Joslyn's participation was approved by our Audit Committee.

November 2020 Public Offering

On November 24, 2020, the Company announced the closing of an underwritten public offering for gross proceeds of approximately $6.0 million, which included the full exercise of the underwriter's over-allotment option to purchase additional shares, prior to deducting underwriting discounts and commissions and offering expenses payable by the Company.

The offering was comprised of 14,189,189 shares of common stock at a price to the public of $0.37 per share. The Company granted the underwriter a 45-day option to purchase up to 2,128,378 additional shares of common stock of the Company at the public offering price, less underwriting discounts and commissions. The underwriter exercised its option in full to purchase 2,128,378 additional shares of common stock, which the indicated gross proceeds reflect.

The Company intends to use the net proceeds of the offering primarily to continue funding our pre-clinical development of our SARS-CoV-2 vaccine, Terra CoV-2 and our lantibiotics program and for general corporate purposes, including research and development activities, capital expenditures and working capital.

Dr. Frederick Telling who is a Director of the Company, participated in the offering through the purchase of 100,000 shares of the Company's common stock. Dr. Telling's participation was approved by the Company's Audit Committee.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The following table provides the aggregate fees billed for professional services rendered by the Company's principal accountants, Mayer Hoffman McCann P.C. ("MHM"), in the categories indicated during each of the past two fiscal years ended December 31:

Services Rendered	2020	2019
Audit Fees (1)	$ 154,250	$ 151,500
Audit-Related Fees (2)	—	—
Tax Fees (3)	6,800	12,200
All Other Fees (4)	—	—
	$ 161,050	$ 163,700

(1) *Audit Fees*. This category includes fees for professional services provided in conjunction with the audit of the Company's financial statements and with the audit of management's assessment of internal control over financial reporting and the effectiveness of internal control over financial reporting, review of the Company's quarterly financial statements, assistance and review of documents filed with the Securities and Exchange Commission, consents, and comfort letters and attestation services provided in connection with statutory and other regulatory filings and engagements.

(2) *Audit-Related Fees*. This category includes fees for assurance and related professional services associated with due diligence related to mergers and acquisitions, consultation on accounting standards or transactions, internal control reviews and assistance with internal control reporting requirements, services related to the audit of employee benefit plans, and other attestation services not required by statute or regulation.

(3) *Tax Fees*. This category includes fees for professional services provided related to tax compliance, tax planning and tax advice.

(4) *All Other Fees*. There were no other fees paid to Mayer Hoffman McCann P.C.

Substantially all MHM's personnel, who work under the control of MHM shareholders, are employees of wholly-owned subsidiaries of CBIZ, Inc., which provides personnel and various services to MHM in an alternative practice structure.

Pre-Approval Policy

The Audit Committee approves in advance all audit and non-audit services to be performed by the Company's independent registered public accounting firm. The Audit Committee considers whether the provision of any proposed non-audit services is consistent with the Securities and Exchange Commission rules on auditor independence and has pre-approved certain specified audit and non-audit services to be provided by MHM for up to twelve (12) months from the date of the pre-approval. If there are any additional services to be provided, a request for pre-approval must be submitted by management to the Audit Committee for its consideration.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

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

1. The financial statements and accompanying report of independent registered public accounting firm are set forth immediately following the signature page of this report on pages F-1 through F-23.

2. All financial statement schedules are omitted because they are inapplicable, not required or the information is included elsewhere in the financial statements or the notes thereto.

3. The exhibits required to be filed by this report or able to be incorporated by reference are listed in the "Exhibit Index" following the financial statements.

(b) Other Exhibits

Exhibits required by Item 601 of Regulation S-K are submitted (or incorporated by reference) and listed in a separate section herein immediately following the F pages under the heading "Exhibit Index" and are incorporated herein by reference by reference. No exhibits in addition to those previously filed or listed in item 15(a) (3) and filed herein.

(c) Not Applicable.

ITEM 16. FORM 10-K SUMMARY

None.

EXHIBIT INDEX

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
3.1	Amended and Restated Articles of Incorporation as amended prior to December 29, 2017 (including certificates of designation of Series A, B and C Preferred Stock)	8-K	001-32188	3.1	12/29/17	
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation dated effective December 29, 2017	8-K	001-32188	3.2	12/29/17	
3.3	Articles of Amendment to Amended and Restated Articles of Incorporation effective January 19, 2018	8-K	001-32188	3.1	1/19/18	
3.4	Articles of Amendment to Amended and Restated Articles of Incorporation.	8-K	001-32188	3.4	6/26/18	
3.5	Bylaws	SB-2	333-100568	3.2	10/16/02	
3.6	First Amendment to Bylaws	8-K	001-32188	3.1	6/9/10	
3.7	Second Amendment to Bylaws	8-K	001-32188	3.1	8/24/10	
4.1	Specimen Stock Certificate	10-K	001-32188	4.1	3/29/19	
4.2	Form of Investor Warrant.	8-K	001-32188	4.1	4/10/18	
4.3	Form of Warrant to purchase shares of Common Stock.	S-1/A	333-224950	4.2	7/9/18	
4.4	Form of Series 2 Warrant	8-K	001-32188	4.2	3/25/19	
4.5	Warrant dated May 1, 2020	8-K	001-3288	4.1	5/4/20	
4.6	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act Of 1934					X
10.1	Amended and Restated Exclusive Channel Collaboration Agreement by and between Oragenics, Inc. and Eleszto Genetika, Inc. dated as of March 1, 2021("Lantibiotic ECC").*					X
10.2	Lease Agreement between the Company and Hawley-Wiggins LLC dated October 28, 2011 (13700 Progress Blvd, Alachua, FL 32615).	10-K	001-32188	10.20	4/16/12	
10.3	Amendment to Lease Agreement between the Company and Hawley-Wiggins LLC dated July 13, 2014 (13700 Progress Blvd, Alachua, FL 32615).	10-Q	001-32188	10.2	8/7/14	

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
10.4	Second Amendment to Lease Agreement between the Company and Hawley-Wiggins LLC dated June 7, 2019 (13700 Progress Blvd, Alachua, FL 32615).	10-K	001-32188	10.15	3/4/20	
10.5	Non-exclusive intellectual property and biological materials license agreement with the National Institute of Allergy and Infectious Diseases, an institute within the National Institutes of Health	10-Q	001-32188	10.2	8/14/20	
10.6	Sales Agent Agreement dated February 1, 2021**.	8-K	001-32188	1.1	2/1/21	
10.7	2012 Equity Incentive Plan. +	8-K	001-32188	4.1	10/25/12	
10.8	First Amendment to 2012 Equity Incentive Plan. +	8-K	001-32188	4.2	5/5/17	
10.9	Second Amendment to 2012 Equity Incentive Plan. +	8-K	001-32188	4.3	12/29/17	
10.10	Third Amendment to 2012 Equity Incentive Plan. +	8-K	001-32188	4.4	6/26/18	
10.11	Fourth Amendment to 2012 Equity Incentive Plan. +	8-K	001-32188	4.5	6/21/19	
10.12	Form of Employee Stock Option Agreement. +	10-K	001-32188	10.26	3/26/13	
10.13	Form of Consultant Stock Option Agreement. +	10-K	001-32188	10.27	3/26/13	
10.14	Form of Notice of Grant of Stock Options and Stock Option Award Agreement (Employee). +	8-K	001-32188	10.1	3/18/15	
10.15	Form of Notice of Grant of Stock Options and Stock Option Award Agreement (Directors). +	10-K	001-32188	10.23	3/4/20	
10.16	Form of Director Restricted Stock Award Agreement. +	8-K	001-32188	10.3	3/18/15	
10.17	Amended and Restated Executive Employment Agreement between the Company and Michael Sullivan dated effective January 1, 2015. +	8-K	001-32188	10.1	2/25/15	
10.18	Executive Employment Agreement between the Company and Martin Handfield dated May 11, 2010. +	10-Q	001-32188	10.16	11/14/11	
10.19	Executive Employment Agreement between the Company and Alan Joslyn dated effective June 6, 2016. +	8-K	001-32188	10.1	6/6/16	
10.20	First Amendment to Employment Agreement between the Company and Alan Joslyn effective June 6, 2018. +	8-K	001-32188	10.1	6/11/18	
10.21	Second Amendment to Employment Agreement between the Company and Alan Joslyn effective June 6, 2020.	8-K	001-32188	10.3	6/5/20	
21.1	Subsidiaries of Registrant					X
23.1	Consent of Mayer Hoffman McCann P.C., an independent public accounting firm.					X
24.1	Powers of Attorney (included on signature page).					X

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).					X
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase					X
101.LAB	XBRL Taxonomy Extension Label Linkbase					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase					X

* Confidential treatment has been granted as to certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended, or Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

** Non-material schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplemental copies of any of the omitted schedules and exhibits upon request by the SEC.

\+ Executive management contract or compensatory plan or arrangement.

SIGNATURES

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

Dated: March 1, 2021

ORAGENICS, INC.

By: */s/ Alan Joslyn*
Alan Joslyn
President and Chief Executive Officer

POWER OF ATTORNEY

Each of the undersigned officers and directors of Oragenics, Inc., hereby constitutes and appoints Alan Joslyn and Michael Sullivan, their true and lawful attorney-in-fact and agent, for them and in their name, place and stead, in any and all capacities, to sign their name to any and all amendments to this Report on Form 10-K, and other related documents, and to cause the same to be filed with the Securities and Exchange Commission, granting unto said attorneys, full power and authority to do and perform any act and thing necessary and proper to be done in the premises, as fully to all intents and purposes as the undersigned could do if personally present, and the undersigned for himself hereby ratifies and confirms all that said attorney shall lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report 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/ Alan Joslyn Alan Joslyn	President and Chief Executive Officer	March 1, 2021
/s/ Michael O. Sullivan Michael O. Sullivan	Chief Financial Officer (Principal Accounting and Financial Officer)	March 1, 2021
/s/ Robert C. Koski Robert C. Koski	Director	March 1, 2021
/s/ Frederick W. Telling Frederick W. Telling	Chairman and Director	March 1, 2021
/s/ Charles L. Pope Charles L. Pope	Director	March 1, 2021
/s/ Alan W. Dunton Alan W. Dunton	Director	March 1, 2021
/s/ Kimberly M. Murphy Kimberly M. Murphy	Director	March 1, 2021

Oragenics, Inc.

Consolidated Financial Statements

Years Ended December 31, 2020 and 2019

Index

Report of Independent Registered Public Accounting Firm

To the Board of Directors and
Shareholders of Oragenics, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Oragenics, Inc. ("Company") as of December 31, 2020 and 2019, and the related consolidated statements of operations, changes in shareholders' equity, and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019 and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current year audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Classification of Warrant Contract

As described in Notes 3 and 7 to the financial statements, in May 2020, in connection with the asset acquisition of Noachis Terra, Inc. ("Noachis Terra"), the former sole shareholder of Noachis Terra received warrants (the "Noachis Terra warrants") under a warrant contract to purchase 9,200,000 shares of the Company's common stock as part of the consideration paid for the assets acquired. As a result, the Company recorded the fair value of the equity classified warrants of $3,403,099 to research and development expenses.

We identified the consideration of the classification of the Noachis Terra warrants as either a liability or equity instrument as a critical audit matter. The assessment of the Noachis Terra warrants' classification involves an evaluation of the relevant terms and provisions of the warrant contract to determine the appropriate accounting for the recognition of the warrant contract in the financial statements. The accounting guidance applicable to the classification of the warrant contract is complex and therefore, applying such guidance to the contract terms required significant judgment. Auditing management's conclusions related to the classification of the Noachis Terra warrants involved especially challenging auditor judgment to determine the proper classification.

The primary procedures we performed to address this critical audit matter included:

- Obtaining, reviewing, and evaluating the terms of the Noachis Terra stock purchase agreement and warrant contract to identify relevant terms that affect the recognition of the Noachis Terra warrants in the financial statements.
- Applying our understanding of the terms and conditions of these contracts to the applicable provisions of US GAAP to ascertain if management's conclusions regarding the classification of the warrant contract as equity is appropriate. Personnel with specialized knowledge and skills in accounting for financial instruments were used to assist in assessing management's conclusions for the accounting for the Noachis Terra warrants.

/s/ Mayer Hoffman McCann P.C.

We have served as the Company's auditor since 2005
Clearwater, Florida
March 1, 2021

Oragenics, Inc.
Consolidated Balance Sheets
December 31, 2020 and 2019

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 17,639,575	$ 18,267,994
Prepaid expenses and other current assets	343,106	570,071
Total current assets	17,982,681	18,838,065
Property and equipment, net	42,713	91,968
Operating lease right-of-use assets	655,138	822,684
Total assets	$ 18,680,532	$ 19,752,717
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 937,020	$ 1,541,415
Short-term notes payable	228,227	143,864
Operating lease liabilities	176,900	165,096
Total current liabilities	1,342,147	1,850,375
Long-term liabilities		
Operating lease liabilities	493,790	670,690
Total long-term liabilities	493,790	670,690
Shareholders' equity:		
Preferred stock, no par value; 50,000,000 shares authorized; 9,417,000 and 9,417,000 Series A shares, 6,600,000 and 6,600,000 Series B shares, 133.483 and 113.941 Series C shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	7,174,854	6,513,396
Common stock, $0.001 par value; 200,000,000 shares authorized 91,766,928 and 46,124,803 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	91,767	46,125
Additional paid-in capital	164,022,957	138,024,957
Accumulated deficit	(154,444,983)	(127,352,826)
Total shareholders' equity	16,844,595	17,231,652
Total liabilities and shareholders' equity	$ 18,680,532	$ 19,752,717

See accompanying Report of Independent Registered Public Accounting Firm and notes to the consolidated financial statements.

Oragenics, Inc.
Consolidated Statements of Operations
For the Years Ended December 31, 2020 and 2019

	Year Ended December 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 22,107,563	$ 12,120,318
General and administrative	4,533,893	3,757,251
Total operating expenses	26,641,456	15,877,569
Loss from operations	(26,641,456)	(15,877,569)
Other income (expense):		
Interest income	89,294	320,011
Interest expense	(10,685)	(7,300)
Local business tax	(2,400)	(1,601)
Other income	1,795	456
Forgiveness of Paycheck Protection Program loan and accrued interest	132,753	—
Total other income (expense), net	210,757	311,566
Loss before income taxes	(26,430,699)	(15,566,003)
Income tax benefit	—	—
Net loss	$ (26,430,699)	$ (15,566,003)
Basic and diluted net loss per share	$ (0.47)	$ (0.37)
Shares used to compute basic and diluted net loss per share	56,531,246	42,283,947

See accompanying Report of Independent Registered Public Accounting Firm and notes to the consolidated financial statements.

Oragenics, Inc.
Consolidated Statements of Changes in Shareholders' Equity
For the Years Ended December 31, 2020 and 2019

	Common Stock		Preferred Stock		Additional Paid In	Accumulated	Total Shareholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balances at December 31, 2018	29,433,135	$ 29,433	16,017,101.733	$ 6,100,182	$ 126,125,976	$ (111,373,608)	$ 20,881,983
Compensation expense relating to option issuances	—	—	—	—	552,997	—	552,997
Issuance of common stock - shelf takedown, net of expenses	16,666,668	16,667	—	—	11,334,010	—	11,350,676
Series C dividend	—	—	12.208	413,214	—	(413,214)	—
Issuance of common stock in exchange for services	25,000	25	—	—	11,975	—	12,000
Net loss	—	—	—	—	—	(15,566,003)	(15,566,003)
Balances at December 31, 2019	46,124,803	$ 46,125	16,017,113.941	$ 6,513,396	$ 138,024,957	$ (127,352,826)	$ 17,231,652
Compensation expense relating to option issuances	—	—	—	—	1,491,165	—	1,491,165
Issuance of common stock from warrant exercise	5,680,114	5,680	—	—	5,176,723	—	5,182,403
Series C dividend	—	—	19.542	661,458	—	(661,458)	—
Issuance of common stock and warrants for the acquisition of Noachis Terra	9,200,000	9,200	—	—	8,021,499	—	8,030,699
November 2020 public offering of common stock- net of expenses	16,317,567	16,318	—	—	5,383,057	—	5,399,375
December 2020 registered direct offering of common stock- net of expenses	14,444,444	14,444	—	—	5,925,556	—	5,940,000
Net loss	—	—	—	—	—	(26,430,699)	(26,430,699)
Balances at December 31, 2020	91,766,928	$ 91,767	16,017,133.483	$ 7,174,854	$ 164,022,957	$ (154,444,983)	$ 16,844,595

See accompanying Report of Independent Registered Public Accounting Firm and notes to the consolidated financial statements.

Oragenics, Inc.
Consolidated Statements of Cash Flows
For the Years Ended December 31, 2020 and 2019

	Year Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (26,430,699)	$ (15,566,003)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	51,705	62,622
Stock-based compensation expense	1,491,165	552,997
Stock issued in exchange for services	—	12,001
Stock issued for purchase of Noachis Terra	8,030,699	—
Forgiveness of Paycheck Protection Program loan and accrued interest	(132,753)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	640,749	1,427,481
Accounts payable and accrued expenses	(603,730)	498,059
Net cash used in operating activities	(16,952,864)	(13,012,843)
Cash flows from investing activities:		
Purchase of property and equipment	—	(25,214)
Net cash used by investing activities	—	(25,214)
Cash flows from financing activities:		
Borrowings under short-term notes payable	132,088	—
Payments on short-term notes payable	(329,421)	(252,926)
Proceeds from issuance of common stock for warrant exercise	5,182,403	11,350,676
Net proceeds from issuance of common stock	11,339,375	—
Net cash provided by financing activities	16,324,445	11,097,750
Net decrease in cash and cash equivalents	(628,419)	(1,940,307)
Cash and cash equivalents at beginning of the year	18,267,994	20,208,301
Cash and cash equivalents at end of the year	$ 17,639,575	$ 18,267,994
Supplemental disclosure of cash flow information:		
Interest paid	$ 10,020	$ 7,300
Non-cash investing and financing activities:		
Borrowings under short term notes payable for prepaid expense	$ 413,784	$ 272,577
Stock dividend on Series C preferred stock	$ 661,458	$ 413,214
Par value of common stock issued in exchange for services	$ —	$ 25

See accompanying Report of Independent Registered Public Accounting Firm and notes to the consolidated financial statements.

1. Basis of Presentation

The Company

Oragenics, Inc. (formerly known as Oragen, Inc.) (the "Company" or "we") was incorporated in November, 1996; however, operating activity did not commence until 1999. We are focused on the creation of the Terra CoV-2 immunization product candidate to combat the novel coronavirus pandemic and the further development of effective treatments for novel antibiotics against infectious disease.

Basis of Presentation

The accompanying consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States ("US GAAP") including the assumption of a going concern basis which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business.

The Company has incurred recurring losses and negative cash flows from operations since inception. To date the Company has not generated significant revenues from operations. The Company incurred a net loss of $(26,430,699) and used cash of $16,952,864 in its operating activities during the year ended December 31, 2020. As of December 31, 2020, the Company had an accumulated deficit of $(154,444,983) and cash flows from operations were negative throughout 2020.

Historically, the Company's major sources of cash have been comprised of proceeds from various public and private offerings of its common stock, preferred stock, warrant exercises, income earned on grants and interest income. From 2012 through 2020, the Company raised approximately $92 million in gross proceeds ($13.0 million in fiscal year 2020) from various public and private offerings of its common stock. The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes the working capital at December 31, 2020, together with the proceeds from the additional sales of common stock and warrant exercises and net of the redemption of the Series C Preferred Stock of approximately $5.6 million, (See Subsequent Event Note 14), will be sufficient to meet the business objectives, as presently structured, through the second quarter of 2022.

The Company's ability to continue operations after its current cash resources are exhausted depends on its ability to obtain additional financing or achieve profitable operations, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in the Company's focus and direction of its research and development programs, competitive and technical advances, or other developments. Additional financing will be required to continue operations after the Company exhausts its current cash resources and to continue its long-term plans for clinical trials and new product development. There can be no assurance that any such financing can be realized by the Company, or if realized, what the terms thereof may be, or that any amount that the Company is able to raise will be adequate to support the Company's working capital requirements until it achieves profitable operations.

The Company intends to seek additional funding through sublicensing arrangements, joint venturing or partnering, sales of rights to technology, government grants and public or private financings and may receive funding through the exercise of outstanding warrants. The Company's future success depends on its ability to raise capital and ultimately generate revenue and attain profitability. The Company cannot be certain that additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to it or, if available, will be on terms acceptable to the Company. If the Company issues additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of its common stock, and the Company's current shareholders may experience dilution. If the Company is unable to obtain funds when needed or on acceptable terms, the Company may be required to curtail its current development programs, cut operating costs and forego future development and other opportunities.

2. Significant Accounting Policies

Basis of Consolidation

The consolidated financial statements include the accounts of Oragenics, Inc. and our wholly-owned subsidiary Noachis Terra, Inc. All intercompany balances and transactions have been eliminated.

New Accounting Standards

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies that we adopt as of the specified effective date. Unless otherwise discussed, the Company does not believe that the impact of recently issued standards that are not yet effective will have a material impact on its financial position or results of operations upon adoption.

Recent Accounting Standards Not Yet Adopted

Income Taxes

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.

Use of Estimates

The preparation of consolidated financial statements in conformity with US 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, as well as the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. The principal areas of estimation reflected in the consolidated financial statements are stock-based compensation, and valuation of warrants.

Cash and Cash Equivalents

Cash and cash equivalents consist of all cash balances and highly liquid investments with an original maturity of three months or less. The Company's cash and cash equivalents are deposited in a financial institution and consist of demand deposits and overnight repurchase agreements and at times deposits are in excess of federally insured limits.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation and amortization. Depreciation is provided on the straight-line method over the estimated useful lives of the assets (three to seven years). Leasehold improvements are amortized over the shorter of the estimated useful life or the lease term of the related asset (three years).

Business Segments

In accordance with US GAAP, the Company is required to report segment information. As the Company only operates principally in one business segment, no additional reporting is required.

Stock-Based Payment Arrangements

Generally, all forms of stock-based payments, including stock option grants, and warrants are measured at their fair value on the awards' grant date using a Black-Scholes pricing model. Restricted stock grants are measured at their fair value at the date of the grant. Stock-based compensation awards issued to non-employees for services rendered are recorded at the fair value of the stock-based payment. The expense resulting from stock-based payments are recorded in research and development expense or general and administrative expense in the consolidated statement of operations, depending on the nature of the services provided. Stock-based payment expense is recorded over the requisite service period in which the grantee provides services to us. To the extent the stock option grants, warrants, or restricted stock grants do not vest at the grant date they are subject to forfeiture.

Stock-Based Compensation

US GAAP requires all stock-based payments to employees, including grants of employee stock options, to be recognized in the consolidated financial statements based on their fair values as of the grant date. Stock-based compensation expense is recorded over the requisite service period in which the grantee provides services to us, to the extent the options do not vest at the grant date and are subject to forfeiture. For performance-based awards that do not include market-based conditions, we record share-based compensation expense only when the performance-based milestone is deemed probable of achievement. We utilize both quantitative and qualitative criteria to judge whether milestones are probable of achievement. For awards with market-based performance conditions, we recognize the grant-date fair value of the award over the derived service period regardless of whether the underlying performance condition is met. In connection with adopting ASU 2016-09, the Company made an accounting policy election to account for forfeitures in compensation expense as they occur.

Warrants

The Company used the Black Scholes Option Pricing Model in calculating the relative fair value of any warrants that have been issued.

Impairment of Long-Lived Assets

The Company periodically reviews their long-lived assets for impairment and reduces the carrying value to fair value whenever events or changes in circumstances indicate that the carrying value may not be recoverable. There were no impairment losses recorded during the years ended December 31, 2020, and 2019.

Research and Development Expenses

Research and development consist of expenses incurred in connection with the discovery and development of our product candidates. These expenses consist primarily of employee-related expenses, which include salaries and benefits and attending science conferences; expenses incurred under our license agreements with third parties and under other agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our nonclinical studies; the cost of acquiring and manufacturing clinical trial materials; facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, and depreciation of fixed assets; license fees, for and milestone payments related to, in-licensed products and technology; stock-based compensation expense; and costs associated with nonclinical activities and regulatory approvals. The Company expenses research and development costs as incurred.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rate is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced to estimated amounts expected to be realized by the use of a valuation allowance. Based on our historical operating losses, a valuation allowance has been recognized for all deferred tax assets.

Under US GAAP, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, US GAAP provides guidance on derecognition, classification, interest and penalties, accounting for interim periods, disclosure and transition.

Concentrations

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains cash accounts in commercial banks, which may, at times, exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash and cash equivalents. As of December 31, 2020, the uninsured portion of this balance was $17,389,575. As of December 31, 2019, the uninsured portion of this balance was $18,017,994.

3. Acquisition

On May 1, 2020, the Company entered into a Stock Purchase Agreement with the sole shareholder of Noachis Terra Inc. ("NTI"), pursuant to which the Company acquired one hundred percent (100%) of the total issued and outstanding common stock of NTI (the "Transaction"). In exchange, the shareholder received the following: (i) cash consideration equal to $1,925,000, of which approximately $500,000 was applied to extinguish NTI's pre-Transaction liabilities (a portion of which were due to the shareholder); (ii) 9,200,000 shares of the Company's common stock; and (iii) warrants to purchase 9,200,000 shares of the Company's common stock, which warrants carry an exercise price of $1.25 per share, a five-year term, and may not be exercised until the first anniversary of the Transaction's closing. The Company is also obligated to pay the former sole shareholder of NTI contingent consideration based upon the exercise of certain of the Company's currently outstanding warrants as follows: (i) twenty percent (20%) of the cash proceeds received by the Company upon exercise of the Company's warrants carrying an exercise price of $0.90 and (ii) forty-five percent (45%) of the cash proceeds received by the Company upon exercise of the Company's warrants carrying an exercise price of $1.00, in each case, for so long as the warrants remain outstanding.

At the closing of the Transaction, the aggregate fair value of purchase consideration was $9,955,699, consisting of $1,925,000 of cash, the Company's common stock (9,200,000 shares), and warrants to purchase the Company's common stock, as follows:

	Fair Value
Cash - Initial Cash Payment	$ 1,925,000
Equity - Common Stock	4,627,600
Equity - Warrants	3,403,099
Total fair value of consideration	$ 9,955,699

The Company determined that the acquisition should be accounted for as an asset purchase. The asset which was acquired was in-process research and development which does not have any alternative uses and therefore the aggregate fair value of the purchase price was recorded in research and development expenses in 2020.

4. Property and Equipment, net

Property and equipment, net consists of the following as of December 31, 2020 and 2019:

	2020	2019
Furniture and fixtures	$ 20,742	$ 20,742
Laboratory equipment	944,657	944,657
Leasehold improvements	487,871	487,871
Office and computer equipment	302,825	302,825
	1,756,095	1,756,095
Accumulated depreciation and amortization	(1,713,382)	(1,664,127)
Property and equipment, net	$ 42,713	$ 91,968

Depreciation and amortization expense for the years ending December 31, 2020 and 2019 was $51,705 and $62,622 respectively.

5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following as of December 31, 2020 and 2019:

	2020	2019
Accounts payable trade	$ 330,379	$ 1,207,231
Bonus	247,683	—
Collaboration Agreements	—	131,089
Professional fees	84,251	55,000
Vacation	158,721	143,095
Consulting fees	115,986	5,000
Total accounts payable and accrued expenses	$ 937,020	$ 1,541,415

6. Short-Term Notes Payable

The Company had the following short-term notes payable as of December 31, 2020 and 2019:

	2020	2019
Product liability insurance financing of $17,688 due in monthly installments of $1,599 including principal and interest at 5.69% with the final payment being made on February 14, 2020, respectively	$ —	$ 3,177
Directors' and officers' liability insurance financing of $413,784 and $254,889 due in monthly installments of $38,638 and $23,842 including principal and interest at 5.39% and 5.74% through June 24, 2021 and June 24, 2020, respectively	228,227	140,687
Total short-term notes payable	$ 228,227	$ 143,864

Paycheck Protection Program

On May 5, 2020, the Company received loan proceeds in the amount of $132,088 under the Paycheck Protection Program (the "PPP"). The PPP, established by the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") administered by the Small Business Administration, provides for loans to qualifying businesses for amounts up to 2.5 times the average monthly payroll expenses of the qualifying business. The loan and accrued interest were subject to forgiveness after an initial period of eight weeks (extended to twenty-four weeks on June 5, 2020) as long as the Company used the proceeds for eligible purposes, including payroll, benefits, rent, and utilities and maintains it payroll levels. On November 19, 2020, the Company received notice from the Small Business Administration that the loan amount of $132,088 plus accrued interest had been forgiven.

7. Shareholders' Equity

Common Stock

2019 Public Offering

On March 25, 2019, the Company announced the closing of an underwritten public offering for gross proceeds of approximately $12.5 million, which included the partial exercise of the underwriter's over-allotment option to purchase additional shares and warrants, prior to deducting underwriting discounts and commissions and offering expenses payable by the Company.

The offering was comprised of 16,666,668 shares of common stock, together with short-term warrants to purchase up to 8,333,334 shares of common stock, and long-term warrants to purchase up to 8,333,334 shares of common stock, at a price to the public of $0.75. The Company granted the underwriter a 30-day option to purchase up to 2,500,000 additional shares of common stock and/or short-term warrants to purchase 1,250,000 shares of common stock and long-term warrants to purchase 1,250,000 shares of common stock of the Company at the public offering price, less underwriting discounts and commissions. The underwriter did not exercise its option to purchase additional shares of common stock, however the underwriter exercised its option to purchase the short-term warrants to purchase 1,250,000 shares of common stock and long-term warrants to purchase 1,250,000 shares of common stock effective as of the closing.

Each short-term warrant has an exercise price of $0.75 per share of common stock, is immediately exercisable, and will expire on the earlier of (1) the eighteen-month anniversary of the date of issuance and (2) twenty-one trading days following the Company's release of top-line data related to its Phase 2 double blind, placebo controlled clinical trial of AG013. Each long-term warrant has an exercise price of $0.90 per share of common stock, is immediately exercisable and will expire five years following the date of issuance.

The Company used the net proceeds of the offering to fund its clinical trial, pre-clinical development, and for working capital and general corporate purposes. Dr. Frederick Telling and Dr. Alan Joslyn, who are Directors of the Company, participated in the offering through the purchase of 100,000 shares and 66,667 shares, respectively, of the Company's common stock and Series 1 warrants to purchase 50,000 shares and 33,333 shares, and Series 2 warrants to purchase 50,000 shares and 33,333 shares respectively, of the Company's common stock. Dr. Telling and Dr. Joslyn's participation was approved by the Audit Committee.

Acquisition of Noachis Terra

On May 1, 2020, the Company issued 9,200,000 shares of common stock as partial consideration for its acquisition of Noachis Terra Inc. See Note 3. Acquisition.

November 2020 Public Offering

On November 24, 2020, the Company announced the closing of an underwritten public offering for gross proceeds of approximately $6.0 million, which included the full exercise of the underwriter's over-allotment option to purchase additional shares, prior to deducting underwriting discounts and commissions and offering expenses payable by the Company. The offering was comprised of 14,189,189 shares of common stock at a price to the public of $0.37 per share. The Company granted the underwriter a 45-day option to purchase up to 2,128,378 additional shares of common stock of the Company at the public offering price, less underwriting discounts and commissions. The underwriter exercised its option in full to purchase 2,128,378 additional shares of common stock, which the indicated gross proceeds reflect. The Company intends to use the net proceeds of the offering primarily to continue funding our pre-clinical development of our SARS-CoV-2 vaccine, Terra CoV-2 and our lantibiotics program and for general corporate purposes, including research and development activities, capital expenditures and working capital. Dr. Frederick Telling who is a Director of the Company, participated in the offering through the purchase of 100,000 shares of the Company's common stock. Dr. Telling's participation was approved by the Company's Audit Committee.

December 2020 Registered Direct Offering

On December 29, 2020, the Company announced the closing of a registered direct offering for gross proceeds of approximately $6.5 million, prior to deducting placement agent fees and offering expenses payable by the Company. The offering was comprised of 14,444,444 shares of common stock at a price to the public of $0.45 per share. The Company intends to use the net proceeds of the offering primarily to continue funding our pre-clinical development of our SARS-CoV-2 vaccine, Terra CoV-2 and our lantibiotics program and for general corporate purposes, including research and development activities, capital expenditures and working capital.

Other Share Issuances.

On February 1, 2019, the Company issued 12,500 shares of its common stock, and on May 1, 2019, the Company issued an additional 12,500 shares of its common stock as partial consideration for the acquisition of certain services.

During the three month period ending September 30, 2020, the Company issued an additional 5,642,114 shares of common stock as a result of the exercise of certain outstanding warrants as follows: (i) an additional 760,000 warrants of the Company's previously reported remaining outstanding warrants to acquire 4,294,500 shares of Common Stock at an exercise price of $1.00 per share issued in connection with its July 2018 public offering (the "2018 Warrants"), were exercised and (ii) 4,882,114 warrants of the Company's previously reported outstanding warrants to acquire 9,583,334 shares of Common Stock at an exercise price of $0.90 per share issued in connection with its March 2019 public offering (the "2019 Warrants"), were exercised (collectively the "Warrant Exercises"). The Warrant Exercises provided aggregate gross proceeds to the Company of $5,153,902.

Preferred Stock

Issuance of Series A Convertible Preferred Stock Financing

On May 10, 2017 we entered into a securities purchase agreement with three accredited investors, to purchase up to $3,000,000 of Series A Convertible Preferred Stock (the "Series A Preferred Stock Financing"). The sale of the Preferred Stock took place in two separate closings and at the first closing which occurred on May 10, 2017, we received gross proceeds of approximately $1,302,000. The second closing occurred on July 25, 2017 and we received gross proceeds of approximately $1,698,000, which was the balance of the Preferred Stock Financing. The full $3,000,000 of Preferred Stock, and after giving effect to the reverse stock split and the previous conversion of 2,583,000 shares of Series A Preferred Stock into 258,300 shares of the Company's common stock, is convertible into nine hundred, forty-one thousand, seven hundred and one shares of our common stock, based on a fixed conversion price of $2.50 per share on an as-converted basis. In addition, and after giving effect to the reverse stock split, we issued warrants to purchase an aggregate of 462,106 shares of common stock at the first closing and we issued an aggregate of 602,414 shares of common stock at the second closing. The warrants have a term of seven years from the date of issuance are non-exercisable until 6 months after issuance, have an exercise price of $3.10 per share. Proceeds from the Series A Preferred Stock Financing (including the exercise of any warrants for cash) will be used for general corporate purposes, including working capital.

On July 27, 2017, we entered into an agreement to amend the warrants issued in connection with the Series A Preferred Stock Financing to provide notification and objection requirements with respect to the change of control provisions. The change of control provisions in the warrants had previously caused the warrants to be treated as a derivative liability as opposed to being treated as equity on our balance sheet. The warrants have been replaced by amended and restated warrants containing such notification and objection requirements (the "Amended and Restated Common Stock Purchase Warrants") so that the Amended and Restated Common Stock Purchase Warrants are now treated as equity on our balance sheet. All other terms of the original warrants remain unchanged by the Amended and Restated Common Stock Purchase Warrants.

In connection with the Series A Preferred Financing, we filed a Certificate of Designations of Preferences, Rights and Limitations of Series A Preferred Stock with the Secretary of State of the State of Florida, to be effective May 10, 2017. The number of shares of Preferred Stock designated as Series A Preferred Stock is 12,000,000.

In connection with the issuance and sale of the Series A Preferred Stock and warrants, we granted certain demand registration rights and piggyback registration rights with respect to the shares of our Common Stock issuable upon conversion of the Preferred Stock and exercise of the Warrants, pursuant to a Registration Rights Agreement.

Except as otherwise required by law, the Series A Preferred Stock shall have no voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Certificate of Designation, (b) amend its articles of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series A Preferred Stock, (c) increase the number of authorized shares of Series A Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing. Upon any liquidation, dissolution or winding-up by us, whether voluntary or involuntary that is not a Fundamental Transaction (as defined in the Certificate of Designation), the holders of Series A Preferred Stock shall be entitled to receive out of the assets, the greater of (i) the product of the number of shares of Series A Preferred Stock then held by such holder, multiplied by the Original Issue Price; and (ii) the amount that would be payable to such holder in the Liquidation in respect of Common Stock issuable upon conversion of such shares of Series A Preferred Stock if all outstanding shares of Series A Preferred Stock were converted into Common Stock immediately prior to the Liquidation. The Series A Preferred Stock is classified as permanent equity.

The Series B Non-Voting, Convertible Preferred Stock Financing

On November 8, 2017, we completed a private placement of $3,300,000 of Series B Non-Voting, Convertible Preferred Stock (the "Series B Convertible Preferred Stock") pursuant to a Securities Purchase Agreement with four existing shareholders who are accredited investors including an entity affiliated with a director of the Company (the "Series B Preferred Stock Financing").

The full $3,300,000 of Series B Convertible Preferred Stock is convertible, after giving effect to the reverse stock split into one million three hundred and twenty thousand and two shares of our Common Stock, based on a conversion of one share of Series B Preferred Stock into two shares of Common Stock. The purchase price per share of the Series B Preferred Stock is represented by $2.50 per share of the Common Stock on an as converted basis. In addition, and after giving effect to the reverse stock split, we issued to the investors in the private placement accompanying common stock purchase warrants to purchase an aggregate of 1,064,518 shares of Common Stock. The warrants have a term of seven years from the date of issuance, and are non-exercisable until six (6) months after issuance, and after giving effect to the reverse stock split, have an exercise price of $3.10 per share.

In connection with the Series B Preferred Financing, we filed a Certificate of Designation and Rights of Series B Convertible Preferred Stock with the Secretary of State of the State of Florida, to be effective November 8, 2017. The number of shares of Preferred Stock designated as Series B Preferred Stock is 6,600,000.

Except as otherwise required by law, the Series B Preferred Stock shall have no voting rights. However, as long as any shares of Series B Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series B Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock or alter or amend the Certificate of Designation, (b) amend its articles of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series B Preferred Stock, (c) increase the number of authorized shares of Series B Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing.

The Series B Preferred Stock shall rank (i) on par with the Common Stock and Series A Preferred Stock and junior to Series C Preferred Stock as to dividend rights and (ii) junior to Series C Preferred Stock, on par with Series A Preferred Stock and senior to the Common Stock as to distribution of assets upon liquidation, dissolution or winding-up by us, whether voluntary or involuntary.

Upon any liquidation, dissolution or winding-up by us, whether voluntary or involuntary, the holders of Series B Preferred Stock shall be entitled to receive out of the assets, after payment to the holders of Series C Preferred Stock but on par with the holders of Series A Preferred Stock and in preference to the holders of the Common Stock, an amount of cash equal to the greater of (i) the product of the number of shares of Series B Preferred Stock then held by such holder, multiplied by the Original Issue Price; and (ii) the amount that would be payable to such holder in the Liquidation in respect of Common Stock issuable upon conversion of such shares of Series B Preferred Stock if all outstanding shares of Series B Preferred Stock were converted into Common Stock immediately prior to the Liquidation. The Series B Preferred Stock is classified as permanent equity.

The Series C Non-Voting, Non- Convertible Preferred Stock Financing Precigen Debt Conversion

Concurrently with the Series B Preferred Stock Financing, we also entered into a Debt Conversion Agreement (the "Precigen Debt Conversion Agreement") with Precigen, Inc. (formerly Intrexon Corporation ("Intrexon") pursuant to which Precigen exchanged the $2,400,000 unsecured non-convertible promissory note previously issued by us to Precigen (the "Precigen Note"), the accrued interest on the Precigen Note and trade payables owed by us (collectively the "Debt") in the aggregate amount of approximately $3,400,000 for equity in the form of 100 shares of Series C, Non-Voting, Non-Convertible Preferred Stock (the "Series C Preferred Stock") issued by us to Precigen pursuant to the Debt Conversion Agreement which 100 shares have a stated value equal to the amount of the Debt.

In connection with the Precigen Debt Conversion Agreement, we filed a Certificate of Designation and Rights of Series C Non-Convertible Preferred Stock with the Secretary of State of the State of Florida, to be effective November 8, 2017. The number of shares of Preferred Stock designated as Series C Preferred Stock is 1,000.

Each issued and outstanding share of Series C Preferred Stock entitles the holder of record to receive dividends at the annual rate of twelve percent (12%) (the "Initial Rate") of its Stated Value, payable by issuing additional shares of Series C Preferred Stock within thirty days after the end of each calendar year pro-rata for partial years. The Initial Rate was increased to twenty percent (20%) automatically on May 10, 2019, and applicable to the periods thereafter.

The Series C Preferred Stock shall rank senior to the Common Stock, Series A Preferred Stock, Series B Preferred Stock and to any other equity securities issued by us (the "Junior Securities") as to rights upon liquidation, dissolution or winding-up by us, whether voluntary or involuntary. Upon any liquidation, dissolution or winding-up by us, whether voluntary or involuntary, the holders of Series C Preferred Stock shall be entitled to receive, in preference to the Junior Securities, an amount of cash equal to the product of (i) sum of (a) the number of shares of Series C Preferred Stock then held by such holder plus, (b) the number of shares of Series C Preferred Stock issuable to such holder in connection with any accrued but unpaid dividends, multiplied by (ii) the Stated Value, of $33,847.9874 per share, of Series C Preferred Stock ("the Series C Liquidation Amount") and no distribution or payments shall be made in respect of any Junior Securities unless all Series C Liquidation Amounts, if any, are first paid in full.

As a result of the sale by Precigen of its equity interest in Oragenics to TS Biotechnology LLC, future dividend payments would be paid to TS Biotechnology.

Warrants

The Company's outstanding and exercisable warrants as of December 31, 2020 are presented below:

Exercise Price	Total Warrants Outstanding	Exercisable Warrants Outstanding	Expiration Date
$ 3.10	48,387	48,387	9/19/2022
$ 3.10	462,106	462,106	5/10/2024
$ 3.10	602,414	602,414	7/25/2024
$ 3.10	1,064,518	1,064,518	11/8/2024
$ 2.00	900,000	900,000	4/10/2023
$ 1.00	3,534,500	3,534,500	7/17/2025
$ 0.90	4,701,220	4,701,220	3/25/2024
$ 1.25	9,200,000	—	5/1/2025
	20,513,145	11,313,145	

All outstanding warrants are classified as equity on the Company's Consolidated Balance Sheets.

On March 25, 2019, the Company announced the closing of an underwritten public offering for gross proceeds of approximately $12.5 million, which included the partial exercise of the underwriter's over-allotment option to purchase additional shares and warrants, prior to deducting underwriting discounts and commissions and offering expenses payable by the Company.

The offering was comprised of 16,666,668 shares of common stock, together with short-term warrants to purchase up to 8,333,334 shares of common stock, and long-term warrants to purchase up to 8,333,334 shares of common stock, at a price to the public of $0.75. The Company granted the underwriter a 30-day option to purchase up to 2,500,000 additional shares of common stock and/or short-term warrants to purchase 1,250,000 shares of common stock and long-term warrants to purchase 1,250,000 shares of common stock of the Company at the public offering price, less underwriting discounts and commissions. The underwriter exercised its option to purchase the short-term warrants to purchase 1,250,000 shares of common stock and long-term warrants to purchase 1,250,000 shares of common stock effective as of the closing.

Each short-term warrant had an exercise price of $0.75 per share of common stock, and expired in accordance with their terms on May 14, 2020 (with only 38,000 shares being issued upon exercise). Each long-term warrant has an exercise price of $0.90 per share of common stock, is immediately exercisable and will expire five years following the date of issuance.

On May 1, 2020, the Company issued warrants to acquire 9,200,000 shares of Company common stock to the former sole shareholder of Noachis Terra Inc. ("NTI") in connection with the Company's acquisition of NTI (the "NTI Warrants"). The NTI Warrants are exercisable at $1.25 per share, and have a five-year term. The NTI Warrants may not be exercised until the first anniversary of the issuance of the NTI Warrants. See Note 3. Acquisition.

8. Stock Compensation Plan

The Company originally adopted the Oragenics, Inc. 2002 Stock Option and Incentive Plan (the "Stock Incentive Plan") in September 2002 which was subsequently amended on several occasions until it was amended and restated as the Company's 2012 Equity Incentive Plan, as amended (the "2012 Incentive Plan"). The aggregate number of shares of the Company's common stock currently authorized pursuant to its Plan, as amended, is 8,250,000 and the Company's Plan, as amended continues to provide that the maximum number of shares that may be subject to stock options and stock appreciation rights granted to any individual in a calendar year is 1,000,000 shares. The Plan also provides that the maximum number of shares that may be subject to awards (other than stock options and stock appreciation rights) intended to qualify as "performance-based compensation" under Section 162(m) of the Internal Revenue Code that may be granted to any individual in one calendar year is 1,000,000 shares (however, the exception for "performance-based compensation" under Code Section 162(m) was repealed in the Tax Cuts and Jobs Act of 2017, unless the awards intended to qualify for such exception were granted before November 2, 2017). As of December 31, 2020, an aggregate of 5,801,349 shares of common stock are covered by outstanding option awards and 2,207,901 shares of common stock are available for future awards under the Plan.

The purpose of the 2012 Incentive Plan is to advance the interests of the Company by affording certain employees and directors of the Company and key consultants and advisors an opportunity to acquire or increase their proprietary interests in the Company. The 2012 Incentive Plan authorizes the grant of stock options (incentive and non-statutory), stock appreciation rights and restricted stock. Options are granted at the fair market value of the Company's stock on the date of grant. Options can generally vest either immediately or over a period of up to three years from their respective grant dates and expire 10 years from the date of grant. As of December 31, 2020, and 2019, the Company had not awarded any stock appreciation rights under the 2012 Incentive Plan.

Recipients of stock awards under our 2012 Incentive Plan become the owner of record of the stock immediately upon grant, which may be subject to certain restrictions. The balance of unvested restricted stock will be forfeited and automatically transferred back to us at no cost upon the termination of the recipient's employment. Upon vesting of restricted stock that is made to recipients who are employees, the recipient has the option to settle minimum withholding taxes by electing to have us withhold otherwise deliverable shares having a fair market value equal to the required tax obligations ("net-settlement"). The net-settlement shares are then immediately cancelled and retired and reduce the shares available for issuance under the Company's 2012 Incentive Plan.

The Company uses the Black-Scholes option pricing model to estimate the fair value of stock-based awards on the date of grant. The assumptions employed in the calculation of the fair value of share-based compensation expense were calculated as follows for all years presented:

- Expected dividend yield — based on the Company's historical dividend yield.
- Expected volatility — based on the Company's historical market price at consistent points in a period equal to the expected life of the options.
- Risk-free interest rate — based on the US Treasury yield curve in effect at the time of grant.
- Expected life of options — based on the Company's historical life of options exercised, giving consideration to the contractual terms of the grants, vesting schedules and expectations of future employee behavior.

The following table summarizes the assumptions used to estimate the fair value of stock options granted during the years ended December 31, 2020 and 2019:

	2020	2019
Expected dividend yield	0%	0%
Weighted-average expected volatility	149-150%	154-158%
Weighted-average risk-free interest rate	0.61-1.66%	2.10 - 2.43%
Expected life of options	10 years	10 years

Total compensation cost related to stock options was $1,491,165 and $552,996 for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, there was $316,497 of unrecognized compensation costs related to stock options, which is expected to be recognized over a weighted average period of approximately one year.

The following table represents stock option activity for the year ended December 31, 2020:

	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Term (In Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2019	2,486,365	$ 1.47	8.67	$ 22,229
Expired	(1,000)	100.00		
Granted	3,315,984	0.50		
Outstanding at December 31, 2020	5,801,349	$ 0.90	8.52	$ 2,773
Exercisable at December 31, 2020	4,086,855	$ 1.06	8.27	$ 2,773

The following table summarizes the weighted average grant date fair value of stock options granted per share, the total intrinsic value of stock options exercised and the grant date fair value of stock options that vested during the years ended December 31, 2020 and 2019:

	2020	2019
Weighted average grant date fair value of stock options granted per share	$ 0.49	$ 0.49
Intrinsic value of stock options exercised	—	—
Grant date fair value of stock options that vested	$ 1,212,483	$ 522,361

9. License Agreements

NIH License

Through Noachis Terra Inc., the Company is a party to a Patent License and Biological Materials License Agreement (the "License Agreement" or "NIH License"), dated March 23, 2020, with the United States Department of Health and Human Services (the "HHS"), as represented by the National Institute of Allergy and Infectious Diseases ("NIAID"), an Institute within the National Institutes of Health ("NIH"). Under the terms of the License Agreement, the Company holds a nonexclusive, worldwide license to certain specified patent rights (including patent applications, provisional patent applications and Patent Cooperation Treaty ("PCT") patent applications) and biological materials relating to the use of pre-fusion coronavirus spike proteins to exploit products ("Licensed Products") and practice processes ("Licensed Processes") that are covered by the licensed patent rights and biological materials for the purpose of developing and commercializing a vaccine product candidate for SARS-CoV-2.

The License Agreement will expire upon (a) twenty (20) years from the first commercial sale where no licensed patent rights exist or have ceased to exist or (b) the expiration of the last patent contained in the licensed patent rights, unless terminated earlier. None of the applications included in the NIH licensed patent rights have issued yet. The NIH may terminate or modify the license in the event of a material breach, including if the Company does not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such breach or insolvency event. The Company may terminate the license, or any portion thereof, at its sole discretion at any time upon 60 days written notice to the NIH.

Exclusive Channel Collaboration Agreement ("Lantibiotic ECC"):

On June 5, 2012, the Company entered into the Lantibiotic ECC with Precigen, Inc., ILH Holdings, Inc. (n/k/a Eleszto Genetika, Inc. ("EGI")) that governs a "channel collaboration" arrangement in which the Company will use EGI's advanced transgene and cell engineering platforms for the development and production of lantibiotics, a class of peptide antibiotics that are naturally produced in Gram-positive bacteria and contain the characteristic polycyclic thioether amino acids lanthionine and methyllanthonine (collectively, the "Lantibiotics Program"). The Lantibiotic ECC grants the Company an exclusive worldwide license to use patents and other intellectual property of EGI in connection with the research, development, use, importing, exporting, manufacture, sale, and offer for sale of drug products involving the direct administration to humans or companion animals of a lantibiotic for the prevention or treatment of infectious disease ("Oragenics Products"). Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of Oragenics Products, and otherwise is non-exclusive. Subject to limited exceptions, the Company may not sublicense the rights described without EGI's written consent. The Lantibiotic ECC establishes committees comprised of Company and EGI representatives that will govern activities related to the Lantibiotics Program in the areas of project establishment, chemistry, manufacturing and controls matters, clinical and regulatory matters, commercialization efforts and intellectual property matters. The Company has agreed to indemnify and hold EGI harmless from any damages caused as a result of (i) our negligence or willful misconduct, (ii) the use, handling, storage, or transport of EGI Materials (as defined in the Lantibiotic ECC), (iii) our breach of a material representation, warranty or covenant in the Lantibiotic ECC, or (iv) the design, development, manufacture, regulatory approval, handling, storage, transport, distribution, sale or other disposition of any Oragenics Product.

EGI may terminate the Lantibiotic ECC if we fail to use diligent efforts to develop and commercialize Oragenics Products or if we elect not to pursue the development of a Lantibiotics Program identified by EGI that is a "Superior Therapy" as defined in the Lantibiotic ECC. We may voluntarily terminate the Lantibiotic ECC at any time upon 90 days written notice to EGI. Upon termination of the Lantibiotic ECC, the Company may continue to develop and commercialize any Oragenics Product that has been, at the time of termination:

- commercialized by the Company;
- approved by regulatory authorities;
- a subject of an application for regulatory approval that is pending before the applicable regulatory authority; or
- the subject of at least an ongoing Phase 1, Phase 2 or Phase 3 clinical trial in the Field (in the case of a termination by EGI due to an uncured material breach by the Company or a voluntary termination by the Company).

The Company has ongoing obligations and commitments with respect to its License Agreements. See Note 12 — Commitments and Contingencies.

10. Retirement Plan

The Company has a defined contribution Simple Individual Retirement Arrangement plan, which covers all employees and provides for a Company match of up to 3% of all employee compensation to the plan. Total matching contributions made by the Company for the years ended December 31, 2020 and 2019 were $37,407 and $36,074 respectively.

11. Income Taxes

The components of the provision for income taxes for the years ended December 31, 2020 and 2019 are as follows:

	2020	2019
Current	$ —	$ —
Deferred	6,482,623	3,873,976
Valuation Allowance	(6,482,623)	(3,873,976)
Total provision for income taxes	$ —	$ —

At December 31, 2020 and 2019, the Company had temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and their respective income tax bases, as measured by enacted state and federal tax rates, as follows:

	2020	2019
Deferred tax assets (liabilities):		
Net operating loss carryforward	$ 35,740,882	$ 29,424,801
Accrued vacation	41,361	35,933
Non-qualified stock compensation	798,719	638,413
Restricted stock	-	(808)
Total deferred tax assets, net	36,580,962	30,098,339
Less valuation allowance	(36,580,962)	(30,098,339)
Total net deferred taxes	$ —	$ —

The following is a reconciliation of tax computed at the statutory federal rate to the income tax benefit in the statements of operations for the years ended December 31, 2020 and 2019:

	2020	2019
Income tax benefit computed at statutory federal rate of 21% and 21%, respectively	$ (5,550,447)	$ (3,268,861)
State income tax benefits, net of federal expense/benefit	(1,148,414)	(676,343)
Change in valuation allowance	6,482,623	3,873,976
Non-deductible expenses	740	3,065
Other	215,498	68,163
Total	$ —	$ —

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based upon the levels of historical taxable income and projections of future taxable income over which the deferred tax assets are deductible, the Company believes that it is more likely than not that it will not be able to realize the benefits of some of these deductible differences.

Accordingly, a valuation allowance of $36,580,962 and $30,098,339 has been provided in the accompanying consolidated financial statements as of December 31, 2020 and 2019, respectively. The 2020 net change in valuation allowance related to deferred tax assets was an increase of $6,482,623 primarily relating to net operating loss carryforwards. The 2019 net change in valuation allowance related to deferred tax assets was an increase of $3,796,048 primarily relating to net operating loss carryforwards and a change in the effective tax rate.

At December 31, 2020, the Company has federal and state tax net operating loss carryforwards of approximately $142,893,000. Federal and state of Florida tax net operating loss carryforwards generated prior to December 31, 2017 will expire through 2037. Federal and state of Florida tax net operating loss carryforwards generated subsequent to December 31, 2017, do not expire and are no longer subject to taxable income limitation pursuant to the Coronavirus Aid, Relief, and Economic Security Act, passed on March 27, 2020. State of Pennsylvania tax net operating loss carryforwards will expire through 2036. The Company also has federal research and development tax credit carryforwards of approximately $4,043,000. The federal tax credit carryforward will expire beginning in 2021 and continuing through 2040, unless previously utilized.

Utilization of net operating loss carryforwards and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or, could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986 ("IRC Section 382") and with Section 383 of the Internal Revenue Code of 1986, as well as similar state provisions. These ownership changes may limit the amount of net operating loss carryforwards and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change, as defined by IRC Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. The Company has completed several financings since its inception which may result in a change in ownership as defined by IRC Section 382, or could result in a change in control in the future.

For the years ended December 31, 2020 and 2019, the Company incurred $1,129,848 and $503,944, respectively, of additional unrecognized tax benefits that related to research and development credits. The entire amount of this unrecognized tax benefit, if recognized, would result in an increase to the deferred tax asset valuation allowance, and would not have an impact on the effective tax rate.

The Company files its income tax returns in the U.S. federal jurisdiction and in Florida and Pennsylvania. With few exceptions, the Company is no longer subject to federal or state income tax examinations by tax authorities for years before 2014.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

Balance as of December 31, 2018	$	2,249,594
Additions based on tax positions related to the current year		503,944
Additions for return-to-provision true-up		51,183
Reductions for the tax positions of prior years		—
Balance as of December 31, 2019	$	2,804,721
Additions based on tax positions related to the current year		1,129,848
Additions for return-to-provision true-up		108,136
Reductions for the tax positions of prior years		—
Balance as of December 31, 2020	$	4,042,705

Included in the balance at December 31, 2020 and 2019, are $4,042,705 and $2,804,721, respectively, of tax positions for which there is uncertainty about the validity of certain credits. The disallowance of the credits would impact the amount of gross deferred tax assets reflected in the accompanying footnotes.

During the years 2020 and 2019 the Company did not recognize any interest and penalties. Due to the potential offset of the Company's operating loss carryforward for any future activity, the amount attributed to interest and penalties would be immaterial.

12. Commitments and Contingencies

Additional Consideration–NTI Acquisition.

In connection with the Company's acquisition of NTI, the Company is obligated to pay the former sole shareholder of NTI contingent consideration based upon the exercise of certain of the Company's outstanding warrants as follows: (i) twenty percent (20%) of the cash proceeds received by the Company upon exercise of the Company's warrants carrying an exercise price of $0.75 and $0.90 and (ii) forty-five percent (45%) of the cash proceeds received by the Company upon exercise of the Company's warrants carrying an exercise price of $1.00, in each case, for so long as the warrants remain outstanding. The Company's previously issued warrants carrying an exercise price of $0.75 have expired by their terms. As a result, no additional consideration will be due to the former sole shareholder of NTI relating to these warrants.

During the three month period ending September 30, 2020, 760,000 warrants of the Company's previously reported remaining outstanding warrants to acquire 4,294,500 shares of Common Stock at an exercise price of $1.00 per share issued in connection with its July 2018 public offering, were exercised and (ii) 4,882,114 warrants of the Company's previously reported outstanding warrants to acquire 9,583,334 shares of Common Stock at an exercise price of $0.90 per share issued in connection with its March 2019 public offering, were exercised. See Note 7. Shareholders' Equity.

As a result of the Warrant Exercises, the Company paid $1,220,781 of additional consideration to the sole former shareholder of NTI. The additional consideration payment is included in research and development expenses. See also Note 14 Subsequent Events for additional consideration paid to such former shareholder as a result of additional warrant exercises.

NIH License

Through NTI, the Company is a party to a Patent License and Biological Materials License Agreement (the "License Agreement" or "NIH License"), dated March 23, 2020, with the United States Department of Health and Human Services (the "HHS"), as represented by the National Institute of Allergy and Infectious Diseases ("NIAID"), an Institute within the National Institutes of Health ("NIH"). Under the terms of the License Agreement, we hold a nonexclusive, worldwide license to certain specified patent rights (including patent applications, provisional patent applications and Patent Cooperation Treaty ("PCT") patent applications) and biological materials relating to the use of pre-fusion coronavirus spike proteins to exploit products ("Licensed Products") and practice processes ("Licensed Processes") that are covered by the licensed patent rights and biological materials for the purpose of developing and commercializing a vaccine product candidate for SARS-CoV-2.

Under the terms of the NIH License Agreement, the NIAID is entitled to receive a non-creditable, nonrefundable upfront license issue royalty of $30,000 and reimbursement of $11,739 for our pro rata share of the NIAID's past and future patent prosecution-related expenses (which amounts have already been paid). Additionally, the NIAID is entitled to receive lump sum nonrefundable minimum annual royalties, which increase in the year after the first commercial sale of any Licensed Products or the practice of any Licensed Processes, as well as lump sum benchmark royalties following our completion of certain commercial development and sales-related benchmarks. The NIH is entitled to receive earned royalties on the annual net sales of Licensed Products and the practice of any Licensed Processes (subject to certain reductions), at certain low- to mid-single digit royalty rates, which rates vary based on the total amount of annual net sales and the geographic market in which those sales occur. We must provide regular written reports to the NIAID on the development status of and royalty payments relating to the Licensed Products and the Licensed Processes.

The License Agreement will expire upon (a) twenty (20) years from the first commercial sale where no licensed patent rights exist or have ceased to exist or (b) the expiration of the last patent contained in the licensed patent rights, unless terminated earlier. None of the applications included in the NIH licensed patent rights have issued yet. The NIH may terminate or modify the license in the event of a material breach, including if the Company does not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such breach or insolvency event. The Company may terminate the license, or any portion thereof, at its sole discretion at any time upon 60 days written notice to the NIH.

The Lantibiotic ECC

Under the Company's Lantibiotic ECC with ILH Holdings, Inc. (n/k/a Eleszto Genetika, Inc. ("EGI")) (the "Lantibiotic ECC, and subject to certain exceptions, the Company is responsible for, among other things, funding the further anticipated development of lantibiotics toward the goal of commercialization, conducting nonclinical and clinical development of candidate lantibiotics, as well as for other aspects of manufacturing and the commercialization of the product(s). Among other things, EGI is responsible for technology discovery efforts, cell-engineering development, certain aspects of the manufacturing process, and costs of filing, prosecution and maintenance of EGI's patents.

In November of 2017 the Lantibiotic ECC was amended to: (i) consolidate the development milestone payments into one payment of $25,000,000, being due six months after receiving FDA approval of a New Drug Application, (ii) reduce the sublicense revenue percentage we would have had to pay from 50% to 25% of sublicensing revenue, (iii) reduce the royalty rate from 25% of Product Profit to 10% of Net Sales, (iv) revise the form of milestone payments from being share based or cash at the Company's election to only cash, and (v) commit that Diligent Efforts (as defined in the Lantibiotic ECC) in pursuing the Lantibiotic Program would be deemed satisfied in 2018 provided that at least $1,200,000 was budgeted for the advancement of the Lantibiotic Program.

In November of 2017, the Stock Issuance Agreement was also amended. Under the terms of the amendment, the Company has agreed to make certain payments, in cash, to EGI upon our achievement of designated milestones. The milestone events and amounts payable are as follows:

(i) a one-time payment of twenty-five million United States dollars ($25,000,000) within six (6) months of the achievement of the Regulatory Approval Milestone Event meaning receiving approval from the FDA of a New Product Application for an Oragenics Product (or equivalent regulatory action in a foreign jurisdiction);

(ii) a one-time payment of five million United States dollars ($5,000,000) within six (6) months of the achievement of the New Indication Milestone Event meaning receiving approval from the FDA of a Supplemental FDA Application (or an equivalent filing with another equivalent regulatory agency) which Supplemental FDA Application sought approval of an indication for use of the Oragenics Product other than the current regulatory-approved indication; and

(iii) a one-time payment of five million United States dollars ($5,000,000) within six (6) months of the achievement of the New Product Milestone Event meaning receiving approval from the FDA of a New Product Application that is deemed to be a different drug product that the first Oragenics Product that was clinically pursued under the Lantibiotics Program.

Pursuant to the terms of the amendment, we will also pay EGI on a quarterly basis 10% of Net Sales derived in that quarter from the sale of products developed from the Lantibiotic ECC, calculated on an Oragenics Product-by-Oragenics Product basis and we will pay EGI on a quarterly basis 25% of revenue obtained in that quarter from a sublicensor in the event of a sublicensing arrangement.

On July 21, 2016, the Lantibiotics ECC was amended to revise the definition of Field in view of a provisional patent application filing between EGI and Oragenics and to further clarify Oragenics' rights under the Lantibiotic ECC to genetically modified *Streptococcus mutans* that express Lantibiotic(s).

None of the Lantibiotic ECC milestones had been achieved as of December 31, 2020.

Leases

Lab Facility-Alachua. The Company's Alachua facility is being leased from a real estate developer for a term of five years beginning in December 2014. Under the lease agreement, the rental payments range from $9,641 per month to $10,851 per month. In June of 2019, the Company entered into an amendment for the Alachua facility for a term of five years beginning in December of 2019. Under the amended lease agreement, the rental payments range from $12,870 per month to $13,338 per month. Total rental expense for the Alachua facility during the year ended December 31, 2020 was approximately $165,000. The lease may be terminated prior to its stated expiration date upon the payment of nine-months rent.

Corporate Office-Tampa. In November of 2016, the Company entered into an amendment for the leased office space for corporate personnel located in Tampa, FL. The amended lease is for approximately 2,207 square feet. The lease period for the office space is for thirty-six months commencing on March 1, 2017. Lease payments range from $4,138 per month to $4,392 per month inclusive of insurance, taxes and utilities. The lease expires on February 29, 2020. In November of 2019, the Company entered into an amendment for the Tampa facility for a term of three years beginning in March of 2020. Under the amended lease agreement, the rental payments range from $4,524 per month to $4,800 per month. Total rent expense under this lease was approximately $61,000 for the year ended December 31, 2020.

Supplemental balance sheet information related to leases is as follows:

	December 31, 2020
Operating lease right-of-use assets	$ 655,138
Operating lease liabilities - Short term	$ 176,900
Operating lease liabilities - Long term	493,790
Total operating lease liabilities	$ 670,690

	For the Twelve Months Ended December 31, 2020	For the Twelve Months Ended December 31, 2019
Weighted Average Remaining Lease Term In Years		
Operating leases	3.46	4.46
Weighted Average Discount Rate		
Operating leases	5.70%	5.70%

Maturities of operating lease liabilities are as follows:

Year ended December 31:	
2021	210,561
2022	217,379
2023	169,657
2024	146,718
Total	$ 744,315
Less: Imputed interest	(73,625)
Present value of lease liabilities	$ 670,690

The cost component of operating leases is as follows:

	For the Twelve Months Ended December 31, 2020	For the Twelve Months Ended December 31, 2019
Operating lease cost	$ 226,090	$ 214,359
Short-term lease cost	2,149	3,989
Total lease cost	$ 228,239	$ 218,348

Supplemental cash flow information related to operating leases is as follows:

	For the Twelve Months Ended December 31, 2020	For the Twelve Months Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ (225,681)	$ (201,256)
Non-cash investing and financing activities:		
Additions to ROU assets obtained from:		
Right-of-use assets obtained in exchange for new operating lease liabilities	—	$ 176,027
Right-of-use assets and lease liabilities obtained from lease modifications	—	$ 815,937

13. Unaudited Quarterly Financial Information

The quarterly interim financial information shown below has been prepared by the Company's management and is unaudited. It should be read in conjunction with the audited consolidated financial statements appearing herein.

	2020			
	First	Second	Third	Fourth
Revenues	$ —	$ —	$ —	$ —
Total operating expenses	(5,231,762)	(12,352,306)	(4,508,367)	(4,549,021)
Net Loss	(5,187,760)	(12,337,296)	(4,496,560)	(4,409,083)
Loss per share:				
Basic and diluted net loss per share from continuing operations	$ (0.11)	$ (0.24)	$ (0.08)	$ (0.04)

	2019			
	First	Second	Third	Fourth
Revenues	$ —	$ —	$ —	$ —
Total operating expenses	3,394,210	4,904,854	3,920,453	3,658,053
Net Loss	(3,325,717)	(4,806,460)	(3,836,549)	(3,597,278)
Loss per share:				
Basic and diluted net loss per share from continuing operations	$ (0.11)	$ (0.10)	$ (0.08)	$ (0.08)

14. Subsequent Events

ATM Offering-Sales Agreement. On February 1, 2021, the Company entered into a Sales Agreement (the "Sales Agreement") with A.G.P./Alliance Global Partners, as sales agent (the "Sales Agent"), pursuant to which the Company may offer and sell through or to the Sales Agent (the "Offering") up to $20.0 million in shares of its common stock (the "Shares") at-the-market. Through February 12, 2021, the Company sold an aggregate of 15,406,618 shares of its common stock at-the-market pursuant to the Sales Agreement for aggregate net proceeds to the Company of approximately $19.3 million. Any Shares offered and sold in the Offering were issued pursuant to the Company's universal shelf registration statement on Form S-3 (the "Shelf Registration Statement") and the prospectus supplement relating to the Offering filed with the Securities and Exchange Commission (the "SEC") on February 1, 2021. The Offering will terminate upon (a) the election of the Agent upon the occurrence of certain adverse events, (b) 10 days' advance notice from one party to the other, or (c) the sale of the Shares equating to $20 million. Under the terms of the Sales Agreement, the Sales Agent is entitled to a commission at a fixed rate of 3.0% of the gross proceeds from each sale of shares under the Sales Agreement.

Series C Preferred Stock Dividend and Series C Preferred Stock Redemption. On February 11, 2021, we provided a notice of redemption, for approximately $5.6 million, to the holder of our Series C Preferred Stock, with a redemption date of March 13, 2021 (which included the dividend of 26.697 shares paid on January 28, 2021 and any accrued dividends due through the redemption date), after which time the Series C Preferred Stock will be cancelled and no further dividends will accrue. The applicable portion of the net proceeds received from the above referenced ATM Offering are being utilized for the redemption.

Warrant Exercises. Between February 9, 2021 and February 25, 2021 the Company issued an additional 2,472,573 shares of common stock as a result of the exercise of certain outstanding warrants as follows: (i) warrants to acquire 360,000 shares of Common Stock at an exercise price of $1.00 per share issued in connection with its July 2018 public offering were exercised and (ii) warrants to acquire 2,112,573 shares of Common Stock at an exercise price of $0.90 per share issued in connection with its March 2019 public offering were exercised (the "Warrant Exercises"). The Warrant Exercises provided aggregate gross proceeds to the Company of $2,261,315.

Additional Consideration Payment – Noachis Terra Acquisition. As a result of the Warrant Exercises, the Company paid $542,263 of additional consideration to the sole former shareholder of Noachis Terra. The additional consideration payment will be included in operating expenses.

Exhibit 4.6

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

Oragenics, Inc. ("Oragenics," "we," "our," or "us") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock.

DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms that are included in our amended and restated articles of incorporation (as amended) and our bylaws (as amended) as well as the specific agreements such descriptions relate to. This summary is qualified in its entirety by the specific terms and provisions contained in our restated articles of incorporation, bylaws and the specific agreements described herein, copies of which we have filed as exhibits to our Annual Report on Form 10-K and are incorporated herein by reference.

Overview

Authorized Capital Stock

Our authorized capital stock consists of 200,000,000 shares of common stock, par value $0.001, and 50,000,000 shares of preferred stock, without par value.

Listing

Our common stock is listed and principally traded on the NYSE American under the symbol "OGEN."

Common Stock

Voting

The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the shareholders. Approval of an amendment of our articles of incorporation, a merger, a share exchange, a sale of all our property or dissolution must be approved by a majority of all votes entitled to be cast. Such votes may be cast in person or by proxy as provided in Article I Section 8 of our bylaws.

Dividends

Subject to preferences that may be applicable to any outstanding preferred stock, the holders of our common stock are entitled to receive ratably all dividends, if any, as may be declared from time to time by our Board of Directors out of the funds legally available.

In the event of the liquidation, dissolution or winding up of the Company, the holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities, subject to prior distribution rights of preferred stock, if any, then outstanding. The common stock has no preemptive or conversion rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and non-assessable.

Rights upon Liquidation

Upon our liquidation, dissolution or winding-up, after payment in full of our liabilities and the amounts required to be paid to holders of any outstanding shares of preferred stock, if any, all holders of our common stock, along with the holders of our Series A Convertible Preferred Stock and Series B Convertible Preferred Stock on an "as if" converted basis, will be entitled to receive a pro rata distribution of all of our assets and funds legally available for distribution.

Redemption and Pre-Emptive Rights

No shares of our common stock are subject to redemption or have preemptive rights to purchase additional shares of our common stock or any of our other securities except for the Equity Participation Right described below.

Fully Paid and Non-assessable

All of our outstanding shares of common stock are fully paid and non-assessable.

Preferred Stock

Our Board of Directors has the authority, without action by our shareholders, to designate and issue up to 50,000,000 shares of preferred stock in one or more series or classes and to designate the rights, preferences and privileges of each series or class, which may be greater than the rights of our common stock. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, redemption rights, liquidation preferences, the number of shares constituting any class or series and the designation of the class or series. Terms selected by our Board of Directors in the future could decrease the amount of earnings and assets available for distribution to holders of shares of common stock or adversely affect the rights and powers, including voting rights, of the holders of shares of common stock without any further vote or action by the stockholders. As a result, the rights of holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of the Series A Convertible Preferred Stock, and Series B Convertible Preferred Stock or any other preferred stock that may be issued by us in the future, which could have the effect of decreasing the market price of our common stock. As of February 25, 2021, we have 16,017,000 shares of preferred stock issued and outstanding (excluding shares of Series C Preferred Stock which we have provided a notice of redemption to the holder which is to occur on March 13, 2021).

Transfer Agent and Registrar

The transfer agent and registrar of our common stock is Continental Stock Transfer & Trust Company, 1 State Street 30th Floor, New York, New York 10004, telephone: (212) 509-4000.

Certain Anti-Takeover Provisions

Florida Law

We are not subject to the statutory anti-takeover provisions under Florida law because in our articles of incorporation we have specifically elected to opt out of both the "control-share acquisitions" (F.S. 607.0902) and the "affiliated transactions" (F.S. 607.0901) statutes. Since these anti-takeover statutes do not apply to a corporation that has specifically elected to opt out of such provisions, we would not be able to invoke the protection of such statutes in the event of a hostile takeover attempt.

Articles of Incorporation and Bylaw Provisions

Our articles of incorporation and bylaws contain provisions that could have an anti-takeover effect. These provisions include

- authorization of the issuance of "blank check" preferred stock that could be issued by our Board of Directors without shareholder approval and that may be substantially dilutive or contain preferences or rights objectionable to an acquiror;
- the ability of the Board of Directors to amend the bylaws without shareholder approval;
- vacancies on our Board may only be filled by the remaining Directors and not our shareholders; and
- requirements that only our Board, our President or holders of more than 10% of our shares can call a special meeting of shareholders.

These provisions in our articles of incorporation and bylaws could delay or discourage transactions involving an actual or potential change in control of us, including transactions in which shareholders might otherwise receive a premium for their shares over their current prices. Such provisions could also limit the ability of shareholders to approve transactions that shareholders may deem to be in their best interests and could adversely affect the price of our common stock.

Equity Participation Right- Eleszto Genetika, Inc.

Pursuant to the amended and restated exclusive channel collaboration agreement, which incorporated the stock issuance agreement with Eleszto Genetika, Inc. ("EGI" formerly known as ILH Holdings, Inc.) (assignee of Precigen Inc. f/k/a Intrexon Corporation). EGI is entitled, at its election, to participate in future securities offerings by us that constitute "qualified financings" and purchase securities equal to 30% of the number of shares of common stock or other securities sold in such offering (exclusive of Intrexon's purchase). For this purpose, a "qualified financing" means a sale of common stock or equity securities convertible into common stock in a public or private offering, raising gross proceeds of at least $1,000,000, where the sale of shares is either registered under the Securities Act of 1933, as amended, at the time of issuance or we agree to register the resale of such shares.

Registration Rights

Series A Preferred Stock Private Placement. Pursuant to the May 10, 2017 Registration Rights Agreement, we granted certain demand registration rights and piggyback registration rights with respect to the shares of our Common Stock issuable upon conversion of the Series A Preferred Stock and the exercise of the common stock warrants that were issued commensurate with the issuance of the Series A Preferred Stock.

Series B Preferred Stock Private Placement. Pursuant to the November 8, 2017 Amended and Restated Registration Right Agreement, we granted certain demand registration rights and piggyback registration rights with respect to the shares of our Common Stock issuable upon conversion of the Series B Preferred Stock and the exercise of the common stock warrants that were issued commensurate with the issuance of the Series B Preferred Stock.. The Amended and Restated Registration Rights Agreement amended the previous registration rights agreement entered into in connection with our Series A Preferred Stock Financing in May 2017.

[***] Portions of this exhibit have been redacted pursuant to Item 601(b)(2) of Regulation S-K as (i) not material and (ii) likely to cause competitive harm if publicly disclosed. The Company hereby undertakes to furnish unredacted copies of this exhibit upon request by the Securities and Exchange Commission; provided, however, that the Company may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for such unredacted copies of this exhibit.

EXHIBIT 10.1

AMENDED AND RESTATED

EXCLUSIVE CHANNEL COLLABORATION AGREEMENT

THIS AMENDED AND RESTATED EXCLUSIVE CHANNEL COLLABORATION AGREEMENT (the "**Agreement**") is made and entered into effective as of March 1, 2021 (the "**Effective Date**") by and between **ELESZTO GENETIKA, INC**., a Delaware corporation with offices at 1881 Grove Avenue Radford, Virginia 24141 ("**EGI**"), and **ORAGENICS, INC.,** a Florida corporation having its principal place of business at 4902 Eisenhower Blvd., Suite 125, Tampa, FL 33634 ("**Oragenics**"). EGI and Oragenics may be referred to herein individually as a "**Party**", and collectively as the "**Parties**."

RECITALS

WHEREAS, on June 5, 2012, Oragenics and Intrexon Corporation ("**Intrexon**") entered into (i) that certain Exclusive Channel Collaboration Agreement which was subsequently amended on July 16, 2016 and November 8, 2017 (the "**Lantibiotic ECC**") and (ii) a Stock Issuance Agreement which was subsequently amended on November 8, 2017, to provide for milestone payments in cash (the "**Stock Issuance Agreement**");

WHEREAS, effective January 1, 2020 Intrexon assigned the Lantibiotic ECC and Stock Issuance Agreement to its wholly owned subsidiary, ILH Holdings, Inc. ("**ILH Holdings**");

WHEREAS, in early January 2020 Intrexon sought to change its name to Precigen, Inc. ("**Precigen**") and consummate a restructuring;

WHEREAS, as part of the Precigen restructuring, Precigen entered into a Stock and Asset Purchase Agreement with TS Biotechnology Holdings, LLC ("**TS Bio**") effective January 31, 2020 whereby Precigen sold to TS Bio (i) all of the Oragenics common and preferred stock it held, and (ii) all of the equity interest in its wholly owned subsidiary, ILH Holdings;

WHEREAS, on February 24, 2020, ILH Holdings changed its name to Eleszto Genetika, Inc.; and

WHEREAS, the Parties desire to amend and restate the Lantibiotic ECC to (i) reflect the changes in the names of the Parties following the assignment, (ii) remove provisions that were no longer applicable, (iii) incorporate prior amendments, as applicable, and (iv) incorporate any remaining rights and obligations under the Stock Issuance Agreement into this Agreement and thereafter terminate the Stock Issuance Agreement.

NOW THEREFORE, in consideration of the foregoing and the covenants and promises contained herein, the Parties agree as follows:

ARTICLE 1

Definitions

As used in this Agreement, the following capitalized terms shall have the following meanings:

1.1 "**Affiliate**" means, with respect to a particular Party, any other person or entity that directly or indirectly controls, is controlled by, or is in common control with such Party. As used in this Section 1.1, the term "controls" (with correlative meanings for the terms "controlled by" and "under common control with") means the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of an entity, or the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract, or otherwise. Notwithstanding the foregoing, any person, corporation, partnership, or other entity that would be an Affiliate of a Party solely because it and such Party are under common control by Randal J. Kirk shall not be deemed to be an Affiliate of such Party solely by reason of such control by Randal J. Kirk, with the caveat that, notwithstanding the foregoing, any entity affiliated with Randal J. Kirk shall be deemed to be an Affiliate solely for purposes of Article 9.

1.2 "**Applicable Laws**" has the meaning set forth in Section 8.2(d)(xii).

1.3 "**Authorizations**" has the meaning set forth in Section 8.2(d)(xii).

1.4 "**CC**" has the meaning set forth in Section 2.2(b).

1.5 "**Channel-Related Program IP**" has the meaning set forth in Section 6.1(c).

1.6 "**Claims**" has the meaning set forth in Section 9.1.

1.7 "**CMCC**" has the meaning set forth in Section 2.2(b).

1.8 "**Committees**" has the meaning set forth in Section 2.2(a).

1.9 "**Commercialize**" or "**Commercialization**" means any activities directed to marketing, promoting, distributing, importing for sale, offering to sell and/or selling Oragenics Products.

1.10 "**Confidential Information**" means each Party's confidential Information, inventions, non-public know-how or non-public data disclosed pursuant to this Agreement or any other confidentiality agreement between the Parties and shall include, without limitation, manufacturing, technical, marketing, financial, personnel and other business information and plans, whether in oral, written, graphic or electronic form.

1.11 "**Control**" means, with respect to Information, a Patent or other intellectual property right, that a Party owns or has a license from a Third Party to such right and has the ability to grant a license or sublicense as provided for in this Agreement under such right without violating the terms of any agreement or other arrangement with any Third Party.

1.12 RESERVED.

1.13 "**CRC**" has the meaning set forth in Section 2.2(b).

1.14 "**Diligent Efforts**" means, with respect to a Party's obligation under this Agreement, the level of efforts and resources reasonably required to diligently develop, manufacture, and/or Commercialize (as applicable) each Oragenics Product in a sustained manner, consistent with the efforts and resources a similarly situated company working in the Field would typically devote to a product of similar market potential, profit potential, strategic value and/or proprietary protection, based on market conditions then prevailing. With respect to a particular task or obligation, Diligent Efforts requires that the applicable Party promptly assign responsibility for such task and consistently make and implement decisions and allocate resources designed to advance progress with respect to such task or obligation.

1.15 RESERVED.

1.16 "**Excess Product Liability Costs**" has the meaning set forth in Section 9.3.

1.17 "**Executive Officer**" means: (i) the Chief Executive Officer of the applicable Party, or (2) another senior executive officer of such Party who has been duly appointed by the Chief Executive Officer to act as the representative of the Party to resolve, as the case may be, (a) a Committee dispute, provided that such appointed officer is not a member of the applicable Committee and occupies a position senior to the positions occupied by the applicable Party's members of the applicable Committee, or (b) a dispute described in Section 11.1.

1.18 "**FDA**" has the meaning set forth in Section 8.2(d)(xiii).

1.19 "**Field Infringement**" has the meaning set forth in Section 6.3(b)

1.20 "**Field**" means, irrespective of whether such requires regulatory approval (a) the direct administration to humans or other animals of a Lantibiotic as an active pharmaceutical ingredient in drug products for the prevention or treatment of infectious disease, and/or (b) the direct administration to humans or other animals of *Streptococcus mutans* that is genetically modified to express a Lantibiotic *in vivo* as an active pharmaceutical ingredient in drug products for the prevention or treatment of infectious disease.

1.21 "**First Commercial Sale**" means, with respect to an Oragenics Product and country, the first sale to a Third Party of such Oragenics Product in such country after regulatory approval (and any pricing or reimbursement approvals, if necessary) has been obtained in such country.

1.22 "**Fully Loaded Cost**" means the direct cost of the applicable good, product or service plus indirect charges and overheads reasonably allocable to the provision of such good, product or service in accordance with US GAAP. Subject to the approval of a project and its associated budget by the JSC, EGI will bill for its internal direct costs incurred through the use of annualized standard full-time equivalents; such rate shall be based upon the actual fully loaded costs of those personnel directly involved in the provision of such good, product or service. EGI may, from time to time, adjust such full-time equivalent rate based on changes to its actual fully loaded costs and will review the accuracy of its full-time equivalent rate at least quarterly. EGI shall provide Oragenics with reasonable documentation indicating the basis for any indirect charges, any allocable overhead, and any such adjustment in full-time equivalent rate.

1.23 "**Information**" means information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including without limitation, databases, inventions, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, and patent and other legal information or descriptions.

1.24 "**Infringement**" has the meaning set forth in Section 6.3(a).

1.25 "**EGI Channel Technology**" means EGI's current and future technology directed towards the design, identification, culturing, and/or production of cell lines, including without limitation the technology embodied in the EGI Materials and the EGI IP, and specifically including without limitation the following of EGI's platform areas and capabilities: (1) UltraVector®, (2) DNA and RNA MOD engineering, (3) protein engineering, (4) transcription control chemistry, (5) genome engineering, and (6) cell system engineering.

1.26 "**EGI Indemnitees**" has the meaning set forth in Section 9.2.

1.27 "**EGI IP**" means the EGI Patents and EGI Know-How.

1.28 "**EGI Know-How**" means all Information (other than EGI Patents) that (a) is Controlled by EGI as of the Effective Date or during the Term and (b) is reasonably required or useful for Oragenics to conduct the Lantibiotics Program. For the avoidance of doubt, the EGI Know-How shall include any Information (other than EGI Patents) in the Channel-Related Program IP.

1.29 "**[*****] Third Party IP**" has the meaning set forth in Section 3.8(a).

1.30 "**EGI Materials**" means the genetic code and associated amino acids and gene constructs used alone or in combination and such other proprietary reagents including but not limited to plasmid vectors, virus stocks, cells and cell lines, antibodies, and ligand-related chemistry, in each case that are reasonably required or provided to Oragenics to conduct the Lantibiotics Program.

1.31 "**EGI Patents**" means all Patents that (a) are Controlled by EGI as of the Effective Date or during the Term; and (b) are reasonably required or useful for Oragenics to conduct the Lantibiotics Program. For the avoidance of doubt, the EGI Patents shall include any Patent in the Channel-Related Program IP.

1.32 "**EGI Trademarks**" means those trademarks related to the EGI Channel Technology that are established from time to time by EGI for use across its channel partnerships or collaborations.

1.33 "**Inventions**" has the meaning set forth in Section 6.1(b).

1.34 "**IPC**" has the meaning set forth in Section 2.2(b).

1.35 "**JSC**" has the meaning set forth in Section 2.2(b).

1.36 RESERVED.

1.37 RESERVED.

1.38 "**Lantibiotics**" means antibiotic compounds that contain the polycyclic thioether amino acids lanthionine or methyllanthionine, as well as, the unsaturated amino acids dehydroalanine and 2-aminoisobutyric acid.

1.39 "**Lantibiotics Program**" has the meaning set forth in Section 2.1.

1.40 "**Losses**" has the meaning set forth in Section 9.1.

1.41 RESERVED.

1.42 "**Net Sales**" means, with respect to any Oragenics Product, the net sales of such Oragenics Product by Oragenics or an Affiliate of Oragenics (including without limitation net sales of Oragenics Product to a non-Affiliate sublicensee but not including net sales by such non-Affiliate sublicensee), as determined in accordance with US GAAP as the gross amount invoiced on account of sales of Oragenics Product less the usual and customary discounts as determined in accordance with US GAAP. In the case of any sale for value, such as barter or counter-trade other than in an arm's length transaction exclusively for cash, Net Sales shall be deemed to be the net sales at which substantially similar quantities of the product are sold for cash in an arm's length transaction in the relevant country. If Oragenics Product is sold to any third party together with other products or services, the price of such product, solely for purposes of the calculation of Net Sales, shall be deemed to be no less than the price at which such product would be sold in a similar transaction to a third party not also purchasing the other products or services.

1.43 "**Oragenics Indemnitees**" has the meaning set forth in Section 9.1.

1.44 "**Oragenics Independent IP**" has the meaning set forth in Section 6.1(f).

1.45 "**[*****] Third Party IP**" has the meaning set forth in Section 3.8(a).

1.46 "**Oragenics Product**" means any product in the Field that is created, produced, developed, or identified in whole or in part, directly or indirectly, by or on behalf of Oragenics during the Term through use or practice of EGI Channel Technology, EGI IP, or the EGI Materials.

1.47 "**Oragenics Program Patent**" has the meaning set forth in Section 6.2(b).

1.48 "**Oragenics Termination IP**" means all Patents or other intellectual property that Oragenics or any of its Affiliates Controls as of the Effective Date or during the Term that cover, or is otherwise necessary or useful for, the development, manufacture or commercialization of a Reverted Product or necessary or useful for EGI to operate in the Field. Notwithstanding the foregoing, Oragenics Termination IP shall not include Oragenics Independent IP.

1.49 "**Patents**" means (a) all patents and patent applications (including provisional applications), (b) any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, requests for continued examination, confirmations, re-examinations, extensions, supplementary protection certificates and the like of the foregoing, and (c) any foreign or international equivalents of any of the foregoing.

1.50 RESERVED.

1.51 "**Product-Specific Program Patent**" means any issued EGI Patent where all the claims are directed to Inventions that relate solely and specifically to Oragenics Products. In the event of a disagreement between the Parties as to whether a particular EGI Patent is or is not a Product-Specific Program Patent, the Parties shall seek to resolve the issue through discussions at the IPC, provided that if the Parties are unable to resolve the disagreement, the issue shall be submitted to arbitration pursuant to Section 11.2. Any EGI Patent that is subject to such a dispute shall be deemed not to be a Product-Specific Program Patent unless and until (a) EGI agrees in writing that such Patent is a Product-Specific Program Patent or (b) an arbitrator or arbitration panel determines, pursuant to Article 11, that such EGI Patent is a Product-Specific Program Patent.

1.52 "**Product Sublicense**" has the meaning set forth in Section 3.2(c).

1.53 "**Product Sublicensee**" has the meaning set forth in Section 3.2(c).

1.54 "**Proposed Terms**" has the meaning set forth in Section 11.2.

1.55 "**Prosecuting Party**" has the meaning set forth in Section 6.2(c).

1.56 "**Recovery**" has the meaning set forth in Section 6.3(f).

1.57 "**Retained Product**" has the meaning set forth in Section 10.4(a).

1.58 "**Reverted Product**" has the meaning set forth in Section 10.4(c).

1.59 "**SEC**" means the United States Securities and Exchange Commission.

1.60 "**Sublicensing Revenue**" means any cash consideration, or the cash equivalent value of non-cash consideration, regardless of whether in the form of upfront payments, milestones, or royalties, actually received by Oragenics or its Affiliate from a Third Party in consideration for a grant of a sublicense under the EGI IP or any rights to develop or commercialize Oragenics Products, but excluding: (a) any amounts paid as bona fide reimbursement for research and development costs to the extent incurred following such grant; (b) bona fide loans or any payments in consideration for a grant of equity of Oragenics to the extent that such consideration is equal to or less than fair market value (i.e. any amounts in excess of fair market value shall be Sublicensing Revenue); (c) any amounts paid by Oragenics to a Third Party for the right to operate under or utilize Third Party owned intellectual property that is used to make or use an Oragenics Product underlying the Sublicensing Revenue, (d) subject to the waiver provisions of Section 5.2(b), any payments received by Oragenics from permitted sublicensees for the first instance (but not subsequent instances) of attainment of a commercialization milestone event that is the same as (or substantially similar to) a commercialization milestone event for which EGI is entitled to receive an equity-based milestone payment under Section 5.2(a), and (e) amounts received from sublicensees in respect of any Oragenics Product sales that are included in Net Sales.

1.61 "**Superior Therapy**" means a therapy in the Field that, based on the data then available, (a) demonstrably appears to offer either superior efficacy or safety or significantly lower cost of therapy, as compared with both (i) those therapies that are marketed (either by Oragenics or others) at such time for the indication and (ii) those therapies that are being actively developed by Oragenics for such indication; (b) demonstrably appears to represent a substantial improvement over such existing therapies; and (c) has intellectual property protection and a regulatory approval pathway that, in each case, would not present a significant barrier to commercial development.

1.62 "**Support Memorandum**" has the meaning set forth in Section 11.2.

1.63 "**Term**" has the meaning set forth in Section 10.1.

1.64 "**Territory**" means the entire world.

1.65 "**Third Party**" means any individual or entity other than the Parties or their respective Affiliates.

1.66 "**Third Party IP**" has the meaning set forth in Section 3.8(a).

1.67 "**Third Security**" means Third Security, LLC.

1.68 "**US GAAP**" means generally accepted accounting principles in the United States.

ARTICLE 2

Scope of Channel Collaboration; Management

2.1 General. The general purpose of the channel collaboration described in this Agreement will be to use the EGI Channel Technology to research, develop and commercialize products for use in the Field (collectively, the "**Lantibiotics Program**"). As provided below, the JSC shall establish projects for the Lantibiotics Program. Either Party may propose potential projects in the Field for review and consideration by the JSC.

2.2 Committees.

(a) Generally. The Parties desire to establish several committees (collectively, "**Committees**") to oversee the Lantibiotics Program and to facilitate communications between the Parties with respect thereto. Each of such Committees shall have the responsibilities and authority allocated to it in this Article 2. Each of the Committees shall have the obligation to exercise its authority consistent with the respective purpose for such Committee as stated herein and any such decisions shall be made in good faith.

(b) Formation and Purpose. Promptly following the Effective Date, the Parties shall confer and then create the Committees listed in the chart below, each of which shall have the purpose indicated in the chart. To the extent that after conferring both Parties agree that a given Committee need not be created until a later date, the Parties may agree to defer the creation of the Committee until one Party informs the other Party of its then desire to create the so-deferred Committee, at which point the Parties will thereafter promptly create the so-deferred Committee and schedule a meeting of such Committee within one (1) month.

Committee	Purpose
Joint Steering Committee ("**JSC**")	Establish projects for the Lantibiotics Program and establish the priorities, as well as approve budgets for such projects. Approve all subcommittee projects and plans.
Chemistry, Manufacturing and Controls Committee ("**CMCC**")	Establish project plans and review and approve activities and budgets for chemistry, manufacturing, and controls under the Lantibiotics Program.
Clinical/Regulatory Committee ("**CRC**")	Review and approve all research and development plans, clinical projects and publications, and regulatory filings and correspondence under the Lantibiotics Program; review and approve itemized budgets with respect to the foregoing.
Commercialization Committee ("**CC**")	Establish project plans and review and approve activities and budgets for commercialization activities under the Lantibiotics Program.
Intellectual Property Committee ("**IPC**")	Evaluate intellectual property issues in connection with the Lantibiotics Program; review and approve itemized budgets with respect to the foregoing.

2.3 General Committee Membership and Procedure.

(a) Membership. For each Committee, each Party shall designate an equal number of representatives (not to exceed four (4) for each Party) with appropriate expertise to serve as members of such Committee. For the JSC the representatives must all be employees of such Party or an Affiliate of such Party, and for Committees other than the JSC the representatives must all be employees of such Party or an Affiliate of such Party with the caveat that each Party may designate for each such other Committee up to one (1) representative who is not an employee if : (i) such non-employee representative agrees in writing to be bound to the terms of this Agreement for the treatment and ownership of Confidential Information and Inventions of the Parties, and (ii) the other party consents to the designation of such non-employee representative, which consent shall not be unreasonably withheld. Each representative as qualified above may serve on more than one Committee as appropriate in view of the individual's expertise. Each Party may replace its Committee representatives at any time upon written notice to the other Party. Each Committee shall have a chairperson; the chairperson of each committee shall serve for a two-year term and the right to designate which representative to the Committee will act as chairperson shall alternate between the Parties, with Oragenics selecting the chairperson first for the JSC, CRC and CC, and EGI selecting the chairperson first for the CMCC and IPC. The chairperson of each Committee shall be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting of such Committee, and preparing and issuing minutes of each meeting within fifteen (15) days thereafter.

(b) Meetings. Each Committee shall hold meetings at such times as it elects to do so, but in no event shall such meetings be held less frequently than once every six (6) months, with the caveat that both Parties may agree to suspend activities of a given Committee other than the JSC until such time as one Party informs the other Party of its then desire to reactivate the so-suspended Committee, at which point the Parties will thereafter schedule and hold the next meeting for the reactivated Committee within one (1) month. Meetings of any Committee may be held in person or by means of telecommunication (telephone, video, or web conferences). To the extent that a Committee holds any meetings in person, the Parties will alternate in designating the location for such in-person meetings, with Oragenics selecting the first meeting location for each Committee. A reasonable number of additional representatives of a Party may attend meetings of a Committee in a non-voting capacity. Each Party shall be responsible for all of its own expenses of participating in any Committee excepting that an EGI employee or agent serving on a Committee shall not prevent EGI from recouping the Fully Loaded Costs otherwise derived from the labor of that employee or agent in the course of providing manufacturing or support services as set forth in Sections 4.6 and 4.7 below.

(c) Meeting Agendas. Each Party will disclose to the other proposed agenda items along with appropriate information at least three (3) business days in advance of each meeting of the applicable Committee; provided, that a Party may provide its agenda items to the other Party within a lesser period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, so long as such other Party consents to such later addition of such agenda items or the absence of a specific agenda for such Committee meeting.

(d) Limitations of Committee Powers. Each Committee shall have only such powers as are specifically delegated to it hereunder or from time to time as agreed to in writing by the mutual consent of the Parties and shall not be a substitute for the rights of the Parties. Without limiting the generality of the foregoing, no Committee shall have any power to amend this Agreement. Any amendment to the terms and conditions of this Agreement shall be implemented pursuant to Section 12.7 below.

2.4 Committee Decision-Making. If a Committee is unable to reach unanimous consent on a particular matter within thirty (30) days of its initial consideration of such matter, then either Party may provide written notice of such dispute to the Executive Officer of the other Party. The Executive Officers of each of the Parties will meet at least once in person or by means of telecommunication (telephone, video, or web conferences) to discuss the dispute and use their good faith efforts to resolve the dispute within thirty (30) days after submission of such dispute to the Executive Officers. If any such dispute is not resolved by the Executive Officers within thirty (30) days after submission of such dispute to such officers, then the Executive Officer of the Party specified in the applicable subsection below shall have the authority to finally resolve such dispute acting in good faith.

(a) Casting Vote at JSC. If a dispute at the JSC is not resolved pursuant to Section 2.4 above, then the Executive Officer of Oragenics shall have the authority to finally resolve such dispute.

(b) Casting Vote at CMCC. If a dispute at the CMCC is not resolved pursuant to Section 2.4 above, then (i) in the case of any disputes relating to the EGI Materials, the manufacture of an Oragenics Product active pharmaceutical ingredient, or the manufacturing of other components of Oragenics Products contracted for or manufactured by EGI, the Executive Officer of EGI shall have the authority to finally resolve such dispute; and (ii) in the case of any other disputes, the Executive Officer of Oragenics shall have the authority to finally resolve such dispute.

(c) Casting Vote at CRC. If a dispute at the CRC is not resolved pursuant to Section 2.4 above, then the Executive Officer of Oragenics shall have the authority to finally resolve such dispute.

(d) Casting Vote at CC. If a dispute at the CC is not resolved pursuant to Section 2.4 above, then the Executive Officer of Oragenics shall have the authority to finally resolve such dispute.

(e) Casting Vote at IPC. If a dispute at the IPC is not resolved pursuant to Section 2.4 above, then the Executive Officer of EGI shall have the authority to finally resolve such dispute, provided that such authority shall be shared by the Parties with respect to Product-Specific Program Patents (i.e., neither Party shall have the casting vote on such matters, and any such disputes shall be resolved pursuant to Article 11).

(f) Other Committees. If any additional Committee other than those set forth in Section 2.2(b) is formed, then the Parties shall, at the time of such formation, agree on which Party shall have the authority to finally resolve a dispute that is not resolved pursuant to Section 2.4 above.

(g) Restrictions. Neither Party shall exercise its right to finally resolve a dispute at a Committee in accordance with this Section 2.4 in a manner that (i) excuses such Party from any of its obligations specifically enumerated under this Agreement; (ii) expands the obligations of the other Party under this Agreement; (iii) negates any consent rights or other rights specifically allocated to the other Party under this Agreement; (iv) purports to resolve any dispute involving the breach or alleged breach of this Agreement; (v) resolves a matter if the provisions of this Agreement specify that mutual agreement is required for such matter; or (vi) would require the other Party to perform any act that is inconsistent with applicable law.

ARTICLE 3

License Grants

3.1 Licenses to Oragenics.

(a) Subject to the terms and conditions of this Agreement, EGI hereby grants to Oragenics a license under the EGI IP to research, develop, use, import, export, make, have made, sell, and offer for sale Oragenics Products in the Field in the Territory. Such license shall be exclusive (even as to EGI) with respect to any clinical development, selling, offering for sale or other Commercialization of Oragenics Products in the Field, and shall be otherwise non-exclusive.

(b) Subject to the terms and conditions of this Agreement, EGI hereby grants to Oragenics a non-exclusive, royalty-free license to use and display the EGI Trademarks, solely in connection with the Commercialization of Oragenics Products, in the promotional materials, packaging, and labeling for Oragenics Products, as provided under and in accordance with Section 4.9.

3.2 Sublicensing. Except as provided below, Oragenics shall not sublicense the rights granted under Section 3.1 to any Third Party, or transfer the EGI Materials to any Third Party, or otherwise grant any Third Party the right to research, develop, use, or Commercialize Oragenics Products or use or display the EGI Trademarks, in each case except with EGI's written consent, which written consent may be withheld in EGI's sole discretion. Notwithstanding the foregoing, Oragenics shall have a limited right to sublicense under the circumstances described in Sections 3.2(a) through 3.2(c) below. The parties shall agree, in connection with any such sublicense not covered under Sections 3.2(a) through 3.2(c) below, on the applicable Sublicensing Revenue Rate (as defined herein) with respect to such sublicense.

(a) Oragenics may transfer, to the extent reasonably necessary, EGI Materials that are or express active pharmaceutical ingredients to a Third Party contractor performing fill/finish responsibilities for Oragenics Products, and may grant any sublicenses necessary to enable such Third Party to perform such activities.

(b) Oragenics may, with EGI's written consent, which written consent shall not be unreasonably withheld, conditioned, or delayed, sublicense the rights granted under Section 3.1 to an Affiliate, or transfer the EGI Materials to an Affiliate, or grant an Affiliate the right to research, develop, use, or Commercialize Oragenics Products or use or display the EGI Trademarks. In the event that EGI consents to any such grant or transfer to an Affiliate, Oragenics shall remain responsible for, and be guarantor of, the performance by any such Affiliate and shall cause such Affiliate to comply with the provisions of this Agreement in connection with such performance (as though such Affiliate were Oragenics), including any payment obligations owed to EGI hereunder.

(c) Oragenics may grant a sublicense of the rights granted under Section 3.1 to a Third Party licensee of any Oragenics Product (a "**Product Sublicensee**") to the extent necessary to permit such Third Party to research, develop, use, import, export, make, have made, sell, and offer for sale that Oragenics Product (a "**Product Sublicense**"), provided, that (i) such Product Sublicense is expressly limited to the appropriate Oragenics Product, (ii) does not grant the Product Sublicensee any rights to EGI IP other than that incorporated into the Oragenics Product at the time of the Product Sublicense, (iii) does not purport to relieve Oragenics of any of its obligations under this Agreement, (iv) the Product Sublicensee agrees in writing, in a document in form reasonably acceptable to EGI and to which EGI is an express third party beneficiary, to abide by the following provisions of this Agreement: Sections 3.1., 3.3-3.6, 3.8, 3.10, and 3.11 and Articles VI, VII, and X), and (v) the Product Sublicense is presented in full to the JSC by Oragenics before execution by Oragenics and the prospective Product Sublicensee and as soon as is reasonably practical for the purpose of allowing the JSC to review and comment upon the terms and scope of the Product Sublicense agreement before execution.

3.3 Limitation on Sublicensees. None of the enforcement rights under the EGI Patents that are granted to Oragenics pursuant to Section 6.3 shall be transferred to, or exercised by, a sublicensee except with EGI's prior written consent, which may be withheld in EGI's sole discretion.

3.4 No Non-Permitted Use. Oragenics hereby covenants that it shall not, nor shall it permit any Affiliate or, if applicable, (sub)licensee, to use or practice, directly or indirectly, any EGI IP, EGI Channel Technology, or EGI Materials for any purposes other than those expressly permitted by this Agreement.

3.5 Exclusivity. EGI and Oragenics mutually agree that, under the channel collaboration established by this Agreement, it is intended that the Parties will be exclusive to each other in the Field. To this end, neither EGI nor its Affiliates shall make the EGI Channel Technology or EGI Materials available to any Third Party for the purpose of developing or Commercializing products in the Field, and neither EGI nor any Affiliate shall pursue (either by itself or with a Third Party or Affiliate) the research, development or Commercialization of any product for purpose of sale in the Field, outside of the Lantibiotics Program. Further, other than Oragenics' activities within the Lantibiotics Program, neither Oragenics nor its Affiliates shall pursue (either by itself or with a Third Party or Affiliate) the research, development or Commercialization of any product that uses, incorporates, references in a related regulatory filing, or is produced from EGI Channel Technology, EGI Materials, or EGI IP for purpose of sale in the Field. For clarity, Oragenics may continue to research, develop, use, manufacture, and Commercialize Lantibiotics using traditional synthetic chemistry techniques insofar as and for so long as such synthetic chemistry efforts are and remain entirely independent of the Lantibiotics Program and such Lantibiotic does not use, incorporate, reference in a related regulatory filing, or get produced from EGI Channel Technology, EGI Materials, or EGI IP.

3.6 Off Label Use. For purpose of clarity, (a) following the First Commercial Sale of an Oragenics Product, the use by direct or indirect purchasers or other users of Oragenics Products outside the Field (i.e. "off label use") shall not constitute a breach by Oragenics of the terms of Section 3.3 or 3.4, provided that neither Oragenics nor its Affiliate (nor any Third Party under contract with either of them) marketed or promoted Oragenics Products for such off-label use; and (b) following the First Commercial Sale of a product by EGI, an EGI Affiliate, or a Third Party sublicensee, collaborator, or partner of EGI, the use by direct or indirect purchasers or other users of such products in the Field (i.e. "off label use") shall not constitute a breach by EGI of the terms of Section 3.4, provided that neither EGI nor its Affiliate (nor any Third Party under contract with either of them) marketed or promoted such products for such off-label use.

3.7 No Prohibition on EGI. Except as explicitly set forth in Sections 3.1 and 3.4, nothing in this Agreement shall prevent EGI from practicing or using the EGI Materials, EGI Channel Technology, and EGI IP for any purpose, and to grant to Third Parties the right to do the same. Without limiting the generality of the foregoing, Oragenics acknowledges that EGI has all rights, in EGI's sole discretion, to make the EGI Materials, EGI Channel Technology (including any active pharmaceutical ingredient used in an Oragenics Product), and EGI IP available to Third Party channel partners or collaborators for use in fields outside the Field.

3.8 Rights to Clinical and Regulatory Data. Oragenics shall own and control all clinical data and regulatory filings relating to Commercialization of Oragenics Products during the Term. Oragenics shall provide full copies of all clinical and non-clinical data and reports, regulatory filings, and communications from regulatory authorities that relate specifically and solely to Oragenics Products. To the extent that there exist any clinical and non-clinical data and reports, regulatory filings, and communications from regulatory authorities owned by Oragenics or a Product Sublicensee that relate both to Oragenics Products and other products produced by Oragenics or a Product Sublicensee outside the Field, Oragenics shall provide (or require that the Product Sublicensee provide) to EGI upon EGI's request copies of the portions of such data, reports, filings, and communications that relate to Oragenics Products. EGI shall be permitted, directly or in conjunction with or through partners or other channel collaborators, to reference this data, reports, filings, and communications relating to Oragenics Products in regulatory filings made to obtain regulatory approval for products indicated for use in fields outside the Field. EGI shall have the right to use any such information in developing and Commercializing products outside the Field and to license any Third Parties to do so.

3.9 Third Party Licenses.

(a) [*****] shall obtain, **[*****]**, any licenses from Third Parties that are required in order to practice the EGI Channel Technology in the Field where the licensed intellectual property is directed towards the manufacture of gene constructs, genetic transformation, methods for altering or controlling genetic expression, or cell lines (but excluding intellectual property directed to any specific Lantibiotic) ("**[*****] Third Party IP**"). Other than with respect to **[*****]** Third Party IP, **[*****]** shall be solely responsible for obtaining, at its sole expense, any licenses from Third Parties that **[*****]** determines, in its sole discretion, are required in order to lawfully make, use, sell, offer for sale, or import Oragenics Products ("**[*****] Third Party IP**"). **[*****]** Third Party IP and **[*****]** Licensed Third Party IP are collectively referred to as "**Third Party IP**".

(b) In the event that either Party desires to license from a Third Party any **[*****]** Third Party IP or Oragenics Licensed Third Party IP, such Party shall so notify the other Party, and the IPC shall discuss such Third Party IP and its applicability to the Oragenics Products and to the Field. As provided above in Section 3.9(a), **[*****]** shall have the sole right and responsibility to pursue a license under **[*****]** Third Party IP, and **[*****]** hereby covenants that it shall not itself directly license such **[*****]** Third Party IP at any time, provided that **[*****]** may (but shall not be obligated to) obtain such a license directly if the Third Party owner or licensee of such **[*****]** Third Party IP brings an infringement action against **[*****]** or its Affiliates and, after written notice to **[*****]** of such action, **[*****]** fails to obtain a license to such **[*****]** Third Party IP within ninety (90) days after such notice. Following the IPC's discussion of any **[*****]** Third Party IP, subject to Section 3.9(c), **[*****]** shall have the right to pursue a license under **[*****]** Third Party IP, at **[*****]** sole expense. For the avoidance of doubt, EGI may at any time obtain a license under **[*****]** Third Party IP outside the Field, at **[*****]** sole expense, provided that if **[*****]** decides to seek to obtain such a license, it shall use reasonable efforts to coordinate its licensing activities in this regard with **[*****]**.

(c) [*****] shall provide the proposed terms of any license under **[*****]** Third Party IP and the final version of the definitive license agreement for any **[*****]** Third Party IP to the IPC for review and discussion prior to signing, and shall consider **[*****]** comments thereto in good faith. To the extent that **[*****]** obtains a license under **[*****]** Third Party IP, **[*****]** shall provide the final version of the definitive license agreement for such **[*****]** Third Party IP to the IPC. If **[*****]** acquires rights under any Third Party IP outside the Field, it will do so on a non-exclusive basis unless it obtains the prior written consent of EGI for such license outside the Field to be exclusive. Any Party that is pursuing a license to any Third Party IP with respect to the Field under this Section 3.9 shall keep the other Party reasonably informed of the status of any negotiations relating thereto. For purposes of clarity, (i) any costs incurred by EGI in obtaining and maintaining licenses to **[*****]** Third Party IP shall be borne solely by **[*****]**, and (ii) any costs incurred by **[*****]** in obtaining and maintaining licenses to **[*****]** Third Party IP (and, to the limited extent provided in subsection (b), **[*****]** Third Party IP) shall be borne solely by **[*****].**

(d) For any Third Party license under which Oragenics or its Affiliates obtain a license under Patents claiming inventions or know-how specific to or used or incorporated into the development, manufacture, and/or Commercialization of Oragenics Products, Oragenics shall use commercially reasonable efforts to ensure that Oragenics will have the ability, pursuant to Section 10.4(h), to assign such agreement to EGI or grant a sublicense to EGI thereunder (having the scope set forth in Section 10.4(h)).

(e) The licenses granted to Oragenics under Section 3.1 may include sublicenses under EGI IP that has been licensed to EGI by one or more Third Parties. Any such sublicenses are subject to the terms and conditions set forth in the applicable upstream license agreement, subject to the cost allocation set forth in Section 3.9(c), provided that EGI shall either provide unredacted copies of such upstream license agreements to Oragenics or shall disclose in writing to Oragenics all of such terms and conditions that are applicable to Oragenics. Oragenics shall not be responsible for complying with any provisions of such upstream license agreements unless, and to the extent that, such provisions have been disclosed to Oragenics as provided in the preceding sentence.

(f) If either Party receives notice from a Third Party concerning activities of a Party taken in conjunction with performance of obligations under this Agreement, which notice alleges infringement by a Party of, or offers license under, Patents or other intellectual property rights owned or controlled by that Third Party, the receiving Party shall inform the other party thereof within five (5) business days.

3.10 Licenses to EGI. Subject to the terms and conditions of this Agreement, Oragenics hereby grants to EGI a non-exclusive, worldwide, fully-paid, royalty-free license, under any applicable Patents or other intellectual property Controlled by Oragenics or its Affiliates, solely to the extent necessary for EGI to conduct those responsibilities assigned to it under this Agreement, which license shall be sublicensable solely to EGI's Affiliates or to any of EGI's permitted subcontractors.

3.11 Restrictions Relating to EGI Materials. Oragenics and its permitted sublicensees shall use the EGI Materials solely for purposes of the Lantibiotics Program and not for any other purpose without the prior written consent of EGI. With respect to the EGI Materials comprising EGI's vector assembly technology, Oragenics shall not, and shall ensure that Oragenics personnel and permitted sublicensees do not (a) distribute, sell, lend or otherwise transfer such EGI Materials to any Third Party; (b) co-mingle such EGI Materials with any other proprietary biological or chemical materials without EGI's written consent; or (c) analyze such EGI Materials or in any way attempt to reverse engineer or sequence such EGI Materials.

ARTICLE 4

Other Rights and Obligations

4.1 Development and Commercialization. Subject to Sections 4.6 and 4.7, Oragenics shall be solely responsible for the performance of the Lantibiotics Program and the development and commercialization of Oragenics Products in the Field. Oragenics shall be responsible for all costs incurred in connection with the Lantibiotics Program except that EGI shall be responsible for the following: (a) costs of establishing manufacturing capabilities and facilities in connection with EGI's manufacturing obligation under Section 4.6 (provided, however, that EGI may include an allocable portion of such costs, through depreciation and amortization, when calculating the Fully Loaded Cost of manufacturing Oragenics Product, to the extent such allocation, depreciation, and amortization is permitted by US GAAP, it being recognized that the majority of non-facilities scale-up costs cannot be capitalized and amortized under US GAAP); (b) costs of basic research with respect to the EGI Channel Technology and EGI Materials (i.e., platform improvements) but, for clarity, excluding research described in Section 4.7 or research requested by the JSC for the development of an Oragenics Product (which research costs shall be reimbursed by Oragenics); (c) **[*****]**; and (d) costs of filing, prosecution and maintenance of EGI Patents. The costs encompassed within subsection (a) above shall include the scale-up of EGI Materials and related active pharmaceutical ingredients for clinical trials and commercialization of Oragenics Products undertaken pursuant to Section 4.6, which shall be at EGI's cost whether it elects to conduct such efforts internally or through Third Party contractors retained by either EGI or Oragenics (with EGI's consent).

4.2 Transfer of Technology and Information. The JSC shall develop a plan and protocol for each project and timing for the transfer of relevant data and EGI Materials.

4.3 Information and Reporting. Oragenics will keep EGI informed about Oragenics' efforts to develop and commercialize Oragenics Products, including reasonable and accurate summaries of Oragenics' (and its Affiliates' and, if applicable, (sub)licensees') global development plans (as updated), including preclinical, clinical and regulatory plans, global marketing plans (as updated), progress towards meeting the goals and milestones in such plans and explanations of any material deviations, and significant developments in the development and/or commercialization of the Oragenics Products, including initiation or completion of a clinical trial, submission of a United States or international regulatory filing, receipt of a response to such United States or international regulatory filing, clinical safety event, receipt of Regulatory Approval, or commercial launch. As set forth in Section 3.8 above, Oragenics shall also provide to EGI copies of all final preclinical protocols and reports, final clinical protocols and reports, and regulatory correspondence and filings generated by Oragenics as soon as practical after they become available. EGI will keep Oragenics informed about EGI's efforts (a) to establish manufacturing capabilities and facilities for Oragenics Products (and EGI Materials relevant thereto) and otherwise perform its manufacturing responsibilities under Section 4.6 and (b) to undertake discovery-stage research for the Lantibiotics Program with respect to the EGI Channel Technology and EGI Materials. Unless otherwise provided herein, such disclosures by Oragenics and EGI will be made in the course of JSC meetings at least once every six (6) months while Oragenics Products are being developed or commercialized anywhere in the world, and shall be reflected in the minutes of such meetings.

4.4 Regulatory Matters. At all times after the Effective Date, Oragenics shall own and maintain, at its own cost, all regulatory filings and regulatory approvals for Oragenics Products that Oragenics is developing or Commercializing pursuant to this Agreement. As such, Oragenics shall be responsible for reporting all adverse events related to such Oragenics Products to the appropriate regulatory authorities in the relevant countries, in accordance with the applicable laws and regulations of such countries. To the extent that EGI will itself develop, or in collaboration with other third parties develop, EGI Materials outside of the Field, EGI may request that Oragenics and EGI establish and execute a separate safety data exchange agreement, which agreement will address and govern the timely exchange of safety information generated by Oragenics, EGI, and relevant third parties with respect to specific EGI Materials. The decision to list or not list Patents in any regulatory filing for an Oragenics Product (for example, as required by 21 C.F.R. § 314.53(b)), add or delete a Patent from a regulatory filing, or to otherwise identify a Patent to a third party in compliance with laws or regulations relating to regulatory approvals (for example, in compliance with 42 U.S.C. § 262(a)(1)(A)(k) et seq.) shall be determined by EGI, after consultation with Oragenics, except with respect to Product Specific Program Patents, which will be mutually determined by the Parties.

4.5 Diligence.

(a) Oragenics shall use, and shall require its Product Sublicensees to use, Diligent Efforts to develop and commercialize Oragenics Products.

(b) Without limiting the generality of the foregoing, EGI may, from time to time, notify Oragenics that it believes it has identified a Superior Therapy, and in such case EGI shall provide to Oragenics its then-available information about such therapy and reasonable written support for its conclusion that the therapy constitutes a Superior Therapy. Oragenics shall have the following obligations with respect to such proposed Superior Therapy: (i) within sixty (60) days after such notification, Oragenics shall prepare and deliver to the JSC for review and approval a development plan detailing how Oragenics will pursue the Superior Therapy (including a proposed budget); (ii) Oragenics shall revise the development plan as directed by the JSC; and (iii) following approval of the development plan by the JSC, Oragenics shall use Diligent Efforts to pursue the development of the Superior Therapy under the Lantibiotics Program in accordance with such development plan. If Oragenics fails to comply with the foregoing obligations, or if Oragenics unreasonably exercises its casting vote at the JSC to either (x) prevent the approval of a development plan for a Superior Therapy; (y) delay such approval more than sixty (60) days after delivery of the development plan to the JSC; or (z) approve a development plan that is insufficient in view of the nature and magnitude of the opportunity presented by the Superior Therapy, then EGI shall have the termination right set forth in Section 10.2(c) (subject to the limitation set forth therein). For clarity, any dispute arising under this 4.5, including any dispute as to whether a proposed project constitutes a Superior Therapy (as with any other dispute under this Agreement) shall be subject to dispute resolution in accordance with Article 11.

(c) The activities of Oragenics' Affiliates and any permitted sublicensees shall be attributed to Oragenics for the purposes of evaluating Oragenics' fulfillment of the obligations set forth in this Section 4.5.

4.6 Manufacturing. EGI shall have the option and, in the event it so elects, shall use Diligent Efforts, to perform any manufacturing activities in connection with the Lantibiotics Program that relate to the EGI Materials, the manufacture of bulk drug product, the manufacturing of bulk quantities of other components of Oragenics Products, or any earlier steps in the manufacturing process for Oragenics Products. To the extent that EGI so elects, EGI may request that Oragenics and EGI establish and execute a separate manufacturing and supply agreement, which agreement will establish and govern the production, quality assurance, and regulatory activities associated with manufacture of EGI Materials. Except as provided in Section 4.1, any manufacturing undertaken by EGI pursuant to the preceding sentence shall be performed in exchange for cash payments equal to EGI's Fully Loaded Cost in connection with such manufacturing, on terms to be negotiated by the Parties in good faith. In the event that EGI does not manufacture EGI Materials, bulk drug product or bulk quantities of other components of Oragenics Products, then EGI shall provide to Oragenics or a contract manufacturer selected by Oragenics and approved by EGI all Information Controlled by EGI that is related to the manufacturing of such EGI Materials, bulk drug product or bulk qualities of other components of Oragenics Products, for use in the Field and is reasonably necessary to enable Oragenics or such contract manufacturer (as appropriate) for the sole purpose of manufacturing such EGI Materials, bulk drug product or bulk quantities of other components of Oragenics Products, in each case as manufactured by EGI. The costs and expenses incurred by EGI in carrying out such transfer shall be borne by EGI. Any manufacturing Information transferred hereunder to Oragenics or its contract manufacturer shall not be further transferred to any Third Party or Oragenics Affiliate without the prior written consent of EGI; provided, however, that EGI shall not unreasonably withhold such consent if necessary to permit Oragenics to switch manufacturers.

4.7 Support Services. From time to time, on an ongoing basis, Oragenics shall request, or EGI may propose, that EGI perform certain support services with respect to the Lantibiotics Program. To the extent that the Parties mutually agree that EGI should perform such services, the Parties shall negotiate in good faith the terms under which services would be performed, it being understood that EGI would be compensated for such services by cash payments equal to EGI's Fully Loaded Cost in connection with such services.

4.8 Compliance with Law. Each Party shall comply, and shall ensure that its Affiliates, (sub)licensees and Third Party contractors comply, with all applicable laws, regulations, and guidelines applicable to the Lantibiotics Program, including without limitation those relating to the transport, storage, and handling of EGI Materials and Oragenics Products.

4.9 Trademarks and Patent Marking. To the extent permitted by applicable law and regulations, Oragenics shall, and shall ensure that the packaging, promotional materials, and labeling for Oragenics Products shall carry, in a conspicuous location, the applicable EGI Trademark(s), subject to Oragenics' reasonable approval of the size, position, and location thereof. Consistent with the U.S. patent laws, Oragenics shall ensure that Oragenics Products, or its packaging or accompanying literature as appropriate, bear applicable and appropriate patent markings for EGI Patent numbers. Oragenics shall provide EGI with copies of any materials containing the EGI Trademarks or patent markings prior to using or disseminating such materials, in order to obtain EGI'S approval thereof. Oragenics' use of the EGI Trademarks and patent markings shall be subject to prior review and approval of the IPC. Oragenics acknowledges EGI's sole ownership of the EGI Trademarks and agrees not to take any action inconsistent with such ownership. Oragenics covenants that it shall not use any trademark confusingly similar to any EGI Trademarks in connection with any products (including any Oragenics Product). From time to time during the Term, EGI shall have the right to obtain from Oragenics samples of Oragenics Product sold by Oragenics or its Affiliates or sublicensees, or other items which reflect public uses of the EGI Trademarks or patent markings, for the purpose of inspecting the quality of such Oragenics Products, the use of the EGI Trademarks, or the accuracy of the patent markings. In the event that EGI inspects under this Section 4.9, EGI shall notify the result of such inspection to Oragenics in writing thereafter. Oragenics shall comply with reasonable policies provided by EGI from time-to-time to maintain the goodwill and value of the EGI Trademarks.

4.10 EGI Equity Purchase Participation Right. EGI shall be entitled to, at its election, participate in each Qualified Financing (as hereinafter defined) conducted by the Company and may purchase as part of, or in connection with, such Qualified Financing an amount of Common Stock or other of the Company's securities equal to up to 30% of the number of shares of Common Stock (or other of the Company's securities) issued and sold by the Company in the Qualified Financing (excluding the securities sold pursuant to this Section 5.3) (collectively, the "**Equity Purchase Participation Right**"). For the purposes of this Section 5.3, a "**Qualified Financing**" shall mean a sale by the Company of Common Stock, or equity securities convertible into Common Stock, in a public or private offering, raising gross cash proceeds of at least $1,000,000 where the shares sold are either registered under the Securities Act on issuance, or the Company agrees to register such shares following the issuance of such shares. The price per share paid by EGI in any such Qualified Financing shall be the same as that paid by the other investors in such Qualified Financing, and upon the exercise of the Equity Purchase Participation Right EGI shall receive securities of the same type and with the same rights, preferences and privileges as the other investors in such Qualified Financing, including, for example, any warrant coverage, subject to the execution by EGI of the investment documents entered into by the other investors in the Qualified Financing.

In the event that the Company intends to conduct a Qualified Financing:

(a) Upon receipt of written notice from the Company that it intends to conduct a Qualified Financing, EGI shall, within ten (10) days of receipt of such documents, notify the Company as to whether EGI wishes to participate in the Qualified Financing. Upon such election, and subject to Section 5.3(b), the Company shall permit EGI to participate in such offering in the amount elected by EGI in accordance with the preceding sentence.

(b) If counsel to the Company or counsel to any underwriter in a public offering that is a Qualified Financing advises the Company that EGI's inclusion is not permissible under and in compliance with applicable securities laws (including without limitation Section 6 of the Securities Act), the offering and sale of securities to EGI's pursuant to this Section 5.3 shall be made by the Company in a concurrent private placement and not in such public offering. In any such private placement: (i) the offer of the securities in such private placement shall be made on the same terms and conditions as the offer of the securities in the public offering, and (ii) the closing of the private placement shall occur concurrently with the closing of the Qualified Financing.

ARTICLE 5

Compensation

5.1 Technology Access Fee. In partial consideration for Oragenics' appointment as an exclusive channel collaborator and the other rights granted to Oragenics hereunder, within thirty (30) days of execution of this Agreement Oragenics issued the number of shares of Oragenics' common stock, in accordance with the terms and conditions of that certain Stock Issuance Agreement on June 5, 2012, which shares are termed the Technology Access Fee Shares in the Stock Issuance Agreement.

5.2 Milestones.

(a) Oragenics Milestones. Upon the first instance of attainment of certain commercialization milestone events by an Oragenics Product (whether such attainment is achieved by Oragenics or by a permitted sublicensee), Oragenics has agreed to pay EGI milestone payments as set forth below. The milestone payments are each payable in cash (subject to Section 5.2(c)) by wire transfer to the account specified by EGI. The specific milestone payments due to EGI upon achievement of each milestone event are set forth in 5.2(b).

(b) Milestone Payments. Subject to the terms and conditions of this Agreement, upon the first instance of attainment of the commercialization milestones as set forth below, and with respect to only the first Oragenics Product developed under this Agreement that reaches any such milestone, the Company has agreed to make certain milestone payments (each a "**Milestone Payment**" and together "**Milestone Payments**") as set forth in this Section 5.2(b). The Milestone Payments are each payable in cash (subject to Section 5.2(c) of this Agreement by wire transfer to the account specified by EGI. The specific milestone payments due to EGI upon achievement of each of the Milestone Events are set forth in Sections 5.2(b)(i) through 5.2(b)(iii) below.

(i) The Company shall pay EGI a one-time milestone payment in cash of twenty five million United States dollars ($25,000,000) (subject to Section 5.2(c) of this Agreement) within six (6) months of the first instance of the achievement of the Regulatory Approval Milestone Event.

(ii) The Company shall pay EGI a one-time milestone payment in cash of five million United States dollars ($5,000,000) (subject to Section 5.2(c) of this Agreement) within six (6) months of the first instance of the achievement of the New Indication Milestone Event.

(iii) The Company shall pay EGI a one-time milestone payment in cash of five million United States dollars ($5,000,000) (subject to Section 5.2(c) of this Agreement) within six (6) months of the first instance of the achievement of the New Product Milestone Event.

(iv) As used in this Section:

(A) "**FDA New Product Application**" means a "New Drug Application" or a "Biologics License Application" (as both of such are defined according to relevant FDA guidelines and regulations establishing the mechanisms for the submission of new drug products in the United States of America for regulatory approval prior to commercial sale and marketing), but excluding any Supplemental FDA Applications.

(B) "**New Indication Milestone Event**" means for a given Oragenics Product, the approval of a Supplemental FDA Application with the FDA (or an equivalent filing with another equivalent regulatory agency) which Supplemental FDA Application sought approval of an indication for use of an Oragenics Product other than the current regulatory-approved indication for the respective Oragenics Product. For the avoidance of doubt and clarification purposes, any occurrence of the New Indication Milestone Event shall not also be deemed the occurrence of the New Product Milestone Event or vice versa.

(C) "**New Product Milestone Event**" means for a given Oragenics Product, the approval of a FDA New Product Application for such Oragenics Product that is deemed (according to relevant FDA guidelines) to be a different drug product than the first Oragenics Product that was clinically pursued under the Lantibiotics Program (as defined in this Agreement). For purposes of the New Product Milestone Event, the subject Oragenics Product shall be deemed to be a "different" Oragenics Product from the first Oragenics Product (and thus constitute an occurrence of the New Product Milestone Event) if regulatory approval of the subject Oragenics Product had to be obtained from the FDA under a different FDA New Product Application than the first Oragenics Product. For the avoidance of doubt and clarification purposes, any occurrence of the New Product Milestone Event shall not also be deemed the occurrence of the New Indication Milestone Event or vice versa.

(D) "**Regulatory Approval Milestone Event**" means for a given Oragenics Product, the approval of a FDA New Product Application for such Oragenics Product by the FDA or equivalent regulatory action in a foreign jurisdiction.

(E) "**Supplemental FDA Application**" means a "Supplemental New Drug Application" or a "Supplemental Biologics License Application" (as both of such are defined according to relevant FDA guidelines and regulations establishing the mechanisms for the submission of data in support of the FDA granting approval for new, amended, and/or expanded label indications for a prior-approved drug product in the United States of America).

The event giving rise to a milestone payment under subsections (i) through (iii) of this Section 5.2(b) shall be a "**Milestone Event**" and together, the "**Milestone Events**."

(c) Product Sublicense Milestones. If (A) a commercialization milestone event occurs that gives rise to a right for EGI to receive a payment from Oragenics under Section 5.2(a), (B) that milestone event is achieved by an Oragenics Product licensed to a Product Sublicensee under a respective Product Sublicense, and (C) Oragenics is due to receive a milestone payment from the Product Sublicensee for achievement of that same (or substantially similar) milestone event by the sublicensed Oragenics Product under the respective Product Sublicense, then EGI may elect at its own discretion to waive that particular milestone payment from Oragenics for that particular commercialization milestone

5.3 RESERVED.

5.4 Revenue Sharing.

(a) No later than thirty (30) days after each calendar quarter in which there is positive Net Sales arising from the sale of any Oragenics Product in the Field in the Territory, Oragenics shall pay a royalty to EGI of ten percent (10%) of such Net Sales, on an Oragenics Product-by-Oragenics Product basis. Commencing with the Effective Date, in the event that no Net Sales occur for a particular Oragenics Product in any calendar quarter, neither Oragenics nor EGI shall owe any payments hereunder with respect to such Oragenics Product.

(b) No later than thirty (30) days after each calendar quarter in which Oragenics or any Oragenics Affiliate receives Sublicensing Revenue, Oragenics shall pay to EGI a percentage of such Sublicensing Revenue equal to the applicable Sublicensing Revenue Rate. "Sublicensing Revenue Rate" means a percentage of Sublicensing Revenue applicable to a proposed sublicense by Oragenics as follows: (a) with respect to any sublicense of a Lantibiotics Oragenics Product (including new indications thereof), any revenues Oragenics receives from a Product Sublicensee under a Product Sublicense that are not a percentage of Product Sublicensee's Net Sales of Oragenics Products, and any amounts recovered under Section 6.3(f), the Sublicensing Revenue Rate shall be twenty five percent (25%); and (b) with respect to any other sublicense, the Sublicensing Revenue Rate shall be determined in accordance with Section 3.2.

5.5 Method of Payment. Except for payments payable as and made in the form of common stock, payments due to EGI under this Agreement shall be paid in United States dollars by wire transfer to a bank in the United States designated in writing by EGI. All references to "dollars" or "$" herein shall refer to United States dollars.

5.6 Payment Reports and Records Retention. Within thirty (30) days after the end of each calendar quarter during which Net Sales have been generated or during which Sublicensing Revenue has been received, Oragenics shall deliver to EGI a written report that shall contain at a minimum for the applicable calendar quarter:

(a) gross sales of each Oragenics Product (on a country-by-country basis);

(b) itemized calculation of Net Sales, showing all applicable deductions;

(c) itemized calculation of Sublicensing Revenue, including any offsets claimed for Third Party license costs;

(d) the amount of the payment (if any) due pursuant to Section 5.4(a) and/or 5.4(b);

(e) the amount of the payment (if any) made or made due by the achievement of an applicable commercialization milestone event during the present calendar quarter;

(f) the amount of taxes, if any, withheld to comply with any applicable law; and

(g) the exchange rates used in any of the foregoing calculations.

For three (3) years after each sale or other commercial use of Oragenics Product, after incurring any component item Oragenics incorporated into its calculation of Sublicensing Revenues, payments in accord with Section 5.2(b), or Net Sales as reported to EGI, Oragenics shall keep (and shall ensure that its Affiliates and, if applicable, (sub)licensees shall keep) complete and accurate records of such sales, commercial use, or component item in sufficient detail to confirm the accuracy of the payment calculations hereunder.

5.7 Audits.

(a) Upon the written request of EGI, Oragenics shall permit an independent certified public accounting firm of internationally recognized standing selected by EGI, and reasonably acceptable to Oragenics, to have access to and to review, during normal business hours and upon no less than thirty (30) days prior written notice, the applicable records of Oragenics and its Affiliates to verify the accuracy and timeliness of the reports and payments made by Oragenics under this Agreement. Such review may cover the records for sales made in any calendar year ending not more than three (3) years prior to the date of such request. The accounting firm shall disclose to both Parties whether the royalty reports and/or know-how reports conform to the provisions of this Agreement and/or US GAAP, as applicable, and the specific details concerning any discrepancies. Such audit may not be conducted more than once in any calendar year.

(b) If such accounting firm concludes that additional amounts were owed during such period, Oragenics shall pay additional amounts, with interest from the date originally due as set forth in Section 5.9, within thirty (30) days of receipt of the accounting firm's written report. If the amount of the underpayment is greater than five percent (5%) of the total amount actually owed for the period audited, then Oragenics shall in addition reimburse EGI for all costs related to such audit; otherwise, EGI shall pay all costs of the audit. In the event of overpayment, any amount of such overpayment shall be fully creditable against amounts payable for the immediately succeeding calendar quarter(s); provided, however, that if such overpayment is reasonably expected to exceed the amount projected to be payable to EGI by Oragenics over next **[*****]**, EGI will promptly repay to Oragenics any amount exceeding that projected amount.

(c) EGI shall (i) treat all information that it receives under this Section 5.7 in accordance with the confidentiality provisions of Article 7 and (ii) cause its accounting firm to enter into an acceptable confidentiality agreement with Oragenics obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement, in each case except to the extent necessary for EGI to enforce its rights under this Agreement.

5.8 Taxes. The Parties will cooperate in good faith to obtain the benefit of any relevant tax treaties to minimize as far as reasonably possible any taxes which may be levied on any amounts payable hereunder. Oragenics shall deduct or withhold from any payments any taxes that it is required by applicable law to deduct or withhold. Notwithstanding the foregoing, if EGI is entitled under any applicable tax treaty to a reduction of the rate of, or the elimination of, applicable withholding tax, it may deliver to Oragenics or the appropriate governmental authority (with the assistance of Oragenics to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Oragenics of its obligation to withhold tax, and Oragenics shall apply the reduced rate of withholding tax, or dispense with withholding tax, as the case may be, provided that Oragenics has received evidence of EGI's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least fifteen (15) days prior to the time that the payment is due. If, in accordance with the foregoing, Oragenics withholds any amount, it shall make timely payment to the proper taxing authority of the withheld amount, and send to EGI proof of such payment within forty-five (45) days following that latter payment.

5.9 Late Payments. Any amount owed by Oragenics to EGI under this Agreement that is not paid within the applicable time period set forth herein shall accrue interest at the lower of (a) two percent (2%) per month, compounded, or (b) the highest rate permitted under applicable law.

ARTICLE 6

Intellectual Property

6.1 Ownership.

(a) Subject to the license granted under Section 3.1, all rights in the EGI IP shall remain with EGI.

(b) Oragenics and/or EGI may solely or jointly conceive, reduce to practice or develop discoveries, inventions, processes, techniques, and other technology, whether or not patentable, in the course of performing the Lantibiotics Program (collectively "**Inventions**"). Each Party shall promptly provide the other Party with a detailed written description of any such Inventions that relate to the Field. Inventorship shall be determined in accordance with United States patent laws.

(c) EGI shall solely own all right, title and interest in all Inventions related to EGI Channel Technology, together with all Patent rights and other intellectual property rights therein (the "**Channel-Related Program IP**"). Oragenics hereby assigns all of its right, title and interest in and to the Channel-Related Program IP to EGI. Oragenics agrees to execute such documents and perform such other acts as EGI may reasonably request to obtain, perfect and enforce its rights to the Channel-Related Program IP and the assignment thereof.

(d) Notwithstanding anything to the contrary in this Agreement, any discovery, invention, process, technique, or other technology, whether or not patentable, that is conceived, reduced to practice or developed by Oragenics solely or jointly through the use of the EGI Channel Technology, EGI IP, or EGI Materials in breach of the terms and conditions of this Agreement, together with all patent rights and other intellectual property rights therein, shall be solely owned by EGI and shall be included in the Channel-Related Program IP.

(e) All information regarding Channel-Related Program IP shall be Confidential Information of EGI. Oragenics shall be under appropriate written agreements with each of its employees, contractors, or agents working on the Lantibiotics Program, pursuant to which such person shall grant all rights in the Inventions to Oragenics (so that Oragenics may convey certain of such rights to EGI, as provided herein) and agree to protect all Confidential Information relating to the Lantibiotics Program.

(f) All rights, technology, and intellectual property (A) owned by Oragenics or licensed from a Third Party by Oragenics as of the Effective Date, or (B) thereafter developed by Oragenics independent of the Lantibiotics Program, EGI Channel Technology, EGI IP or EGI Materials, shall be owned by and remain the property of Oragenics (the "**Oragenics Independent IP**").

6.2 Patent Prosecution.

(a) EGI shall have the sole right, but not the obligation, to (a) conduct and control the filing, prosecution and maintenance of the EGI Patents, and (b) conduct and control the filing, prosecution, and maintenance of any applications for patent term extension and/or supplementary protection certificates for the EGI Patents that may be available as a result of the regulatory approval of any Oragenics Product. At the reasonable request of EGI, Oragenics shall cooperate with EGI in connection with such filing, prosecution, and maintenance, at EGI's expense. Under no circumstances shall Oragenics (a) file, attempt to file, or assist anyone else in filing, or attempting to file, any Patent application, either in the United States or elsewhere, that claims or uses or purports to claim or use or relies for support upon an Invention owned by EGI, (b) use, attempt to use, or assist anyone else in using or attempting to use, the EGI Know-How, EGI Materials, or any Confidential Information of EGI to support the filing of a Patent application, either in the United States or elsewhere, that contains claims directed to the EGI IP, EGI Materials, or the EGI Channel Technology, or (c) without prior approval of the IPC, file, attempt to file, or assist anyone else in filing, or attempting to file, any application for patent term extension or supplementary protection certificate, either in the United States or elsewhere, that relies upon the regulatory approval of an Oragenics Product.

(b) Oragenics shall have the sole right, but not the obligation, to conduct and control the filing, prosecution and maintenance of any Patents claiming Inventions that are owned by Oragenics or its Affiliates and not assigned to EGI under Section 6.1(c) ("**Oragenics Program Patents**"). At the reasonable request of Oragenics, EGI shall cooperate with Oragenics in connection with such filing, prosecution, and maintenance, at Oragenics' expense.

(c) The Prosecuting Party shall be entitled to use patent counsel selected by it and reasonably acceptable to the non-Prosecuting Party (including in-house patent counsel as well as outside patent counsel) for the prosecution of the EGI Patents and Oragenics Program Patents, as applicable. The Prosecuting Party shall:

(i) regularly provide the other Party in advance with reasonable information relating to the Prosecuting Party's prosecution of Patents hereunder, including by providing copies of substantive communications, notices and actions submitted to or received from the relevant patent authorities and copies of drafts of filings and correspondence that the Prosecuting Party proposes to submit to such patent authorities (it being understood that, to the extent that any such information is readily accessible to the public, the Prosecuting Party may, in lieu of directly providing copies of such information to such other Party, provide such other Party with sufficient information that will permit such other Party to access such information itself directly);

(ii) consider in good faith and consult with the non-Prosecuting Party regarding its timely comments with respect to the same; provided, however, that if, within fifteen (15) days after providing any documents to the non-Prosecuting Party for comment, the Prosecuting Party does not receive any written communication from the non-Prosecuting Party indicating that it has or may have comments on such document, the Prosecuting Party shall be entitled to assume that the non-Prosecuting Party has no comments thereon;

(iii) consult with the non-Prosecuting Party before taking any action that would reasonably be expected to have a material adverse impact on the scope of claims within the EGI Patents and Oragenics Program Patents, as applicable.

As used above "**Prosecuting Party**" means EGI in the case of EGI Patents and Oragenics in the case of Oragenics Program Patents.

6.3 Infringement of Patents by Third Parties.

(a) Except as expressly provided in the remainder of this Section 6.3, EGI shall have the sole right to take appropriate action against any person or entity directly or indirectly infringing any EGI Patent (or asserting that an EGI Patent is invalid or unenforceable) (collectively, "**Infringement**"), either by settlement or lawsuit or other appropriate action.

(b) Notwithstanding the foregoing, Oragenics shall have the first right, but not the obligation, to take appropriate action to enforce Product-Specific Program Patents against any Infringement that involves a commercially material amount of allegedly infringing activities in the Field ("**Field Infringement**"), either by settlement or lawsuit or other appropriate action. If Oragenics fails to take the appropriate steps to enforce Product-Specific Program Patents against any Field Infringement within one hundred eighty (180) days of the date one Party has provided notice to the other Party pursuant to Section 6.3(g) of such Field Infringement, then EGI shall have the right (but not the obligation), at its own expense, to enforce Product-Specific Program Patents against such Field Infringement, either by settlement or lawsuit or other appropriate action.

(c) With respect to any Field Infringement that cannot reasonably be abated through the enforcement of Product-Specific Program Patents pursuant to Section 6.3(b) but can reasonably be abated through the enforcement of EGI Patent(s) (other than the Product-Specific Program Patents), EGI shall be obligated to choose one of the following courses of action: (i) enforce one or more of the applicable EGI Patent(s) in a commercially reasonable manner against such Field Infringement, or (ii) **[*****]**. The Party enforcing the applicable EGI Patent(s) shall bear the costs and expenses of such enforcement. The determination of which EGI Patent(s) to assert shall be made by EGI in its sole discretion; provided, however, that EGI shall consult in good faith with Oragenics on such determination. For the avoidance of doubt, EGI has no obligations under this Agreement to enforce any EGI Patents against, or otherwise abate, any Infringement that is not a Field Infringement.

(d) In the event a Party pursues an action under this Section 6.3, the other Party shall reasonably cooperate with the enforcing Party with respect to the investigation and prosecution of any alleged, threatened, or actual Infringement, at the enforcing Party's expense.

(e) Oragenics shall not settle or otherwise compromise any action under this Section 6.3 in a way that diminishes the rights or interests of EGI outside the Field or adversely affects any EGI Patent without EGI's prior written consent, which consent shall not be unreasonably withheld. EGI shall not settle or otherwise compromise any action under this Section 6.3 in a way that diminishes the rights or interests of Oragenics in the Field or adversely affects any EGI Patent with respect to the Field without Oragenics' prior written consent, which consent shall not be unreasonably withheld.

(f) Except as otherwise agreed to by the Parties in writing, any settlements, damages or other monetary awards recovered pursuant to a suit, proceeding, or action brought pursuant to Section 6.3 will be allocated first to the costs and expenses of the Party controlling such action, and second, to the costs and expenses (if any) of the other Party (to the extent not otherwise reimbursed), and any remaining amounts (the **"Recovery"**) will be shared by the Parties as follows: In any action initiated by EGI pursuant to Section 6.3(a) that does not involve Field Infringement, or in any action initiated by EGI pursuant to Section 6.3(b), EGI shall retain one hundred percent (100%) of any Recovery. In any action initiated by Oragenics pursuant to Section 6.3(b), Oragenics shall retain one hundred percent (100%) of any Recovery, **[*****]**. In any action initiated by EGI or Oragenics pursuant to Section 6.3(c), the enforcing Party shall retain one hundred percent (100%) of any Recovery.

(g) Oragenics shall promptly notify EGI in writing of any suspected, alleged, threatened, or actual Infringement of which it becomes aware, and EGI shall promptly notify Oragenics in writing of any suspected, alleged, threatened, or actual Field Infringement of which it becomes aware.

ARTICLE 7

CONFIDENTIALITY

7.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement any Confidential Information disclosed to it by the other Party pursuant to this Agreement, except to the extent that the receiving Party can demonstrate by competent evidence that specific Confidential Information:

(a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party, other than under an obligation of confidentiality to a Third Party, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others; or

(e) was independently discovered or developed by the receiving Party without the use of Confidential Information belonging to the disclosing Party, as documented by the receiving Party's written records.

The foregoing non-use and non-disclosure obligation shall continue (i) indefinitely, for all Confidential Information that qualifies as a trade secret under applicable law; or (ii) for the Term of this Agreement and for seven (7) years thereafter, in all other cases.

7.2 Authorized Disclosure. Notwithstanding the limitations in this Article 7, either Party may disclose the Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances:

(a) complying with applicable laws or regulations or valid court orders, *provided that* the Party making such disclosure provides the other Party with reasonable prior written notice of such disclosure and makes a reasonable effort to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the disclosure and/or requiring that the terms and conditions of this Agreement be used only for the purposes for which the law or regulation required, or for which the order was issued;

(b) to regulatory authorities in order to seek or obtain approval to conduct clinical trials, or to gain regulatory approval, of Oragenics Products or any products being developed by EGI or its other licensees and/or channel partners or collaborators, provided that the Party making such disclosure (i) provides the other Party with reasonable opportunity to review any such disclosure in advance and to suggest redactions or other means of limiting the disclosure of such other Party's Confidential Information and (ii) does not unreasonably reject any such suggestions;

(c) disclosure to investors and potential investors, acquirers, or merger candidates who agree to maintain the confidentiality of such information, *provided that* such disclosure is used solely for the purpose of evaluating such investment, acquisition, or merger (as the case may be);

(d) disclosure on a need-to-know basis to Affiliates, licensees, sublicensees, employees, consultants or agents (such as CROs and clinical investigators) who agree to be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 7; and

(e) disclosure of the terms of this Agreement by EGI to collaborators and other channel partners or collaborators who agree to be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Article 7.

7.3 Publicity; Publications. The Parties agree that the public announcement of the execution of this Agreement shall be substantially in the form of the press release mutually agreed to by the Parties. Each Party will provide the other Party with the opportunity to review and comment, prior to submission or presentation, on external reports, publications and presentations (e.g., press releases, reports to government agencies, abstracts, posters, manuscripts and oral presentations) that refer to the Lantibiotics Program or programs that are approved by the JSC. For such reports, publications, and presentations, the disclosing Party will provide the other Party at least fifteen (15) calendar days for review of the proposed submission or presentation. For reports and manuscripts, the disclosing Party will provide the other Party at least thirty (30) calendar days for review of the report or manuscript. The presenting Party will act in good faith to incorporate the comments of the other Party and shall, in any event, redact any Confidential Information of the other Party and cooperate with the other Party to postpone such submissions or presentations if necessary to provide the other Party with sufficient time to prepare and file any related Patent applications before the submission or presentation occurs, as appropriate.

7.4 Terms of the Agreement. Each Party shall treat the terms of this Agreement as the Confidential Information of other Party, subject to the exceptions set forth in Section 7.2. Notwithstanding the foregoing, each Party acknowledges that the other Party may be obligated to file a copy of this Agreement with the SEC, either as of the Effective Date or at some point during the Term. Each Party shall be entitled to make such a required filing, provided that it requests confidential treatment of certain commercial terms and sensitive technical terms hereof to the extent such confidential treatment is reasonably available to it. In the event of any such filing, the filing Party shall provide the other Party with a copy of the Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party's comments thereon to the extent consistent with the legal requirements governing redaction of information from material agreements that must be publicly filed. The other Party shall promptly provide any such comments.

7.5 Proprietary Information and Operational Audits.

(a) For the purpose of confirming compliance with the Field-limited licenses granted in Article 3, the diligence obligations of Article 4, and the confidentiality obligations under Article 7, Oragenics acknowledges that EGI's authorized representative(s), during regular business hours may (i) examine and inspect Oragenics' facilities and (ii) inspect all data and work products relating to this Agreement. Any examination or inspection hereunder shall require five (5) business days written notice from EGI to Oragenics. Oragenics will make itself and the pertinent employees and/or agents available, on a reasonable basis, to EGI for the aforementioned compliance review.

(b) For the purpose of confirming compliance with the diligence obligations of Section 4.6, and the confidentiality obligations under Article 7, EGI acknowledges that Oragenics authorized representative(s), during regular business hours may (i) examine and inspect EGI's facilities and (ii) inspect all data and work products relating to this Agreement. Any examination or inspection hereunder shall require five (5) business days written notice from Oragenics to EGI. EGI will make itself and the pertinent employees and/or agents available, on a reasonable basis, to Oragenics for the aforementioned compliance review.

(c) In view of the EGI Confidential Information, EGI Know-How, and EGI Materials transferred to Oragenics hereunder, EGI from time-to-time, but no more than quarterly, may request that Oragenics confirm the status of the EGI Materials at Company (i.e. how much used, how much shipped, to whom and any unused amounts destroyed (by whom, when) as well as any amounts returned to EGI or destroyed). Within ten (10) business days of Oragenics' receipt of any such written request, Oragenics shall provide the written report to EGI.

7.6 EGI Commitment. EGI shall use reasonable efforts to obtain an agreement with its other licensees and channel partners or collaborators to enable Oragenics to disclose confidential information of such licensees and channel partners or collaborators to regulatory authorities in order to seek or obtain approval to conduct clinical trials, or to gain regulatory approval of, Oragenics Products, in a manner consistent with the provisions of Section 7.2(b).

ARTICLE 8

Representations And Warranties

8.1 Representations and Warranties of Oragenics. Oragenics hereby represents and warrants to EGI that, as of the Effective Date:

(a) Corporate Power. Oragenics is duly organized and validly existing under the laws of Florida and has corporate full power and authority to enter into this Agreement and to carry out the provisions hereof.

(b) Due Authorization. Oragenics is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person executing this Agreement on Oragenics' behalf has been duly authorized to do so by all requisite corporate action.

(c) Binding Agreement. This Agreement is a legal and valid obligation binding upon Oragenics and enforceable in accordance with its terms, except as such enforcement may be limited by applicable bankruptcy, insolvency, reorganization, arrangement, moratorium or other similar laws affecting creditors' rights, and subject to general equity principles and to limitations on availability of equitable relief, including specific performance. The execution, delivery and performance of this Agreement by Oragenics does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound. Oragenics is aware of no action, suit or inquiry or investigation instituted by any governmental agency which questions or threatens the validity of this Agreement.

8.2 Representations and Warranties of EGI. EGI hereby represents and warrants to Oragenics that, as of the Effective Date:

(a) Corporate Power. EGI is duly organized and validly existing under the laws of Virginia and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof.

(b) Due Authorization. EGI is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person executing this Agreement on EGI's behalf has been duly authorized to do so by all requisite corporate action.

(c) Binding Agreement. This Agreement is a legal and valid obligation binding upon EGI and enforceable in accordance with its terms, except as such enforcement may be limited by applicable bankruptcy, insolvency, reorganization, arrangement, moratorium or other similar laws affecting creditors' rights, and subject to general equity principles and to limitations on availability of equitable relief, including specific performance. The execution, delivery and performance of this Agreement by EGI does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound. EGI is aware of no action, suit or inquiry or investigation instituted by any governmental agency which questions or threatens the validity of this Agreement.

(d) Additional Intellectual Property Representations.

(i) EGI possesses sufficient rights to enable EGI to grant all rights and licenses it purports to grant to Oragenics with respect to the EGI IP under this Agreement;

(ii) The EGI IP existing as of the Effective Date constitute all of the intellectual property Controlled by EGI as of such date that is necessary for the development, manufacture or Commercialization of Oragenics Products;

(iii) EGI has not granted, and during the Term EGI will not grant, any right or license, to any Third Party under the EGI IP that conflicts with the rights or licenses granted or to be granted to Oragenics hereunder;

(iv) There is no pending litigation, and EGI has not received any written notice of any claims or litigation, seeking to invalidate or otherwise challenge the EGI IP or EGI's rights therein;

(v) None of the EGI IP is subject to any pending re-examination, opposition, interference or litigation proceedings;

(vi) All of the EGI Patents have been filed and prosecuted in accordance with all applicable laws and have been maintained, with all applicable fees with respect thereto (to the extent such fees have come due) having been paid;

(vii) EGI has entered into agreements with each of its current and former officers, employees and consultants involved in research and development work, including development of the EGI's products and technology providing EGI, to the extent permitted by law, with title and ownership to patents, patent applications, trade secrets and inventions conceived, developed, reduced to practice by such person, solely or jointly with other of such persons, during the period of employment by EGI (except where the failure to have entered into such an agreement would not have a material adverse effect on the rights granted to Oragenics herein), and EGI is not aware that any of its employees or consultants is in material violation thereof;

(viii) To EGI's knowledge, there is no infringement, misappropriation or violation by third parties of any EGI Channel Technology or EGI IP in the Field;

(ix) There is no pending or, to EGI's knowledge, threatened action, suit, proceeding or claim by others against EGI that EGI infringes, misappropriates or otherwise violates any intellectual property or other proprietary rights of others in connection with the use of the EGI Channel Technology or EGI IP, and EGI has not received any written notice of such claim;

(x) To EGI's knowledge, no employee of EGI is the subject of any claim or proceeding involving a violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, non-disclosure agreement or any restrictive covenant to or with a former employer (A) where the basis of such violation relates to such employee's employment with EGI or actions undertaken by the employee while employed with EGI and (B) where such violation is relevant to the use of the EGI Channel Technology in the Field;

(xi) None of the EGI Patents owned by EGI or its Affiliates, and, to EGI's knowledge, the EGI Patents licensed to EGI or its Affiliates, have been adjudged invalid or unenforceable by a court of competent jurisdiction or applicable government agency, in whole or in part, and there is no pending or, to EGI's knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such EGI Patents; and

(xii) Except as otherwise disclosed in writing to Oragenics, EGI: (A) is in material compliance with all statutes, rules or regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product that is under development, manufactured or distributed by EGI in the Field ("**Applicable Laws**"); (B) has not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the United States Food and Drug Administration (the "**FDA**") or any other federal, state, local or foreign governmental or regulatory authority alleging or asserting material noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws ("**Authorizations**"), which would not, individually or in the aggregate, result in a material adverse effect; (C) possesses all material Authorizations necessary for the operation of its business as described in the Field and such Authorizations are valid and in full force and effect and EGI is not in material violation of any term of any such Authorizations; and (D) since January 1, 2011, (1) has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from the FDA or any other federal, state, local or foreign governmental or regulatory authority or third party alleging that any product operation or activity is in material violation of any Applicable Laws or Authorizations and has no knowledge that the FDA or any other federal, state, local or foreign governmental or regulatory authority or third party is considering any such claim, litigation, arbitration, action, suit investigation or proceeding; (2) has not received notice that the FDA or any other federal, state, local or foreign governmental or regulatory authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any material Authorizations and has no knowledge that the FDA or any other federal, state, local or foreign governmental or regulatory authority is considering such action; (3) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were materially complete and correct on the date filed (or were corrected or supplemented by a subsequent submission); and (4) has not, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post-sale warning, "dear doctor" letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to EGI's knowledge, no third party has initiated, conducted or intends to initiate any such notice or action.

except, in each of (ix) through (xii), for any instances which would not, individually or in the aggregate, result in a material adverse effect on the rights granted to Oragenics hereunder or EGI's ability to perform its obligations hereunder.

8.3 Warranty Disclaimer. EXCEPT FOR THE EXPRESS WARRANTIES PROVIDED IN THIS ARTICLE 8 EACH PARTY HEREBY DISCLAIMS ANY AND ALL OTHER WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF TITLE, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 9

Indemnification

9.1 Indemnification by EGI. EGI agrees to indemnify, hold harmless, and defend Oragenics and its Affiliates and their respective directors, officers, employees, and agents (collectively, the "**Oragenics Indemnitees**") from and against any and all liabilities, damages, costs, expenses, or losses (including reasonable legal expenses and attorneys' fees) (collectively, "**Losses**") resulting from any claims, suits, actions, demands, or other proceedings brought by a Third Party (collectively, "**Claims**") to the extent arising from (a) the negligence or willful misconduct of EGI or any of its Affiliates, or their respective employees or agents, (b) the use, handling, storage or transport of EGI Materials by or on behalf of EGI or its Affiliates, licensees (other than Oragenics) or sublicensees; or (c) breach by EGI of any representation, warranty or covenant in this Agreement. Notwithstanding the foregoing, EGI shall not have any obligation to indemnify the Oragenics Indemnitees to the extent that a Claim arises from (i) the negligence or willful misconduct of Oragenics or any of its Affiliates, licensees, or sublicensees, or their respective employees or agents; or (ii) a breach by Oragenics of a representation, warranty, or covenant of this Agreement.

9.2 Indemnification by Oragenics. Oragenics agrees to indemnify, hold harmless, and defend EGI, its Affiliates and Third Security, and their respective directors, officers, employees, and agents (and any Third Parties which have licensed to EGI intellectual property rights within EGI IP on or prior to the Effective Date, to the extent required by the relevant upstream license agreement) (collectively, the "**EGI Indemnitees**") from and against any Losses resulting from Claims, to the extent arising from any of the following: (a) the negligence or willful misconduct of Oragenics or any of its Affiliates or their respective employees or agents; (b) the use, handling, storage, or transport of EGI Materials by or on behalf of Oragenics or its Affiliates, licensees, or sublicensees; (c) breach by Oragenics of any material representation, warranty or covenant in this Agreement; or (d) the design, development, manufacture, regulatory approval, handling, storage, transport, distribution, sale or other disposition of any Oragenics Product by or on behalf of Oragenics or its Affiliates, licensees, or sublicensees. Notwithstanding the foregoing, Oragenics shall not have any obligation to indemnify the EGI Indemnitees to the extent that a Claim arises from (i) the negligence or willful misconduct of EGI or any of its Affiliates, or their respective employees or agents; or (ii) a breach by EGI of a representation, warranty, or covenant of this Agreement.

9.3 Product Liability Claims. Notwithstanding the provisions of Section 9.2, any Losses arising out of any Third Party claim, suit, action, proceeding, liability or obligation involving any actual or alleged death or bodily injury arising out of or resulting from the development, manufacture or Commercialization of any Oragenics Products for use or sale in the Field, to the extent that such Losses exceed the amount (if any) covered by the applicable Party's product liability insurance ("**Excess Product Liability Costs**"), shall be paid by **[*****]**, except to the extent such Losses arise out of any Third-Party Claim based on the gross negligence or willful misconduct of a Party, its Affiliates, or its Affiliates' Sublicensees, or any of the respective officers, directors, employees and agents of each of the foregoing entities, in the performance of obligations or exercise of rights under this Agreement.

9.4 Control of Defense. As a condition precedent to any indemnification obligations hereunder, any entity entitled to indemnification under this Article 9 shall give written notice to the indemnifying Party of any Claims that may be subject to indemnification, promptly after learning of such Claim. If such Claim falls within the scope of the indemnification obligations of this Article 9, then the indemnifying Party shall assume the defense of such Claim with counsel reasonably satisfactory to the indemnified Party. The indemnified Party shall cooperate with the indemnifying Party in such defense. The indemnified Party may, at its option and expense, be represented by counsel of its choice in any action or proceeding with respect to such Claim. The indemnifying Party shall not be liable for any litigation costs or expenses incurred by the indemnified Party without the indemnifying Party's written consent, such consent not to be unreasonably withheld. The indemnifying Party shall not settle any such Claim if such settlement (a) does not fully and unconditionally release the indemnified Party from all liability relating thereto or (b) adversely impacts the exercise of the rights granted to the indemnified Party under this Agreement, unless the indemnified Party otherwise agrees in writing.

9.5 Insurance. Immediately prior to, and during marketing, Oragenics shall maintain in effect and good standing a product liability insurance policy issued by a reputable insurance company in amounts considered standard for the industry. Immediately prior to, and during the conduct of any clinical trials, Oragenics shall maintain in effect and good standing a clinical trials liability insurance policy issued by a reputable insurance company in amounts considered standard for the industry. At EGI's reasonable request, Oragenics shall provide EGI with all details regarding such policies, including without limitation copies of the applicable liability insurance contracts. Oragenics shall use reasonable efforts to include EGI as an additional insured on any such policies.

ARTICLE 10

TERM; TERMINATION

10.1 Term. The term of this Agreement shall commence upon the Effective Date and shall continue until terminated pursuant to Section 10.2 or 10.3 (the "**Term**").

10.2 Termination for Material Breach; Termination Under Section 4.5(b)

(a) Either Party shall have the right to terminate this Agreement upon written notice to the other Party if the other Party commits any material breach of this Agreement that such breaching Party fails to cure within sixty (60) days following written notice from the nonbreaching Party specifying such breach, provided, however, that solely for purposes of Section 9.5 the cure period shall be ninety (90) days.

(b) EGI shall have the right to terminate this Agreement under the circumstances set forth in Section 4.5(b) upon written notice to Oragenics, such termination to become effective sixty (60) days following such written notice unless Oragenics remedies the circumstances giving rise to such termination within such sixty (60) day period.

(c) EGI shall have the right to terminate this Agreement should Oragenics execute any purported assignment of this Agreement contrary to the prohibitions in Section 12.8, such termination occurring upon EGI providing written notice to Oragenics and becoming effective immediately upon such written notice.

(d) In recognition of the need for Oragenics to raise capital necessary to carry out its obligations under this Agreement, notwithstanding the foregoing, during the twelve (12) month period commencing on the Effective Date, neither Party shall have the right to terminate this Agreement under Section 10.2(a) based on the failure of the other Party to use Diligent Efforts or to comply with any other diligence obligations hereunder (including Section 4.5), nor shall EGI have the right to terminate this Agreement under Section 10.2(c).

10.3 Termination by Oragenics. Oragenics shall have the right to voluntarily terminate this Agreement in its entirety upon ninety (90) days written notice to EGI at any time, provided that such notice may not be given during the eighteen (18) month period commencing on the Effective Date.

10.4 Effect of Termination. In the event of termination of this Agreement pursuant to Section 10.2 or Section 10.3, the following shall apply:

(a) Retained Products. Oragenics shall be permitted to continue the clinical development and Commercialization in the Field of any Oragenics Product that, at the time of termination, satisfies at least one of the following criteria (a "**Retained Product**"):

(i) the particular Oragenics Product is being sold by Oragenics triggering profit sharing payments therefor under Section 5.4(a) of this Agreement,

(ii) the particular Oragenics Product has received regulatory approval,

(iii) the particular Oragenics Product is a subject of an application for regulatory approval in the Field that is pending before the applicable regulatory authority,

(iv) the particular Oragenics Product is the subject of at least an ongoing Phase 1, Phase 2 or Phase 3 clinical trial in the Field (in the case of a termination by EGI due to an Oragenics uncured breach pursuant to Section 10.2(a) or a termination by Oragenics pursuant to Section 10.3).

Such right to continue development and commercialization shall be subject to Oragenics' full compliance with the payment provisions in Article 5, a continuing obligation for Oragenics to use in accord with Sections 4.5(a) and 4.5(c) Diligent Efforts to develop and commercialize any Retained Products, and all other provisions of this Agreement that survive termination.

(b) Termination of Licenses. Except as necessary for Oragenics to continue to obtain regulatory approval for, clinically develop, use, manufacture and Commercialize the Retained Products in the Field as permitted by Section 10.4(a), all rights and licenses granted by EGI to Oragenics under this Agreement shall terminate and shall revert to EGI without further action by either EGI or Oragenics. Oragenics' license with respect to Retained Products shall be exclusive or non-exclusive, as the case may be, on the same terms as set forth in Section 3.1.

(c) Reverted Products. All Oragenics Products other than the Retained Products shall be referred to herein as the "**Reverted Products**." Oragenics shall immediately cease, and shall cause its Affiliates and, if applicable, (sub)licensees to immediately cease, all development and Commercialization of the Reverted Products, and Oragenics shall not use or practice, nor shall it cause or permit any of its Affiliates or, if applicable, (sub)licensees to use or practice, directly or indirectly, any EGI IP with respect to the Reverted Products. Oragenics shall immediately discontinue making any representation regarding its status as a licensee or channel collaborator of EGI with respect to the Reverted Products.

(d) EGI Materials. Oragenics shall promptly return, or at EGI's request, destroy, any EGI Materials in Oragenics' possession or control at the time of termination other than any EGI Materials necessary for the continued development, regulatory approval, use, manufacture and Commercialization of the Retained Products in the Field.

(e) Licenses to EGI. Oragenics is automatically deemed to grant to EGI a worldwide, fully paid, royalty-free, non-exclusive, irrevocable, license (with full rights to sublicense) under the Oragenics Termination IP, to make, have made, import, use, offer for sale and sell Reverted Products and to use the EGI Channel Technology, the EGI Materials, and/or the EGI IP in the Field, subject to any exclusive rights held by Oragenics in Reverted Products pursuant to Section 10.4(c). The Parties shall also take such actions and execute such other instruments and documents as may be reasonably necessary to document such license to EGI.

(f) Regulatory Filings. Oragenics shall promptly assign to EGI, and will provide full copies of, all regulatory approvals and regulatory filings that relate specifically and solely to Reverted Products. Oragenics shall also take such actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights thereunder to EGI. To the extent that there exist any regulatory approvals and regulatory filings that relate both to Reverted Products and other products, Oragenics shall provide copies of the portions of such regulatory filings that relate to Reverted Products and shall reasonably cooperate to assist EGI in obtaining the benefits of such regulatory approvals with respect to the Reverted Products.

(g) Data Disclosure. Oragenics shall provide to EGI copies of the relevant portions of all material reports and data, including clinical and non-clinical data and reports, obtained or generated by or on behalf of Oragenics or its Affiliates to the extent that they relate to Reverted Products, within sixty (60) days of such termination unless otherwise agreed, and EGI shall have the right to use any such Information in developing and commercializing Reverted Products and to license any Third Parties to do so.

(h) Third-Party Licenses. At EGI's request, Oragenics shall promptly provide to EGI copies of all Third-Party agreements under which Oragenics or its Affiliates obtained a license under Patents claiming inventions or know-how specific to or used or incorporated into the development, manufacture and/or commercialization of the Reverted Products. At EGI's request such that EGI may Commercialize the Reverted Products, Oragenics shall promptly work with EGI to either (A) assign to EGI the Third Party agreement(s), or (B) grant a sublicense (with an appropriate scope) to EGI under the Third Party agreement(s). Thereafter EGI shall be fully responsible for all obligations due for its actions under the sublicensed or assigned Third Party agreements. Notwithstanding the above, if EGI does not wish to assume any financial or other obligations associated with a particular Third Party agreement identified to EGI under this Section 10.4(h), then EGI shall so notify Oragenics and Oragenics shall not make such assignment or grant such sublicense (or cause it to be made or granted).

(i) Remaining Materials. At the request of EGI, Oragenics shall transfer to EGI all quantities of Reverted Product (including active pharmaceutical ingredient or work-in-process) in the possession of Oragenics or its Affiliates. Oragenics shall transfer to EGI all such quantities of Reverted Products without charge, except that EGI shall pay the reasonable costs of shipping.

(j) Third Party Vendors. At EGI's request, Oragenics shall promptly provide to EGI copies of all agreements between Oragenics or its Affiliates and Third Party suppliers, vendors, or distributors that relate to the supply, sale, or distribution of Reverted Products in the Territory. At EGI's request, Oragenics shall promptly: (A) with respect to such Third Party agreements relating solely to the applicable Reverted Products and permitting assignment, immediately assign (or cause to be assigned), such agreements to EGI, and (B) with respect to all other such Third Party agreements, Oragenics shall reasonably cooperate to assist EGI in obtaining the benefits of such agreements. Oragenics shall be liable for any costs associated with assigning a Third Party agreement to EGI or otherwise obtaining the benefits of such agreement for EGI, to the extent such costs are directly related to Oragenics' breach. For the avoidance of doubt, EGI shall have no obligation to assume any of Oragenics' obligations under any Third Party agreement.

(k) Commercialization. EGI shall have the right to develop and commercialize the Reverted Products itself or with one or more Third Parties, and shall have the right, without obligation to Oragenics, to take any such actions in connection with such activities as EGI (or its designee), at its discretion, deems appropriate.

(l) Confidential Information. Each Party shall promptly return, or at the other Party's request destroy, any Confidential Information of the other Party in such Party's possession or control at the time of termination; provided, however, that each Party shall be permitted to retain (i) a single copy of each item of Confidential Information of the other Party in its confidential legal files for the sole purpose of monitoring and enforcing its compliance with Article 7, (ii) Confidential Information of the other Party that is maintained as archive copies on the recipient Party's disaster recovery and/or information technology backup systems, or (iii) Confidential Information of the other Party necessary to exercise such Party's rights in Retained Products (in the case of Oragenics) or Reverted Products (in the case of EGI). The recipient of Confidential Information shall continue to be bound by the terms and conditions of this Agreement with respect to any such Confidential Information retained in accordance with this Section 10.4(l).

10.5 Surviving Obligations. Termination or expiration of this Agreement shall not affect any rights of either Party arising out of any event or occurrence prior to termination, including, without limitation, any obligation of Oragenics to pay any amount which became due and payable under the terms and conditions of this Agreement prior to expiration or such termination. The following portions of this Agreement shall survive termination or expiration of this Agreement: Sections 3.1 (as applicable with respect to 10.4(b), 5.5, 5.7, 6.1, 6.2 (with subsection (c) surviving only to the extent relating to EGI Patents that are relevant to Retained Products that, to EGI's knowledge, are being developed or commercialized at such time, if any), 7.1, 7.2, 7.4, 7.5, 10.4, and 10.5; Articles 9, 11, and 12; and any relevant definitions in Article 1. Further, Article 7 and Sections 4.5(a), 4.5(c), 5.2 through 5.8, and 9.5 will survive termination of this Agreement to the extent there are applicable Retained Products.

ARTICLE 11

Dispute Resolution

11.1 Disputes. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. In the event of any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement (other than disputes arising from a Committee), including, without limitation, any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement, then upon the request of either Party by written notice, the Parties agree to meet and discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one in-person meeting between the Executive Officers of each Party. If the matter is not resolved within thirty (30) days following the written request for discussions, either Party may then invoke the provisions of Section 11.2. For the avoidance of doubt, any disputes, controversies or differences arising from a Committee pursuant to Article 2 shall be resolved solely in accordance with Section 2.4.

11.2 Arbitration. Any dispute, controversy, difference or claim which may arise between the Parties and not from a Committee, out of or in relation to or in connection with this Agreement (including, without limitation, arising out of or relating to the validity, construction, interpretation, enforceability, breach, performance, application or termination of this Agreement) that is not resolved pursuant to Section 11.1 shall, subject to Section 11.10, be settled by binding "baseball arbitration" as follows. Either Party, following the end of the thirty (30) day period referenced in Section 11.1, may refer such issue to arbitration by submitting a written notice of such request to the other Party. Promptly following receipt of such notice, the Parties shall meet and discuss in good faith and seek to agree on an arbitrator to resolve the issue, which arbitrator shall be neutral and independent of both Parties and all of their respective Affiliates, shall have significant experience and expertise in licensing and partnering agreements in the pharmaceutical and biotechnology industries, and shall have some experience in mediating or arbitrating issues relating to such agreements. If the Parties cannot agree on a single arbitrator within fifteen (15) days of request by a Party for arbitration, then each Party shall select an arbitrator meeting the foregoing criteria and the two (2) arbitrators so selected shall select within ten (10) days of their appointment a third arbitrator meeting the foregoing criteria. Within fifteen (15) days after an arbitrator(s) is selected (in the case of the three-person panel, when the third arbitrator is selected), each Party will deliver to both the arbitrator(s) and the other Party a detailed written proposal setting forth its proposed terms for the resolution for the matter at issue (the "**Proposed Terms**" of the Party) and a memorandum (the "**Support Memorandum**") in support thereof. The Parties will also provide the arbitrator(s) a copy of this Agreement, as it may be amended at such time. Within fifteen (15) days after receipt of the other Party's Proposed Terms and Support Memorandum, each Party may submit to the arbitrator(s) (with a copy to the other Party) a response to the other Party's Support Memorandum. Neither Party may have any other communications (either written or oral) with the arbitrator(s) other than for the sole purpose of engaging the arbitrator or as expressly permitted in this Section 11.2; provided that, the arbitrator(s) may convene a hearing if the arbitrator(s) so chooses to ask questions of the Parties and hear oral argument and discussion regarding each Party's Proposed Terms. Within sixty (60) days after the arbitrator's appointment, the arbitrator(s) will select one of the two Proposed Terms (without modification) provided by the Parties that he or she believes is most consistent with the intention underlying and agreed principles set forth in this Agreement. The decision of the arbitrator(s) shall be final, binding, and unappealable. For clarity, the arbitrator(s) must select as the only method to resolve the matter at issue one of the two sets of Proposed Terms, and may not combine elements of both Proposed Terms or award any other relief or take any other action.

11.3 Governing Law. This Agreement shall be governed by and construed under the substantive laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

11.4 Award. Any award to be paid by one Party to the other Party as determined by the arbitrator(s) as set forth above under Section 11.2 shall be promptly paid in United States dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by law, be charged against the losing Party. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Article 11, and agrees that, subject to the United States Federal Arbitration Act, 9 U.S.C. §§ 1-16, judgment may be entered upon the final award in any United States District Court located in New York and that other courts may award full faith and credit to such judgment in order to enforce such award. The award shall include interest from the date of any damages incurred for breach of the Agreement, and from the date of the award until paid in full, at a rate fixed by the arbitrator(s). With respect to money damages, nothing contained herein shall be construed to permit the arbitrator(s) or any court or any other forum to award consequential, incidental, special, punitive or exemplary damages. By entering into this agreement to arbitrate, the Parties expressly waive any claim for consequential, incidental, special, punitive or exemplary damages. The only damages recoverable under this Agreement are direct compensatory damages.

11.5 Costs. Each Party shall bear its own legal fees. The arbitrator(s) shall assess his or her costs, fees and expenses against the Party losing the arbitration.

11.6 Injunctive Relief. Nothing in this Article 11 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding. Specifically, the Parties agree that a material breach by either Party of its obligations in Section 3.4 or Article 7 of this Agreement may cause irreparable harm to the other Party, for which damages may not be an adequate remedy. Therefore, in addition to its rights and remedies otherwise available at law, including, without limitation, the recovery of damages for breach of this Agreement, upon an adequate showing of material breach of such Section 3.4 or Article 7, and without further proof of irreparable harm other than this acknowledgement, such non-breaching Party shall be entitled to seek (a) immediate equitable relief, specifically including, but not limited to, both interim and permanent restraining orders and injunctions, without bond, and (b) such other and further equitable relief as the court may deem proper under the circumstances. For the avoidance of doubt, nothing in this Section 11.6 shall otherwise limit a breaching Party's opportunity to cure a material breach as permitted in accordance with Section 10.2.

11.7 Confidentiality. The arbitration proceeding shall be confidential and the arbitrator(s) shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by law, no Party shall make (or instruct the arbitrator(s) to make) any public announcement with respect to the proceedings or decision of the arbitrator(s) without prior written consent of the other Party. The existence of any dispute submitted to arbitration, and the award, shall be kept in confidence by the Parties and the arbitrator(s), except as required in connection with the enforcement of such award or as otherwise required by applicable law.

11.8 Survivability. Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after termination of this Agreement for any reason.

11.9 Jurisdiction. For the purposes of this Article 11, the Parties acknowledge their diversity and agree to accept the jurisdiction of any United States District Court located in New York for the purposes of enforcing or appealing any awards entered pursuant to this Article 11 and for enforcing the agreements reflected in this Article 11 and agree not to commence any action, suit or proceeding related thereto except in such courts.

11.10 Patent Disputes. Notwithstanding any other provisions of this Article 11, and subject to the provisions of Section 6.2, any dispute, controversy or claim relating to the scope, validity, enforceability or infringement of any EGI Patents shall be submitted to a court of competent jurisdiction in the country in which such Patent was filed or granted.

ARTICLE 12

General Provisions

12.1 Use of Name. No right, express or implied, is granted by this Agreement to either Party to use in any manner the name of the other or any other trade name or trademark of the other in connection with the performance of this Agreement, except that (a) either Party may use the name of the other Party as required by regulations and in press releases accompanying quarterly and annual earnings reports approved by the Audit Committee of the issuer's Board of Directors, and (b) Oragenics may use the EGI Trademarks in accord with license and restrictions set forth herein.

12.2 LIMITATION OF LIABILITY. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS PARAGRAPH IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER ARTICLE 9, OR DAMAGES AVAILABLE FOR BREACHES OF THE OBLIGATIONS SET FORTH IN ARTICLE 7.

12.3 Independent Parties. Neither Party is the employee or legal representative of the other Party for any purpose. Neither Party shall have the authority to enter into any contracts in the name of or on behalf of the other Party. This Agreement shall not constitute, create, or in any way be interpreted as a joint venture, partnership, or business organization of any kind.

12.4 Notice. All notices, including notices of address change, required or permitted to be given under this Agreement shall be in writing and deemed to have been given when delivered if personally delivered or sent by facsimile (provided that the party providing such notice promptly confirms receipt of such transmission with the other party by telephone), on the business day after dispatch if sent by a nationally-recognized overnight courier and on the third business day following the date of mailing if sent by certified mail, postage prepaid, return receipt requested. All such communications shall be sent to the address or facsimile number set forth below (or any updated addresses or facsimile number communicated to the other Party in writing):

If to EGI:	Eleszto Genetika, Inc. Attn: Legal Department 1881 Grove Avenue Radford, VA 24141 (540) 633-7939 (facsimile)
with a copy to:	Eleszto Genetika, Inc. Attn: Legal Department 1881 Grove Avenue Radford, VA 24141 (540) 633-7939 (facsimile)
If to Oragenics:	Oragenics, Inc. 4902 Eisenhower Blvd. Suite 125 Tampa, FL 33634 Attention: Chief Executive Officer Fax: (813) 286-7904
with a copy to:	Shumaker, Loop & Kendrick, LLP 101 E. Kennedy Blvd., Suite 2800 Tampa, FL 33602 Attention: Mark Catchur, Esq. Fax: (813) 229-1660

12.5 Severability. In the event any provision of this Agreement is held to be invalid or unenforceable, the valid or enforceable portion thereof and the remaining provisions of this Agreement will remain in full force and effect.

12.6 Waiver. Any waiver (express or implied) by either Party of any breach of this Agreement shall not constitute a waiver of any other or subsequent breach.

12.7 Entire Agreement; Amendment. This Agreement, including any exhibits attached hereto, constitute the entire, final, complete and exclusive agreement between the Parties and supersede all previous agreements or representations, written or oral, with respect to the subject matter of this Agreement (including any prior confidentiality agreement between the Parties). All information of EGI or Oragenics to be kept confidential by the other Party under any prior confidentiality agreement, as of the Effective Date, shall be maintained as Confidential Information by such other Party under the obligations set forth in Article 7 of this Agreement. This Agreement may not be modified or amended except in a writing signed by a duly authorized representative of each Party.

12.8 Non-assignability; Binding on Successors. Any attempted assignment of the rights or delegation of the obligations under this Agreement shall be void without the prior written consent of the non-assigning or non-delegating Party; provided, however, that either Party may assign its rights or delegate its obligations under this Agreement without such consent (a) to an Affiliate of such Party or (b) to its successor in interest in connection with any merger, acquisition, consolidation, corporate reorganization, or similar transaction, or sale of all or substantially all of its assets, provided that such assignee agrees in writing to assume and be bound by the assignor's obligations under this Agreement. This Agreement shall be binding upon, and inure to the benefit of, the successors, executors, heirs, representatives, administrators and permitted assigns of the Parties. Notwithstanding the foregoing, in the event that either Party assigns this Agreement to its successor in interest by way of merger, acquisition, consolidation, corporate reorganization, or similar transaction, or sale of all or substantially all of its assets (whether this Agreement is actually assigned or is assumed by such successor in interest or its affiliate by operation of law (e.g., in the context of a reverse triangular merger)), the intellectual property rights of such successor in interest or any of its Affiliates other than those licensed in this Agreement shall be automatically excluded from the rights licensed to the other Party under this Agreement.

12.9 Force Majeure. Neither Party shall be liable to the other for its failure to perform any of its obligations under this Agreement, except for payment obligations, during any period in which such performance is delayed because rendered impracticable or impossible due to circumstances beyond its reasonable control, including without limitation earthquakes, governmental regulation, fire, flood, labor difficulties, civil disorder, acts of terrorism and acts of God, provided that the Party experiencing the delay promptly notifies the other Party of the delay.

12.10 No Other Licenses. Neither Party grants to the other Party any rights or licenses in or to any intellectual property, whether by implication, estoppel, or otherwise, except to the extent expressly provided for under this Agreement.

12.11 Non-Solicitation. During the Term and for a period of one (1) year following the end of the Term, neither Oragenics nor EGI may directly or indirectly solicit in order to offer to employ, engage in any discussion regarding employment with, or hire any employee of the other Party or an individual who was employed by the other party with one (1) year prior to such solicitation, discussion, or hire, without the prior approval of such other Party. General employment solicitations or advertisements shall not be considered direct or indirect solicitations, and are not prohibited under this Agreement.

12.12 Legal Compliance. The Parties shall review in good faith and cooperate in taking such actions to ensure compliance of this Agreement with all applicable laws.

12.13 Counterparts. This Agreement may be executed in any number of counterparts (including by facsimile, PDF, or other means of electronic communication), each of which taken together will constitute one and the same instrument, and any of the Parties hereto may execute this Agreement by signing any such counterpart.

[Remainder of page intentionally left blank.]

In Witness Whereof, the Parties hereto have duly executed this Exclusive Channel Collaboration Agreement.

ELESZTO GENETIKA, INC.		**ORAGENICS, INC.**	
By:	*/s/ Theodore J. Fisher*	By:	*/s/ Alan F. Joslyn*
Name:	Theodore J. Fisher	Name:	Alan F. Joslyn
Title:	Secretary	Title:	Chief Executive Officer

[Signature Page to Amended and Restated Exclusive Channel Collaboration Agreement]

Exhibit 21.1

Subsidiaries of Oragenics, Inc.

Name	State or Jurisdiction of Incorporation or Organization
Noachis Terra Inc.	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the inclusion in this Annual Report (Form 10-K) of Oragenics, Inc. of our report dated March 1, 2021, with respect to the 2020 and 2019 financial statements of Oragenics, Inc. We consent to the incorporation of our report by reference in the following Registration Statements:

(i) Form S-8 Registration Statements (Nos. 333-110646, 333-150716, 333-163083, 333-177091, 333-184588, 333-223088, 333-225894 and 333-232301) of Oragenics, Inc. pertaining to the Oragenics, Inc. 2012 Equity Incentive Plan; and

(ii) Registration Statements (Form S-1 Nos. 333-224498, 333-224950 and 333-226150) and (Form S-3 Nos. 333-183685, 333-190609, 333-213321, 333-230422, 333-235763 and 333-238789) and related Prospectus of Oragenics, Inc.

/s/ Mayer Hoffman McCann P.C.

Clearwater, Florida

March 1, 2021

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Alan Joslyn, certify that:

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

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

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

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

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

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

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors:

(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.

Dated this 1st day of March, 2021

By: */s/ Alan F. Joslyn Ph.D.*

Alan F. Joslyn Ph.D.
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Michael Sullivan, certify that:

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

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

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

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

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

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

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors:

(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.

Dated this 1st day of March, 2021

By: */s/ Michael Sullivan*
Michael Sullivan
Chief Financial Officer

Exhibit 32.1

Certification of Chief Executive Officer

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)

In connection with the Annual Report on Form 10-K for the period ended December 31, 2020 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Alan Joslyn, hereby certify, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

/s/ Alan F. Joslyn Ph.D.

Name: Alan F. Joslyn Ph.D.
President and Chief Executive Officer

Date: March 1, 2021

Exhibit 32.2

Certification of Chief Financial Officer

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)

In connection with the Annual Report on Form 10-K for the period ended December 31, 2020 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Michael Sullivan, hereby certify, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

/s/ Michael Sullivan

Name: Michael Sullivan
Chief Financial Officer

Date: March 1, 2021