Filed Pursuant to Rule 424(b)(3)
Registration No. 333-224498

PROSPECTUS

This prospectus relates to the resale of 2,254,567 shares of our common stock which includes 1,354,567 shares of our outstanding common stock and up to 900,000 shares of our common stock issuable upon exercise of certain outstanding warrants.

These shares may be resold from time to time by the entities and person listed in the section titled "Selling Securityholders" beginning on page 52, which we refer to as the selling securityholders. We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of securities by the selling securityholders. Upon the cash exercise of the warrants, however, we will receive the exercise price of the warrants which is $2.00 per share.

The selling securityholders may sell the shares of common stock described in this prospectus in a number of different ways and at varying prices. We provide more information about how a selling securityholder may sell its shares of common stock in the section titled "Plan of Distribution" on page 53. We will pay the expenses incurred in registering the securities covered by the prospectus, including legal and accounting fees.

Our common stock is traded on the NYSE American, under the symbol "OGEN". On April 25, 2018, the last reported sale price of our common stock was $1.47 per share.

AN INVESTMENT IN OUR COMMON STOCK INVOLVES RISKS. SEE THE SECTION ENTITLED "RISK FACTORS" BEGINNING ON PAGE 11.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is May 8, 2018

TABLE OF CONTENTS

You should read this prospectus and any applicable prospectus supplement before making an investment in the securities of Oragenics, Inc. See “Where You Can Find More Information” for more information. You should rely only on the information contained in this prospectus or a prospectus supplement. The Company has not authorized anyone to provide you with different information. This document may be used only in jurisdictions where offers and sales of these securities are permitted. You should assume that information contained in this prospectus, or in any prospectus supplement, is accurate only as of any date on the front cover of the applicable document. Our business, financial condition, results of operations and prospects may have changed since that date. Unless otherwise noted in this prospectus, “Oragenics” “the Company,” “we,” “us,” “our” and similar terms refer to Oragenics, Inc. and ORAGENICS® is a registered trademarks of the Company. All other product and company names are trademarks of their respective owners. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the® or ™ symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Smaller Reporting Company – Scaled Disclosure

Pursuant to Item 10(f) of Regulation S-K promulgated under the Securities Act of 1933, as indicated herein, we have elected to comply with the scaled disclosure requirements applicable to “smaller reporting companies,” including providing two years of audited financial statements.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. Because it is a summary, it does not contain all of the information that you should consider in making your investment decision. Before investing in our securities, you should carefully read this entire prospectus, including our financial statements and the related notes and the information set forth under the sections "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." Some of the statements in this prospectus constitute forward-looking statements that involve risks and uncertainties. See information set forth under the section "Special Note Regarding Forward-Looking Statements."

Overview

We are focused on becoming a leader in developing novel antibiotics against infectious disease and on developing effective treatments for oral mucositis.

Our Oral Mucositis Product Candidate-Clinical

In June of 2015, we entered into a worldwide Exclusive Channel Collaboration Agreement ("Oral Mucositis ECC") with Intrexon Corporation ("Intrexon") and Intrexon Actobiotics NV, a wholly-owned subsidiary of Intrexon, pursuant to which we obtained certain exclusive rights to AG013 as a potential treatment of oral mucositis, or OM for cancer patients, which we intend to continue to develop. AG013, is an oral rinsing solution designed to deliver human Trefoil Factor 1 (hTFF1) to protect and regenerate damaged mucosal lining of the oral cavity.

OM results in a painful inflammation and mucosal ulceration in the lining of the oral cavity, throat and esophagus and is one of the most commonly reported adverse events associated with cancer chemotherapy. Approximately 770,000 patients annually in the US are at an increased risk of developing OM according to cancer statistics provided by the Center for Disease Control (CDC) in 2017. OM has a negative effect on patient well-being and if severe, negatively affects adherence to a patient's cancer treatment regimen. At present, we are not aware of any drug that is approved to prevent the condition broadly and current therapies are primarily palliative in nature, only addressing symptom relief but not treating the underlying causes of the condition.

In a Phase 1b clinical trial in 25 cancer patients with OM, AG013 was safe and well tolerated. Data published in the journal Cancer showed a 35% reduction of the duration of ulcerative OM in the AG013-treated patients versus the placebo-treated patients. Furthermore, close to 30% of the patients treated with AG013 were full responders while all placebo-treated patients developed ulcerative OM. Additionally, in a Phase 1 pharmacokinetic (PK) study in 10 healthy volunteers, AG013 bacteria adhered to the buccal mucosa and actively secrete protein locally, resulting in homogeneous exposure of the entire mucosal surface up to 24 hours after administration of the rinse. During the first quarter of 2016, we conducted a confirmatory animal study on AG013. AG013 has been granted Orphan Drug status in the European Union. In November of 2016, the United States Food and Drug Administration (the "FDA") granted Fast Track designation for AG013, and we believe it may be eligible for Biologic License Application exclusivity as well.

We have developed a Phase 2 protocol for AG013 with the FDA under the fast track designation. The study is a double blind, placebo controlled, evaluation of daily AG013, administered three times a day, oral rinse for the duration of the cancer treatment. The study is expected to enroll between 160-180 evaluable patients receiving chemoradiation over 7 to 9 weeks. The primary endpoint is a reduction, compared to the placebo, in the number of days of severe oral mucositis. In addition, a number of secondary endpoints are being evaluated**.** In August of 2016, we received feedback from the FDA in response to our Type C meeting and the pursuit of a Phase 2 trial on AG013 for the treatment of oral mucositis in head and neck cancer patients. We filed an Investigational New Drug ("IND") update in March 2017 and we initiated the Phase 2 study with AG013 in the United States in 2017 with the expectation that we will expand the trial into Europe in 2018 upon sufficient financing being available to us. The Phase 2 clinical trial of AG013 is a double-blind, placebo-controlled study that will be conducted at approximately 45 clinical sites across the United States and Europe, and is expected to enroll up to 160 – 180 evaluable patients. The purpose of the study is to evaluate the efficacy, safety and tolerability and pharmacokinetics of orally

administered AG013 compared to placebo for reducing OM in patients undergoing chemo-radiation for the treatment of head and neck cancer, as measured by the duration, time to development, and overall incidence of OM. We completed enrollment of the interim analysis cohort of 20 patients in our Phase 2 clinical trial of AG013 for the treatment OM.

Our Antibiotic Product Candidate-Preclinical

Members of our scientific team discovered that a certain bacterial strain 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 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.

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 the Lantibiotic Exclusive Channel Collaboration agreement ("Lantibiotic ECC") with Intrexon for the development and commercialization of the native strain of MU1140 and related homologs using Intrexon's advanced transgene and cell engineering platforms. Through our work with Intrexon, 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 with Intrexon generated a substantial number of homologs of MU1140, and we are continuing our research and development and collaboration efforts with Intrexon 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 when compared to a vancomycin positive control.

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. While we were able to raise additional capital during the year ended December 31, 2017, we currently expect the IND for a first-in-human clinical study of OG716 to be filed with the FDA based on our ability to complete the requisite studies, contingent on sufficient funding.

Other Product Candidates and Technologies.

In addition to our lantibiotics and oral mucositis product candidates, we also have other candidates and technologies in the oral care and weight loss areas. We do not intend to continue to develop these potential product candidates and technologies without partnering with a third party. We out-licensed the continued research and development of our weight loss product candidate in December 2013 to, LPThera LLC, and LPThera LLC continues to work to develop a product for commercial use. Our oral care product candidate SMaRT Replacement Therapy is positioned for out-licensing opportunities.

Recent Developments

Completed Registered Direct Offering and Private Placement. On April 10, 2018, the Company completed a registered direct offering and private placement pursuant to a Securities Purchase Agreement with certain investors pursuant to which the Company issued and sold in a registered offering by the Company directly to the Investors (the "Registered Offering"), an aggregate of 900,000 shares (the "Shares") of common stock, par value $0.001 per share, of the Company (the "Common Stock"), at an offering price of $2.00 per share. In a concurrent private placement (the "Private Placement"), the Company 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 purchase 900,000 shares of Common Stock at an exercise price of $2.00 per share. Each Warrant is exercisable beginning October 10, 2018 and will expire on April 10, 2023. Shares of common stock underlying the aggregate of 900,000 Warrants are being registered for resale by certain of the selling securityholders pursuant to the Registration Statement of which this prospectus forms a part.

Completed Private Placement. On November 8, 2017, the Company completed a private placement of $3.3 million of Series B Non-Voting, Convertible Preferred Stock (the "Series B Preferred Stock"), including the issuance of warrants to acquire 1,064,518 shares of common stock, pursuant to a Securities Purchase Agreement with four existing shareholders who are accredited investors including, the Koski Family Limited Partnership, an entity affiliated with a director of the Company, (the "Series B Preferred Stock Financing").

Completed Debt Conversion. On November 8, 2017, concurrently with the Series B Preferred Stock Financing, the Company also entered into a Debt Conversion Agreement (the "Intrexon Debt Conversion Agreement") with Intrexon Corporation ("Intrexon") pursuant to which Intrexon exchanged the $2.4 million unsecured, non-convertible, promissory note previously issued by the Company to Intrexon (the "Intrexon Note"), the accrued interest on the Intrexon Note and trade payables owed by the Company to Intrexon (collectively the "Debt") in the aggregate amount of approximately $3.4 million for equity in the form of shares of Series C, Non-Voting, Non-Convertible Preferred Stock (the "Series C Preferred Stock") issued by the Company to Intrexon. 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 and pro-rata for partial years. On January 25, 2018 we paid a dividend on our Series C Preferred Stock to Intrexon of 1.733 shares for the portion of the 2017 the Series C Preferred was outstanding. The Initial Rate shall be subject to increase to twenty percent (20%) automatically, after May 10, 2019, if the Series C Preferred Stock is not earlier redeemed by us.

Amended our Exclusive Channel Collaboration Agreements with Intrexon. In connection with the Series B Preferred Stock Financing and the Intrexon Debt Conversion Agreement, on November 8, 2017, we amended (i) our Lantibiotic ECC and the Lantibiotic Stock Issuance Agreement (together the "Lantibiotic Program") and (ii) our Oral Mucositis ECC and Oral Mucositis Stock Issuance Agreement (together the "Oral Mucositis Program").

- The Lantibiotic Program was revised as follows:
    - Consolidated all historical, and yet to be achieved, research and development milestones into a single milestone payment of $25 million to Intrexon, payable within 6 months of first regulatory approval of a NDA or BLA and provides for a payment of $5.0 million to Intrexon within 6 months of regulatory approval of any subsequent supplemental NDA resulting in an expanded new indication or NDA of a subsequent lantibiotic from the lantibiotic library;
    - Reduced the royalty rate from 25% of Product Profit to 10% of Net Sales;

- Reduced the sublicense revenue percentage from 50% to 25%;
- Revised the form of milestone payments from being share based or cash at our election to only cash; and
- Committed 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 expended for the advancement of the Lantibiotic Program.

- The Oral Mucositis Program was revised as follows:
  - Consolidated all historical, and yet to be achieved, research and development milestones into a single milestone payment to Intrexon of $27.5 million payable within 6 months of first regulatory approval of a NDA or a BLA and provides for a payment of $5.0 million to Intrexon within 6 months of regulatory approval of any subsequent supplemental NDA resulting in an expanded new indication or NDA of a subsequent AG013 product;
  - Reduced the sublicense revenue percentage from 50% to 25%.
  - Revised the definition of "Field" in the Oral Mucositis ECC to reflect and clarify that Oragenics has the worldwide exclusive rights to the treatment of Oral Mucositis regardless of its cause.

***Received NYSE Notification of Regained Listing Compliance*.** Following consummation of the Series B Preferred Stock Financing and Debt Conversion, on November 10, 2017, we received notification from NYSE American that the Company is back in compliance with all of the NYSE American continued listing standards. We cannot assure you that we will be able continue to meet the NYSE American listing standards. If do not continue to meet any of the NYSE American listing standards, our common stock may be subject to delisting from NYSE American.

Amended our Articles of Incorporation. On December 29, 2017, we amended our Amended and Restated Articles of Incorporation to increase the number of authorized shares of our common stock from 250,000,000 shares to 450,000,000 (unadjusted for reverse stock split referenced below). The purpose of the increase in the number of authorized shares of our common stock is to provide flexibility in connection with our future financing efforts.

Consummated a Reverse Stock Split. On January 19, 2018 we effected a one for ten reverse stock split of our authorized and outstanding common stock, by filing Articles of Amendment to our Articles of Incorporation. As a result of the reverse stock split (i) proportionate adjustments have been made to the per share exercise price and/or the number of shares issuable upon the exercise or vesting of all stock options and warrants issued by us and outstanding immediately prior to the effective time, which resulted in a proportionate decrease in the number of shares of our common stock reserved for issuance upon exercise or vesting of such stock options and warrants, and, in the case of stock options and warrants, a proportionate increase in the exercise price of all such stock options and warrants; (ii) proportionate adjustments have been made to the conversion price applicable to outstanding shares of Series A and Series B Convertible Preferred Stock; (iii) the number of shares authorized for future grant under our equity incentive/compensation plans immediately prior to the effective time have been reduced proportionately; and (iv) the number of authorized shares of common stock as recently increased have been reduced from 450,000,000 shares to 45,000,000 shares. All share and per share amounts in this registration statement have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Our Products and Product Candidates

Overview

Product/Candidate	Description	Application	Status
AG013	Treatment of Oral Mucositis	Treatment of oral mucositis in cancer patients	Ready to initiate Phase 2 clinical trial
OG716	A homolog of MU1140: Member of lantibiotic class of antibiotics	Healthcare-associated infections	Nonclinical testing
LPT3-04	Naturally occurring chemical agent	Weight loss	Exclusively out-licensed
SMaRT Replacement Therapy	Genetically modified strain of *S. mutans* that does not produce lactic acid	Dental carries-tooth decay	Positioned for partnership opportunities

Our Strategy and Competitive Strengths

We believe that the combination of our proprietary platform technologies and the expertise of our team in the areas of product development and commercialization, are the core elements driving our company. The key elements of our corporate strategy and the competitive advantages we believe these elements provide us include the following:

- patented and patent pending unique platform technologies;
- potentially shorter time to market for product introductions due to disruptive characteristics ;
- efficient advancement of early stage product candidates into late stage development;
- strategic partnerships, joint development and licensing; and
- ability to develop a diversified portfolio in a variety of medical conditions of unmet medical needs based on the expansion of underlying technologies

Strategic Alliance and Relationship

As part of our business strategy, we augment our internal and external development efforts by establishing strategic relationships and alliances with third parties that have technologies, patents, other know how or commercialization capabilities that we believe will be additive to our internal efforts. We have two separate ECC Agreements with Intrexon and its wholly owned subsidiaries Intrexon Actobiotics NV and ActoBio Therapeutics, Inc. as follows:

Our Oral Mucositis ECC

On June 9, 2015, we entered into our Oral Mucositis ECC with Intrexon and Actobiotics, a wholly-owned subsidiary of Intrexon, through which we intend to research, develop and commercialize products, including the continued development and commercialization of AG013, for use in the treatment of oral mucositis in humans through the administration of an effector via genetically modified bacteria, but, in any case, excluding the delivery of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer (collectively, the “Program”). Contemporaneously with the ECC, we also entered into a Stock Issuance Agreement (the “SIA”) with Intrexon which provided for the payment of a technology access fee and the potential future issuance by us of our common stock to Intrexon upon the achievement of designated development milestones. We issued a Convertible Note in the amount of $5,000,000 as payment of the technology access fee associated with the Oral Mucositis ECC which was payable, at our option, in cash or shares of our common stock. The convertible note, including accrued interest, was repaid in December 2015 through the issuance of 338,101 shares of our common stock.

The Oral Mucositis ECC governs the “channel collaboration” arrangement in which we will use Intrexon’s proprietary technology relating to the identification, design and production of genetically modified bacteria for the purpose of developing the Program.

The Oral Mucositis ECC provides for the establishment of committees comprised from us and Intrexon representatives that will govern activities in the areas of project establishment, chemistry, manufacturing and controls, clinical and regulatory matters, commercialization efforts, and intellectual property.

The Oral Mucositis ECC grants us an exclusive worldwide license to utilize Intrexon's and Actobiotics' intellectual property to develop and commercialize products, including the continued development and commercialization of AG013, for use in the treatment of oral mucositis in humans through the administration of an effector via genetically modified bacteria, but, in any case, excluding the delivery of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer, but, in any case, excluding the delivery of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer (the "Field"). It also grants us an exclusive license in the Field under all Information Controlled by Actobiotics (or otherwise by Intrexon) and existing as of the Effective Date relating to the regulatory approval of AG013, including regulatory filings, data, clinical trial reports, and rights thereunder.

In November of 2017 the Oral Mucositis ECC was amended to: (i) consolidate the development milestone payments into one payment of $27,500,000 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; and (iii) revise the field in which we have exclusive rights to our Oral Mucositis product candidate for the treatment of Oral Mucositis to clarify that we have an exclusive right for the treatment of Oral Mucositis in humans regardless of etiology. The November amendment superseded an amendment to the Oral Mucositis ECC in May 2017. Effective January 1, 2018, Intrexon assigned its interest in the Oral Mucositis ECC and related SIA (excluding Intrexon's standstill obligation) to its wholly owned subsidiary, ActoBio Therapeutics, Inc.

Our Lantibiotic ECC

On June 5, 2012, we entered into the Lantibiotic ECC with Intrexon that governs a "channel collaboration" arrangement in which we will use Intrexon'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 establishes committees comprised of our representatives and Intrexon 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. Currently, the Joint Steering Committee has established projects for the Lantibiotics Program and established the priorities, as well as approved the budgets for such projects.

The Lantibiotic ECC grants us an exclusive worldwide license to use patents and other intellectual property of Intrexon 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 Intrexon's written consent.

In November of 2017 we amended the Lantibiotic ECC 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 our 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 expended for the advancement of the Lantibiotic Program.

Risks Associated with Our Business and this Offering

Since our inception, we have incurred substantial losses. Our business and our ability to execute our business strategy are subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this prospectus, and among these important risks are the following:

- Since inception, we have experienced recurring operating losses and negative cash flows and we expect to continue to generate operating losses and consume significant cash resources for the foreseeable future. As a result, our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern. We are unable to predict the extent of any future losses or if or when we will become profitable, if at all. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we do not have sufficient funds to continue operations and satisfy our obligations and liabilities, we could be required to seek bankruptcy protection or other alternatives that would likely result in our stockholders losing some or all of their investment in us.
- We will require substantial additional financing and capital. To raise additional capital, we may in the future issue debt and equity securities or securities convertible into equity securities, any of which may be senior to our common stock as to distributions or in liquidation and may have other rights superior to existing stockholders. We may also issue these securities at prices that may not be the same as, and may be lower than, the price per share paid by other investors, and our stockholders could experience significant dilution.
- As a result of our operating losses in recent years and decline in stockholders' equity, we may be unable to satisfy the continued listing requirements of NYSE American. In the event our common stock is delisted, our stockholders may experience decreased liquidity. On May 10, 2016, we received a deficiency notice from NYSE American stating we were not in compliance with the stockholders' equity requirement. We have subsequently regained compliance, but there is no assurance we will be able to maintain compliance.
- Our operating results may fluctuate significantly, are difficult to predict and could fall below expectations due to a variety of other factors, including: our financial condition, delays in the commencement, enrollment and the timing of clinical testing for our product candidates; the timing and success or failure of clinical trials for our product candidates or competing product candidates; delays in regulatory review and approval of product candidates; the timing and level of investment in research and development activities; the cost of manufacturing; and our ability to obtain additional funding.
- Our business is dependent on the successful development and commercialization of our product candidates, in particular AG013, and OG716. We may never successfully commercialize any of our product candidates. Accordingly, we may not generate revenue through the sale of our product candidates or any future product candidates sufficient to continue operations.
- We have limited experience in the conduct of clinical trials, and may be unable to obtain, regulatory approval for early-stage product candidates. 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, any of which would adversely impact commercialization, our potential to generate revenue, our business and our operating results. 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.
- We rely on a wide variety of third parties for consulting services, including clinical trial management and regulatory affairs. These third parties are selected based on their experience and expertise and our agreements with them are short term in nature and provide for limited liability for the third party. There can be no assurance that these third parties will perform as anticipated by our agreements with them or on a timely basis and we may be unable to secure service from other parties without an increase in costs, delays, or interruptions in the conduct of our clinical program.
- Under our ECCs with Intrexon and its wholly owned subsidiary ActoBio Therapeutics, Inc. we are responsible for, among other things, funding the further anticipated development of lantibiotics and AG013 toward the goal of commercialization, including conducting nonclinical and clinical development of product candidates. Intrexon may terminate such agreement if we do not perform certain specified requirements, including developing therapies identified to us and considered superior by Intrexon. There can be no assurance that we will be able to successfully perform under the ECCs and if the ECCs are terminated it would prevent us from achieving our business objectives.

- 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.
- Even if our current product candidates or any future product candidates obtain regulatory approval, they may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success. Our product candidates, if approved, will also face significant competition and our failure to compete effectively may prevent us from achieving significant market penetration.
- We rely on a single, qualified supplier to manufacture our AG013 product and our OG716 product candidates and our manufacturing contracts are short-term in nature. If we cannot renew these agreements or cannot find replacement manufacturers, we cannot be certain that manufacturing sources will continue to be available or that we can continue to outsource the manufacturing of our products and product candidates on commercially reasonable or acceptable terms.

Corporate and Other Information

We were incorporated in November 1996 and commenced operations in 1999. We consummated our initial public offering in June 2003. We have devoted substantially all of our available resources to our discovery efforts comprising research and development, clinical trials for our product candidates, protection of our intellectual property and the general and administrative support of these operations. We have generated limited revenues from grants and from our former consumer ProBiora3 product business, and have principally funded our operations through the sale of debt and equity securities, including the exercise of warrants issued in connection with financing transactions. In June of 2016, we completed the sale of our consumer probiotics business to ProBiora Health, LLC and as a result, we will no longer generate revenue from sales of consumer probiotic products. Our net revenues were $0 and $464,048, for the years ended December 31, 2017 and 2016, respectively.

As of December 31, 2017 we had an accumulated deficit of $101,400,797 and we have yet to achieve profitability. We incurred net losses of $6,731,525 and $7,013,304 for the years ended December 31, 2017 and 2016, 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 need to raise additional capital. 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 seek to grow and continue to operate our business. There can be no assurance that additional capital will be available to us on acceptable terms, if at all. The report of our independent registered public accounting firm with respect to our financial statements appearing in our Form 10-K contains an explanatory paragraph stating that our operating losses and negative cash flows from operations and our need to raise additional financing and/or financial support prior to July 2018 in order to continue to fund our operations, raise substantial doubt about our ability to continue as a going concern. We believe the working capital at December 31, 2017, will be sufficient to meet the business objectives, as presently structured, through August 2018. As such, there is substantial doubt that we can continue as a going concern beyond that date.

Our executive office is located at, 4902 Eisenhower Boulevard, Suite 125 Tampa, Florida, 33634 and our research facilities are located at 13700 Progress Boulevard, Alachua, Florida 32615. Our telephone number is (813) 286-7900 and our website is http://www.oragenics.com. Information on, or that can be accessed through, our website is not part of this prospectus supplement or the accompanying prospectus and should not be relied on in connection with this offering.

Available Information

We file electronically with the Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Exchange Act. We make available on our website at www.oragenics.com, free of charge, copies of these reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is www.sec.gov.

The information in or accessible through the websites referred to above are not incorporated into, and are not considered part of, this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

The Offering	
Common stock offered by the selling securityholders	2,254,567 shares of our common stock which includes 1,354,567 shares of our outstanding common stock and up to 900,000 shares issuable upon exercise of warrants (which warrants will become exercisable on October 10, 2018 at an exercise price of $2.00 per share and expire on April 10, 2023).
Common stock to be outstanding after this offering	6,986,635 shares (1)
Terms of the offering	The selling securityholders and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their shares covered hereby on the NYSE American or any other stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. See "Plan of Distribution."
Use of Proceeds	We will not receive any of the proceeds from the sale of our common stock by the selling securityholders pursuant to this prospectus. We may receive up to approximately $1,800,000 in aggregate gross proceeds from cash exercises of the warrants, based on the per share exercise price of the warrants. Any proceeds we receive from the exercise of the warrants will be used for working capital and general corporate purposes. See "Use of Proceeds."
NYSE American symbol	"OGEN".
Risk Factors	See "Risk Factors" beginning on page 11 and other information included in this prospectus for a discussion of factors that you should consider carefully before deciding to invest this offering.

(1) The number of shares of our common stock that will be outstanding immediately before and after this offering is based on 6,086,635 shares outstanding as of April 12, 2018 plus the 900,000 shares issuable upon exercise of warrants issued pursuant to the Securities Purchase Agreement dated April 6, 2018 (the "Purchase Agreement") and excludes:

- 2,261,703 shares of common stock issuable upon the conversion of preferred stock outstanding;
- 3,338,058 shares issuable upon the exercise of warrants and options outstanding at a weighted average exercise price of $3.27 per share;
- 264,617 shares of our common stock reserved for future issuance under our Stock Incentive Plan;

Unless otherwise indicated, all information in this prospectus also reflects and assumes no exercise by the underwriters of their option to purchase additional shares of our common stock and/or warrants to purchase shares of our common stock to cover overallotments, if any.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should consider the following risk factors, as well as other information contained in this prospectus, before deciding to invest in our securities. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known or which we consider immaterial as of the date hereof may also have an adverse effect on our business. If any of the matters discussed in the following risk factors were to occur, our business, financial condition, results of operations, cash flows or prospects could be materially adversely affected, the market price of our common stock could decline and you could lose all or part of your investment in our securities.

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 $6.7 million and $7.0 million for the years ended December 31, 2017, and 2016, respectively. As of December 31, 2017 our accumulated deficit was approximately $101.4 million. We have devoted a significant amount of our financial resources to research and development, including our nonclinical development activities and clinical trials. We expect that the costs associated with our exclusive channel partnerships with Intrexon in the area of lantibiotics ("Lantibiotics Program") and with Intrexon's subsidiary ActoBio Therapeutics, Inc. in the area of Oral Mucositis ("Oral Mucositis Program") and the development and commercialization of our product candidates under the Lantibiotics Program (which includes MU1140 homologs) using Intrexon's advanced transgene and cell engineering platforms will continue to increase the level of our overall expenses significantly going forward. 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. We anticipate that our cash resources as of December 31, 2017 will be sufficient to fund our operations as presently structured through August2018. However, changes may occur that would consume our existing capital prior to that time, including the scope and progress of our efforts to develop and commercialize our product candidates. 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 over a longer period of time. 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 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 Phase 2 clinical trial on our AG013 product candidate;
- 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 level of research and development investment required 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 could 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, curtail or forego sales and marketing efforts, and/or forego licensing attractive business opportunities.

Our auditor has 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 contains an explanatory paragraph raising substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that may be necessary in the event we are unable to continue as a going concern. If we are 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 without additional financing through August 2018. Absent sufficient additional financing, we may be unable to remain a going concern.

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 lantibiotics and oral mucositis are keys to our growth strategy.

A key element of our strategy is to discover, develop, validate and commercialize 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 and to develop, validate and commercialize a product

candidate to treat oral mucositis. We cannot assure you that we will be able to successfully complete development of, or commercialize any of our planned future product candidates, or that they will be clinically usable. 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:

- failure of future tests at the research or development stages;
- lack of clinical validation data to support the effectiveness of the test;
- 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;
- 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 studies often is not replicated in later studies. At any point, we may abandon development of new products, 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.

We may be unable to find 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 Intrexon 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 Intrexon 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.

We do not have any product revenue since we sold our consumer probiotics business in June of 2016.

We do not currently have any product revenue since we sold our consumer probiotics business in June of 2016. Prior to the sale, revenues from sales of our ProBiora3 products were our sole source of product revenue.

Our success will depend on our ability to obtain regulatory approval of our product candidates under our Lantibiotics Program and our Oral Mucositis Program and their successful commercialization.

Our product candidates under our Lantibiotics Program and Oral Mucositis Program have not received regulatory approval in any jurisdiction and they 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) and oral mucositis product candidate, respectively. We have performed extensive nonclinical testing using native MU1140 and have since entered into an Exclusive Channel Collaboration Agreement with Intrexon. 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, and subject to sufficient available capital, we would expect to file an Investigational New Drug application with the FDA by the second half of 2018 for OG716. We initiated a Phase 2 clinical trial on our AG013 product candidate in 2017. 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.

Our exclusive channel collaboration agreements with Intrexon and its wholly owned subsidiaries are based on early stage technologies in their fields.

Our exclusive channel collaboration agreements with Intrexon and its wholly owned subsidiaries contemplate the use of Intrexon's advanced transgene and cell engineering platforms for the development and production of lantibiotics and AG013. 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 arrangements with Intrexon.

Pursuant to our exclusive channel collaborations with Intrexon under our Lantibiotics Program and Oral Mucositis Program, we are responsible for future research and development expenses of product candidates developed under such collaborations, including those incurred by Intrexon for research on our behalf as provided in the ECC Agreements with Intrexon. 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 ECCs 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 to add additional personnel to support our Lantibiotics Program and Oral Mucositis Program with Intrexon.

Because our collaborations with Intrexon are 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 ECC Agreements with Intrexon.

We may not be able to retain the exclusive rights licensed to us by Intrexon to develop and commercialize lantibiotic products and AG013 related products.

Under our ECCs with Intrexon we are responsible for, among other things, funding the further anticipated development of lantibiotics and AG013 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). Intrexon may terminate such agreements if we do not perform certain specified requirements, including developing therapies identified to us and considered superior by Intrexon. In addition, we must commit $1.2 million in development costs through the end of 2018 to retain our lantibiotic ECC. There can be no assurance that we will be able to successfully perform under the Oral Mucositis ECC or Lantibiotic ECC and if either ECC is terminated it would prevent us from achieving our business objectives.

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

Our MU1140 homologs and AG013 product candidate are in early stage development and are expected to require partners with substantial financial resources to continue the development of each of these products to commercialization. In addition, none of these product candidates have 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 extensive nonclinical testing using native MU1140 and expect to continue to pursue the nonclinical testing of our MU1140 homologs and other antibiotic product candidates during 2017 toward the goal of filing and IND in 2018. 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 and Oral Mucositis Program or otherwise 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.

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 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;
- the level of expenses associated with our 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.

If we fail to comply with our obligations in the agreements with the University of Florida Research Foundation, Inc., under which we license our rights to MU1140, our license to that product candidate may be terminated and we will be unable to commercialize that product candidate.

We hold our MU1140 product candidate under a license from the University of Florida Research Foundation, Inc., or UFRF. We are required to make minimum annual maintenance payments to the UFRF for the term of the amended license agreement in the amount of $10,000. The minimum annual payments are required to be paid in advance on a quarterly basis (i.e. $2,500 per quarter) for the license. We are also required to pay all patent costs and expenses incurred by the UFRF for the preparation, filing, prosecution, issuance and maintenance of the patents.

The UFRF may terminate our licenses to MU1140 if we breach our obligations to timely pay these amounts, to submit development reports as required under the license agreement or commit any other breach of any other covenants contained in the license agreement and we fail to remedy such breach within 90 days after written notice of such breach by UFRF. There is no assurance that we will be able to comply with these conditions in a timely manner or at all. If our license agreement is terminated, we will be unable to commercialize the product candidate. If we are able to commercialize any product candidates, we are obligated to pay 5% of the selling price of any products developed from the licensed technologies that we may sell as royalty to the UFRF. In addition, if we sublicense any rights granted by the amended license agreements, we are obligated to pay the UFRF 22% of all revenues received from the sublicenses, excluding monies received solely for development costs. We are also obligated to make the following payments to UFRF as follows: a one-time commercialization fee, post-commercialization minimum royalty payments, and a one-time cumulative royalty payment. The one-time commercialization fee would be due on the first anniversary of first commercial sale and is calculated at $5,000 per month between (1) April 1, 2013 (for the MU1140 license agreement) and (2) the month of the first anniversary of a commercial sale. The post-commercialization minimum royalty payments of $50,000 annually would be due following payment of a commercialization fee. The one-time additional royalty payment would be due when total cumulative royalties paid to UFRF exceed $2.0 million, upon which we would be obligated to make a one-time additional payment to UFRF of 10% of the total royalties due to UFRF in the calendar year in which cumulative royalties exceeded $2.0 million. Until commercial sale of any products developed from these licensed product candidates takes place, we will not earn any revenues from these product candidates and will, therefore, need additional financing to fund our required maintenance payments and development expenses, such as through, the sale of our debt or equity securities, or otherwise. There can be no assurance that we will be able to raise the capital necessary to meet our obligations under our licenses. If we are unable to meet our obligations under these licenses, we may lose the licenses to these product candidates and our business, financial condition and results of operations will be materially adversely affected.

If our manufacturers 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 MU1140 homologs, AG013, or any other product candidates under GMPs, as required by the FDA and other regulatory agencies. In order to continue to develop and commercialize our product candidates, 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 MU1140 homologs and our AG013 product candidate. 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 MU1140 product candidates, or our AG013 product candidate 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..

If we are required to find an additional or alternative source of supply, 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 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.

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 studies with any MU1140 homolog. To date, available clinical data for our AG013 product candidate has been limited to a Phase 1b clinical study. It is possible that when future lantibiotic studies are conducted in humans, they will show that our antibiotic 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. It is possible that further clinical testing of our AG013 product candidates could reveal that it is ineffective. 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.

We intend to rely on third parties 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 will 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.

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, including patents exclusively licensed from the University of Florida Research Foundation, Inc. ("UFRF") and Texas A&M University. We are the exclusive worldwide licensee to the patents for MU1140, which are owned by the UFRF. 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 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 MU1140 homologs, from our Lantibiotics Program and Oral Mucositis Program 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:

- 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 studies;
- 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 costly 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 AG013 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 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.

In the case of our product candidate, AG013, because it is a biological product, in order to ensure product consistency, quality, and purity, we must ensure the manufacturing process remains substantially the same over time. The systems used to produce biological products can be sensitive to very minor changes in the manufacturing process. Small process differences can significantly affect the nature of the finished biological product, and more importantly, the way it functions in the body. We will have to tightly control the source and nature of starting materials, and consistently employ numerous process controls that assure predictable manufacturing outcomes. Our ability to ensure that the manufacturing process remains stable over time may be difficult to establish. In addition, for a novel biological product, there may be uncertainties regarding the size and design of our clinical trials to establish safety, efficacy, purity or potency, and there are no assurances that data generated in any clinical trials we might conduct will be acceptable to the FDA or foreign regulatory bodies to support marketing approval.

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 AG013 or 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. In addition, some of our competitors are currently conducting clinical trials for product candidates that treat the same indications as AG013, and patients who are otherwise eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

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.

Use of Patient Reported Outcome ("PROs") in our AG013 clinical trials may delay the development of AG013 or increase our development costs.

Due to the difficulty of objectively measuring the efficacy of AG013, PROs may have an important role in the development and regulatory approval of our AG013 product candidate. PROs involve patients' subjective assessments of efficacy, and this subjectivity increases the uncertainty in determining clinical endpoints. Such assessments can be influenced by factors outside of our control, and can vary widely from day-to-day for a particular patient, and from patient-to-patient and site-to-site within a clinical trial. Furthermore, we intend to use PROs in our planned Phase 2 clinical program for AG013 and if the FDA does not accept or requires changes to the PRO, this could delay clinical development of AG013, increase our costs and necessitate additional clinical trials.

We have limited experience in the conduct of clinical trials and have never obtained approval of any product candidates, and may be unable to do so successfully.

As a company, we have limited experience in conducting clinical trials or progressing a product candidate through to regulatory approval. In part because of this lack of experience, 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.

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 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 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;
- in the case of oral mucositis, patients' perceptions of the condition as one for which medical treatment may be appropriate and a prescription therapy may be available;
- 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 other alternative is available.

Further, 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.

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.

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 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 a competing product 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.

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.

We may be adversely affected by natural disasters 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, could severely disrupt our operations and have a material adverse effect on our business, financial condition, operating results and prospects. 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.

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. 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 United States Patent and Trademark Office (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 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 could harm our reputation or commercial interests. In addition, 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 with Intrexon, we could lose our license rights that are important to our business and development of our product candidates.

We are a party to two ECC agreements with Intrexon that impose various royalty and other obligations on us. If we fail to comply with these obligations, Intrexon 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 ECC agreements 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 claims 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 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.

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 MU1140 and 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 dentists, physicians, patients or the medical and dental 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.

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.

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.

The recently passed U.S. federal income tax reform could adversely affect us.

On December 22, 2017, U.S. federal tax legislation, commonly referred to as the Tax Cuts and Jobs Act (TCJA), was signed into law, significantly reforming the U.S. Internal Revenue Code. The TCJA, among other things, includes changes to U.S. federal tax rates, limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks. We have evaluated the effect of the TCJA on our net operating losses for the quarter and the year ending December 31, 2017. The estimated impact of the TCJA is based on our management's current knowledge and assumptions and recognized impacts could be materially different from current estimates based on our actual results and our further analysis of the new law. The impact of the TCJA on holders of common shares is uncertain and could be adverse. Our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on February 16, 2018, does not discuss any such tax legislation or the manner in which it might affect holders of our common stock. Investors should consult with their own tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

Risks Related to Our Common Stock

We had previously received a non-compliance letter from the NYSE American and we cannot assure you that our shares will continue to be listed on the NYSE American.

The listing of our common stock on the NYSE American is contingent on our compliance with the NYSE American's continued listing standards. On May 10, 2016, we were notified by the NYSE American (formerly known as NYSE MKT) that we were no longer in compliance with the NYSE American continued listing standards

because our last reported stockholders' equity was below continued listing standards. Specifically, we are not in compliance with Section 1003(a)(iii) (requiring stockholders' equity of $6.0 million or more if it has reported losses from continuing operations and/or net losses in its five most recent fiscal years). As of December 31, 2015, we had stockholders' equity of $4.7 million. We were required to submit a plan to the NYSE American by June 10, 2016 advising of actions we have taken or will take to regain compliance with the continued listing standards by November 10, 2017.

We submitted a plan by the June 10, 2016 deadline and were notified that NYSE Regulation has accepted the Company's plan to regain compliance with the NYSE American exchange's continued listing standards set forth in Sections 1003(a)(ii) and 1003(a)(iii) of the NYSE American Company Guide (the "Company Guide") by November 10, 2017, subject to periodic review by the NYSE American for compliance with the initiatives set forth in the plan. On November 9, 2017, the Company filed a Form 8-K report with the Securities and Exchange Commission announcing that its Stockholders' Equity was $6,929,555 on a pro-forma basis. With this information provided, the NYSE American determined the Company had resolved the continued listing deficiency with respect to Section 1003(a)(i), Section 1003(a)(ii) and Section 1003(a)(iii) of the Guide. In a letter dated November 10, 2017, the NYSE American notified the Company that it had successfully regained compliance with the NYSE American continued listing standards.

Going forward, the Company will be subject to the NYSE American's normal continued listing monitoring. In addition, in the event that the Company is again determined to be noncompliant with any of the NYSE American's continued listing standards within twelve (12) months of the notice, the NYSE American will consider the relationship between the Company's previous noncompliance and such new event of noncompliance and take appropriate action which may include implementing truncated compliance procedures or immediately initiating delisting proceedings.

A delisting of our common stock from the NYSE American could negatively affect the price and liquidity of our common stock and could impair our ability to raise capital in the future.

Our principal shareholders have the ability to affect all actions requiring shareholder approval and your interests as a shareholder may conflict with the interests of those persons.

As of April 12, 2018, the KFLP, together with members of the Koski family, beneficially owns approximately 25.3% of our outstanding shares of common stock (which could increase to 34.0% upon the KFLP's conversion of Series B convertible preferred stock and exercise of outstanding warrants to acquire common stock) and Intrexon, together with its CEO, beneficially owns approximately 25.4% of our outstanding shares of common stock. Additionally, Robert C. Koski, serves on our Board of Directors. As a result, our principal shareholders have the ability to affect the outcome of all matters requiring shareholder approval, including the election and removal of directors, amending our charter or by-laws, and agreeing to or preventing mergers, consolidations or the sale of all or substantially all our assets. In particular, this concentration of ownership of our common stock could have the effect of delaying or preventing a change of control of us or otherwise discouraging or preventing a potential acquirer from attempting to obtain control of us. This, in turn, could have a negative effect on the market price of our common stock. It could also prevent our shareholders from realizing a premium over the market price for their shares of common stock. Moreover, the interests of this concentration of ownership may not always coincide with our interests or the interests of other shareholders, and, accordingly, our majority shareholders could cause us to enter into transactions or agreements that we would not otherwise consider. The significant concentration of stock ownership may also adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise. However with respect to Intrexon, the Stock Issuance Agreement we entered into with Intrexon on June 9, 2015, contains a standstill provision pursuant to which, among other things, Intrexon has agreed that until June 9, 2018, subject to certain exceptions and unless invited in writing by the Company to do so, neither Intrexon nor its affiliates will, directly or indirectly: (i) effect or seek, initiate, offer or propose to effect, or cause or participate in any acquisition of securities or assets of the Company; any tender or exchange offer, merger, consolidation or other business combination involving the Company; any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to the Company; or any "solicitation" of "proxies" or consents to vote any voting securities of the Company, or in any way advise or, assist any other person in doing so; (ii) form, join or in any way participate in a "group" with respect to any securities of the Company; (iii) otherwise act to seek to control or influence the management, Board of Directors or policies of the Company;

(iv) take any action reasonably expected to force the Company to make a public announcement regarding any such matters; or (v) enter into any agreements, discussions or arrangements with any third party with respect to any of the foregoing. This standstill provision could also have the effect of delaying, deferring or preventing a change in control that our shareholders might consider to be in their best interests.

Our Series C preferred stock has a preference 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 have a distribution and liquidation preference senior to our common stock in liquidation either of which could negatively affect the value of our common stock and impair our ability to raise additional capital.

On November 8, 2017 we issued to Intrexon Corporation ("Intrexon") approximately $3.4 million of equity in the form of 100 shares of Series C, Non-Voting, Non-Convertible Preferred Stock (the "Series C Preferred Stock"). The shares of Series C are entitled to (payment-in-kind ("PIK") dividends thereon 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 is subject to increase to twenty percent (20%) automatically after May 10, 2019. Upon Liquidation of the Company, whether voluntary or involuntary, each holder of shares of Series C Preferred Stock is entitled to receive, in preference to the holders of Common Stock, Series A Preferred Stock, Series B Preferred Stock and to all other equity securities issued by the Company from time to time (the "Junior Securities"), an amount of cash equal to the product of the number of shares of Series C Non-Convertible Preferred Stock then held by such holder, multiplied by the Stated Value per share of Series C Non-Convertible Preferred Stock plus any accrued but unpaid dividends (the "Series C Liquidation Amount") and no distributions or payments shall be made in respect of any Junior Securities unless all Series C Liquidation Amounts, if any, are first paid in full. The "Stated Value" shall mean $33,847.9874 per share. On January 25, 2018 we paid a dividend on our Series C Preferred Stock to Intrexon of 1.733 shares for the portion of the 2017 the Series C Preferred was outstanding.

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 an example on March 9, 2018, an investor converted 2,583,000 shares of Series A Preferred stock into 258,300 shares of common stock. Following such conversion and as of April 12, 2018 on a post reverse split basis, 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 April 12, 2018, there were currently outstanding warrants to purchase 3,077,425 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.

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 have recently issued a significant number of shares of our common stock in connection with financings and establishing strategic relationships and as a result our outstanding shares of common stock have increased from 2,738,283 shares as of December 31, 2012 to 4,928,335 shares as of December 31, 2017.

In connection with the Oral Mucositis ECC we entered into on June 9, 2015 and which was amended in November of 2017, we will be required, at our option, to pay up to $37.5 million cash to Intrexon or issue up to $37.5 million of additional shares of our common stock to Intrexon upon meeting certain milestone events.

You may also incur additional dilution if performance awards are made pursuant to any long term incentive programs for executives and non-employee directors we may put into place or holders of stock options, whether currently outstanding or subsequently granted, exercise their options, or if warrant holders exercise their warrants to purchase shares of our common stock.

For example, during the year ended December 31, 2013 we issued an aggregate of 72,709 shares of our common stock to our executive officers and non-employee directors pursuant to performance awards under a long term incentive program which expired on December 31, 2014. During the quarters ended March 31, 2015, March 31, 2016 and March 2017, as part of our non-employee director compensation program we issued an aggregate of 20,000, 20,000, and 16,000 restricted shares of our common stock, respectively, to our non-employee directors under the Company's 2012 Equity Incentive Plan.

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.

We cannot assure you that our listing on the NYSE American will increase the liquidity of our common stock or that our shares 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. Historically the daily trading volume of our shares is relatively low which has made our common stock significantly less liquid and there can be no assurance that liquidity will increase as a result of being listed on the NYSE American. 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.

Our stock price has historically been volatile and the trading volume of our stock has been low.

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:

- our level of, and expected future use of, working capital;
- 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 healthcare, dentistry, or biopharmaceutical industries;
- 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;
- 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; and
- the additional sale of common stock by us in capital raising transactions.

Historically, the daily trading volume of our common stock has been relatively low and on some days our stock does not trade at all. An order for the purchase or sale of a large number of our shares could significantly affect the price

at which the order is executed. We cannot guarantee that an active public market for our common stock will be sustained or that the average trading volume will increase. In addition, the stock market in general has experienced significant price and volume fluctuations. Volatility in the market price for particular companies has often been unrelated or disproportionate to the operating performance of those companies. Broad market factors may seriously harm the market price of our common stock, regardless of our operating performance. In addition, securities class action litigation has often been initiated following periods of volatility in the market price of a company's securities. A securities class action suit against us could result in substantial costs, potential liabilities, and the diversion of management's attention and resources. To the extent our stock price fluctuates or remains low, it could impair our ability to raise capital through the offering of additional equity securities.

Future sales of our common stock may depress our stock price.

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 have recently issued a significant number of shares of common stock and the number of outstanding shares has increased from 2,738,283 shares as of December 31, 2012 to 4,928,335 as of December 31, 2017. As of April 12, 2018, there were 6,086,635 shares of our common stock outstanding. In addition there were 16,017,000 shares of our Series A and Series B Convertible Preferred stock outstanding which are convertible into 2,261,703 shares of our common stock and warrants to purchase an additional 3,338,058 shares of our common stock issuable upon exercise of warrants to investors. There were also 260,633 shares issuable upon exercise of options outstanding and an additional 264,617 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 are 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. The resale of shares acquired from us in private transactions could cause our stock price to decline significantly. In addition, the conversion of outstanding shares of Series A and Series B convertible preferred stock issued in 2017 private placements into common stock and the subsequent sale of shares of common stock could also cause our stock price to decline significantly.

We have granted registration rights in connection with certain of our private placements including the 1,354,567 shares of common stock and the up to 900,000 shares of common stock issuable upon the exercise of warrants being registered for resale under this registration statement. On April 10, 2018 we issued 900,000 shares of registered common stock pursuant to a shelf takedown under a Form S-3 registration statement. We also have registered for resale on Form S-1 943,784 of shares of our common stock which we issued in a 2012 private placement. To the extent that shareholders sell shares under these registration statements and shareholders continue to exercise outstanding registration rights it could result in sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur, which could cause the price of our common stock to decline significantly.

In addition, from time to time, certain of our shareholders may be eligible to sell all or some of their restricted shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, subject to certain limitations. 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 costly. 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.

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 costly. 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 $75 million and have annual revenues of less than $50 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.

We cannot assure you that we will realize the anticipated benefits from our recent reverse stock split.

On January 19, 2018, we effected a one-for-ten reverse split of our issued and outstanding shares of our common stock which we anticipated would result in benefits such as improving the perception of our common stock and increasing the appeal of our stock to a broader range of investors. Although we believe that a higher market price of our common stock may help generate greater or broader investor interest, we cannot assure you that the reverse stock split will result in a share price that will attract new investors, including institutional investors, as some investors analysts and other stock market participants have negative perceptions of reverse stock splits. In addition, there can be no assurance that the market price of our common stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our common stock may not necessarily improve. Also it is not uncommon for the market price of a company's common stock to decline in the period following a reverse stock split. If the market price of our common stock declines, the percentage decline may be greater than would have occurred in the absence of a reverse stock split.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

When used in this prospectus, the words "expects," "believes," "hopes," "anticipates," "estimates," "may," "could," "intends," "exploring," "evaluating," "progressing," "proceeding," "will," "expects," and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements in this prospectus under the headings "Our Company," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." These forward-looking statements do not constitute guarantees of future performance. Investors are cautioned that statements which are not strictly historical statements, include, without limitation, statements regarding:

- our financial performance and condition;
- our need to raise significant additional capital and our ability to do so and to continue as a going concern;
- an inability to obtain the capital necessary to fund our operations and research and development activities;
- if we raise additional capital it may be on terms that result in substantial dilution to our existing shareholders;
- success, timing and expenses of our collaboration efforts with Intrexon and expected clinical trials;
- a failure to expand our research activities with Intrexon relating to lantibiotics for infectious diseases or for oral mucositis;
- our inability to achieve success in our identification of homologs or the nonclinical testing of our lantibiotic product candidates;
- our ability to maintain our listing on the NYSE American;
- our expectations and estimates regarding future expenses and expenditures, including our expected use of the net proceeds from this offering, revenue and capital requirements;
- our ability to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act;
- present and future clinical trials and results of such trials, including with respect to AG013;
- 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 and other regulatory agencies;
- 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;
- a lack of acceptance of our product candidates in the marketplace;
- we may be unable to achieve commercial viability and acceptance of our proposed product candidates;
- we may be unable to improve upon, protect and/or enforce our intellectual property;
- we may be unable to enter into strategic collaborations or partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates or maintain strategic collaborations or partnerships;
- a failure by us to become or remain profitable;
- a loss of any of our key scientists or management personnel;
- 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.

- the size and potential growth of, or our ability to capture market share in, the markets for any of our product candidates;
- market and industry trends;
- our competition;
- intellectual property; and
- our liquidity.

These forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated. These risks and uncertainties include, but are not limited to, those risks discussed in "Risk Factors" and elsewhere in this prospectus. These forward-looking statements speak only as of the date made. We assume no obligation or undertaking to update any forward-looking statements to reflect any changes in expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make in our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K filed with the SEC.

SELECTED FINANCIAL DATA

You should read the following selected financial data together with our financial statements and the related notes contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which are incorporated by reference into this prospectus, except that share and per share information for the periods ended December 31, 2017, and 2016 have been revised to reflect the 1-for-10 reverse stock split of our issued and outstanding shares of common stock effective at the close of business on January 19, 2018. The selected data in this section is not intended to replace the financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2017, except that share and per share information for the periods ended December 31, 2017 and 2016 have been revised to reflect the 1-for-10 reverse stock split.

We have derived the statements of operations data for each of the two years ended December 31, 2017 and 2016 from the audited financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2017.

The historical financial information set forth below may not be indicative of our future performance and should be read together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our historical financial statements and notes to those statements included in Item 7 of Part II and Item 6 of Part II, respectively, of our Annual Report on Form 10-K for the year ended December 31, 2017, and any amendment or update thereto reflected in subsequent filings with the SEC, and all other annual, quarterly and other reports that we file with the SEC after the date of the initial registration statement of which this prospectus forms a part and that also are incorporated herein by reference.

	Year Ended December 31,	
	2017	2016
Revenue	$ —	$ —
Net loss from continuing operations	$(6,731,525)	$(8,497,316)
Income from discontinued operations	$ —	$ 1,484,012
Net loss	$(6,731,525)	$(7,013,304)
Basic and diluted net income (loss) per share:		
Net loss from continuing operations	$ (1.37)	$ (1.90)
Net income from discontinued operations	—	0.33
Net loss per share	$ (1.37)	$ (1.57)
Weighted average number of common shares outstanding, basic and diluted	4,926,275	4,460,933

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of securities by the selling securityholders pursuant to this prospectus. We may receive up to approximately $1,800,000 in aggregate gross proceeds from cash exercises of the warrants, based on the per share exercise price of the warrants. Any proceeds we receive from the exercise of the warrants will be used for working capital and general corporate purposes.

MARKET PRICE OF OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Our common stock is quoted on the NYSE American under the ticker symbol “OGEN”. The following table sets forth the high and low bid quotations of our common stock reflected on the NYSE American. These quotations represent inter-dealer prices, without retail mark-up, markdown, or commission, and may not represent actual transactions. The last price of our common stock as reported on the NYSE American on February 9, 2018 was $2.21 per share. As of February 9, 2018, there were approximately 48 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.

	2018		2017		2016	
Period	High	Low	High	Low	High	Low
First quarter	$3.17	$1.60	$8.50	$4.20	$15.40	$7.50
Second quarter	$1.90	$1.55	$5.80	$3.10	$10.40	$5.00
Third quarter	—	—	$6.80	$2.80	$10.60	$4.30
Fourth quarter	—	—	$4.70	$2.10	$11.00	$3.30

DIVIDEND POLICY

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 Intrexon in exchange for obligations we owed to Intrexon. These shares have an accruing dividend of 12% per year payable in additional shares of Series C Preferred stock. On January 25, 2018 we paid a dividend on our Series C Preferred Stock to Intrexon of 1.733 shares for the portion of the 2017 fiscal year the Series C Preferred was outstanding. The accruing dividend increases to 20% per year after May 10, 2019.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information about beneficial ownership of our Common Stock as of April 12, 2018 (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. With respect to the Series A and Series B Preferred Stock Financings (except as to the KFLP) the foregoing table specifically excludes all of the common stock issuable on conversion of the preferred shares and the exercise of the warrants as a result of there being a 4.99% equity blocker which prevents the holders of the preferred shares and the warrants from converting the preferred shares into common stock or exercising the warrants for common stock if such conversion or exercise would result in such holder's ownership at any given time exceeding 4.99% of the Company's outstanding common stock (which blocker may be waived by the holder upon 60 days' prior notice to the Company).

Name and address(1)	Number of shares beneficially owned	Percentage of ownership (2)
5% shareholders		
Koski Family Limited Partnership(3)	2,265,648	34.0%
Randall J. Kirk (4)	1,548,165	25.4%
Sabby Volatility Warrant Master Fund, Ltd. (5)	450,000	7.4%
Directors and officers		
Alan Joslyn (6)	27,667*	
Robert C. Koski(3)(7)	2,013,627	30.2%
Charles L. Pope(8)	54,608*	
Dr. Alan Dunton(8)	47,761*	
Dr. Frederick W. Telling(8)	166,038	2.7%
Michael Sullivan(9)	51,089*	
(All Directors and officers as a group 6 persons) (10)	2,360,790	34.6%

* 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) Percentage ownership of our common stock is based on 6,086,635 shares of common stock outstanding as of April 12, 2018. The following table is based upon information supplied by officers, directors and principal stockholders and a review of Schedules 13D and 13G, if any, and other documents filed with the SEC. We have determined beneficial ownership in accordance with the rules of the SEC. Unless otherwise indicated below, to our knowledge, the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable. In addition, we have deemed shares to be beneficially owned by a person if the person has the right to acquire shares (for example, upon exercise of an option or warrant) within 60 days of April 12, 2018 to be outstanding and to be beneficially owned by such person for the purpose of computing the percentage ownership of that person but have not treated them as outstanding for the purpose of computing the percentage ownership of any other person. As a result, the percentage of outstanding shares of any person as shown in the following table does not necessarily reflect the person's actual voting power at any particular date. The inclusion in the table above of any shares deemed beneficially owned does not constitute an admission of beneficial ownership of those shares.

(3) Based upon information provided by the Koski Family Limited Partnership, or KFLP, in the amendment to its Schedule 13D filing with the SEC on February 14, 2018 and Form 4 filing of November 13, 2017, includes (i) 1,286,483 shares held directly by the KFLP, and (ii) 157,254 shares held directly by KFLP partner Christine Koski, (iii) 104,789 shares held directly by KFLP partner Robert Koski, (iv) 2,800 shares held directly by KFLP partner Koski Management, Inc. (solely owned by Beverly Koski), (v) 91,967 shares held directly by KFLP partner, Thomas Koski, and (vi) 53,086 shares held in trusts which Robert Koski serves as sole trustee (See Note 6 below), (vii) 27,333 option shares able to be acquired upon the exercise of currently exercisable stock options granted pursuant to our Director Compensation program to Robert Koski through June 22, 2018, (viii) 300,000 shares able to be acquired by the KFLP upon conversion of Series B Convertible Preferred Stock, and (ix) 241,936 shares able to be acquired by the KFLP upon exercise of warrants. Christine L. Koski, Robert C. Koski, Thomas L. Koski and Beverly Koski (as sole owner of Koski Management, Inc.) share voting and investment powers as general partners of the KFLP. The address for the KFLP is 3525 Turtle Creek Boulevard, Unit 19-B, Dallas, Texas 75219.

(4) Based upon information provided by Schedule 13D filings with the SEC, dated June 12, 2012, August 3, 2012, October 2, 2013, November 2, 2013, December 26, 2013 and November 13, 2017 and Form 4 dated July 5, 2016 the number of shares includes (i) 1,448,109 shares owned directly by Intrexon Corporation ("Intrexon") that is controlled by Mr. Randal J. Kirk, and (ii) 100,056 shares owned directly by NRM VII Holdings, I, LLC, a Virginia Limited Liability Company that is also controlled by Mr. Kirk. Mr. Kirk is the Chairman and Chief Executive Officer of Intrexon and over which Mr. Kirk, directly and through certain affiliates, has voting and dispositive power of a majority of the outstanding capital stock. Mr. Kirk may therefore be deemed to have voting and dispositive power over the 100,056 shares of common stock owned by NRM Holdings and the 1,448,109 shares of common stock owned by Intrexon. Mr. Kirk disclaims beneficial ownership of such shares, except to the extent of any pecuniary interest therein. Mr. Kirk's principal business office is The Governor Tyler, 1881 Grove Avenue, Radford, Virginia 24141. Intrexon's address as reflected in Schedule 13D is 20358 Seneca Meadows Parkway, Germantown, Maryland 20876.

(5) The information is based upon that certain Securities Purchase Agreement entered into by and between the Company and two accredited investors on April 10, 2018 (the "Purchase Agreement), including Sabby Volatility Warrant Master Fund, Ltd. and the Schedule 13G filed with the Securities and Exchange Commission on April 10, 2018. Pursuant to the Purchase Agreement, Sabby Volatility Warrant Master Fund, Ltd. acquired 450,000 shares of our common stock in a registered direct offering which the table reflects as of such date. In addition to the acquisition of common stock, Sabby Volatility Warrant Master Fund, Ltd. also acquired in a separate private placement a warrant to purchase 450,000 shares of our common stock which is not exercisable for six months from the date of issuance and therefore excluded from the table. The warrant is also subject to a 4.99% ownership blocker, pursuant to which shares of our common stock may not be issued to the extent such issuance would cause Sabby Volatility Warrant Master Fund, Ltd. to beneficially own more than 4.99% of our outstanding common stock. Sabby Management, LLC serves as the investment manager of Sabby Volatility Warrant Master Fund, Ltd. Hal Mintz is the manager of Sabby Management, LLC and has voting and investment control of the securities held by Sabby Volatility Warrant Master Fund, Ltd. Each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over the securities beneficially owned by Sabby Volatility Warrant Master Fund, Ltd., except to the extent of their respective pecuniary interest therein.

(6) Includes 24,667 shares able to be acquired pursuant to currently exercisable stock options and excludes 19,334 shares subject to options that vest thereafter.

(7) In addition to the shares reflected as directly owned by the KFLP, described in Note 3, the share amounts also includes: (i) 104,789 shares owned directly by Mr. Koski, and (ii) 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).

(8) Includes: 30,500 option shares able to be acquired upon the exercise of currently exercisable stock options granted pursuant to our Director Compensation program.

(9) Includes 36,834 shares able to be acquired pursuant to currently exercisable stock options through June 22, 2018 and excludes 11,667 shares subject to options that vest thereafter.

(10) Excludes 157,254 shares owned directly by Christine Koski, 2,800 shares owned directly by Koski Management, Inc. (solely owned by Beverly Koski), and 91,967 shares owned directly by Thomas Koski, which are not directors or employees of the Company, but are general partners of the KFLP. If such shares were included the beneficial ownership percentage of the group would be 38.3%.

HudsonBay Master Fund Ltd. is excluded from this table as it owned less than 5% of the Common Stock as of April 26, 2018.

SELLING SECURITYHOLDERS

This prospectus covers the resale by the selling securityholders of up to an aggregate of 2,254,567 common shares, comprised of (i) 450,000 shares of common stock issued to Intrexon Corporation pursuant to the Stock Issuance Agreement, (ii) 904,567 shares of common stock issued pursuant to the June 30, 2016 Stock Purchase Agreement with the Koski Family Limited Partnership, Intrexon Corporation, and Dr. Frederick Telling and (iii) up to 900,000 shares of common stock issuable upon the exercise of the Warrants. The Warrants will become exercisable on October 10, 2018 at an exercise price of $2.00 per share and will expire on April 10, 2023. Except for selling securityholders Intrexon Corporation, Koski Family Limited Partnership, and Dr. Frederick W. Telling, the ownership of the Warrants and the transactions contemplated pursuant to the Purchase Agreement, the selling securityholders have not had any material relationship with us within the past three years.

The following table sets forth certain information with respect to each selling securityholder, including (i) the shares of our common stock beneficially owned by the selling securityholder prior to this offering, (ii) the number of shares being offered by the selling securityholder pursuant to this prospectus and (iii) the selling securityholder's beneficial ownership after completion of this offering. The registration of the shares of common stock and the shares of common stock issuable to the selling securityholders upon the exercise of the warrants does not necessarily mean that the selling securityholders will sell all or any of such shares. No estimate can be given as to the amount or percentage of shares of common stock that will be held by the selling securityholders after any sales made pursuant to this prospectus because the selling securityholders are not required to sell any of the shares being registered under this prospectus. The table below assumes that the selling securityholders will sell all of the shares of common stock registered in this prospectus.

The table is based on information supplied to us by the selling securityholder with beneficial ownership and percentage ownership determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to shares of stock. This information does not necessarily indicate beneficial ownership for any other purpose. In computing the number of shares beneficially owned by a selling securityholder and the percentage ownership of that selling securityholder, shares of common stock subject to warrants held by that selling securityholder that are exercisable within 60 days after April 27, 2018, are deemed outstanding. Such shares, however, are not deemed outstanding for the purposes of computing the percentage ownership of any other person. The percentage of beneficial ownership after this offering is based on 6,086,635 shares outstanding on April 12, 2018.

The selling securityholders may sell all, some or none of their shares in this offering. See "Plan of Distribution."

Selling Securityholder (1)	Number of Shares of Common Stock Beneficially Owned Prior to Offering	Number of Shares of Common Stock Offered Hereby (2)	Number of Shares of Common Stock Beneficially Owned After Offering	Number of Shares of Common Stock Underlying Options or Warrants Beneficially Owned After Offering	% of Shares of Common Stock Beneficially Owned After Offering
Intrexon Corporation (3)	1,548,165	676,141	872,024	0	13.4%
Koski Family Limited Partnership (4)	2,265,648	581,508	1,684,140	269,269	27.7%
Dr. Frederick Telling (5)	166,038	96,918	69,120	30,500	1.1%
Hudson Bay Master Fund LTD	76,779 (6)	450,000 (7)	76,779	0	1.3%
Sabby Volatility Warrant Master Fund, Ltd.	450,000	450,000 (7)	450,000	0	7.4%

(1) This table and the information in the notes below are based upon information supplied by the selling securityholders, including reports and amendments thereto filed with the SEC on Schedule 13G.

(2) The actual number of shares of common stock offered hereby and included in the registration statement of which this prospectus forms a part includes, in accordance with Rule 416 under the Securities Act, such indeterminate number of additional shares of our common stock as may become issuable in connection with any proportionate adjustment for any stock splits, stock combinations, stock dividends, recapitalizations or similar events with respect to the common stock.

(3) Based upon information provided by Schedule 13D filings with the SEC, dated June 12, 2012, August 3, 2012, October 2, 2013, November 2, 2013, December 26, 2013 and November 13, 2017 and Form 4 dated July 5, 2016 the number of shares includes (i) 1,448,109 shares owned directly by Intrexon Corporation ("Intrexon") that is controlled by Mr. Randal J. Kirk, and (ii) 100,056 shares owned directly by NRM VII Holdings, I, LLC, a Virginia Limited Liability Company that is also controlled by Mr. Kirk. Mr. Kirk is the Chairman and Chief Executive Officer of Intrexon and over which Mr. Kirk, directly and through certain affiliates, has voting and dispositive power of a majority of the outstanding capital stock. Mr. Kirk may therefore be deemed to have voting and dispositive power over the 100,056 shares of common stock owned by NRM Holdings and the 1,448,109 shares of common stock owned by Intrexon. Mr. Kirk disclaims beneficial ownership of such shares, except to the extent of any pecuniary interest therein. Mr. Kirk's principal business office is The Governor Tyler, 1881 Grove Avenue, Radford, Virginia 24141. Intrexon's address as reflected in Schedule 13D is 20358 Seneca Meadows Parkway, Germantown, Maryland 20876.

(4) Based upon information provided by the Koski Family Limited Partnership, or KFLP, in the amendment to its Schedule 13D filing with the SEC on February 14, 2018 and Form 4 filing of November 13, 2017, includes (i) 1,286,483 shares held directly by the KFLP, and (ii) 157,254 shares held directly by KFLP partner Christine Koski, (iii) 104,789 shares held directly by KFLP partner Robert Koski, (iv) 2,800 shares held directly by KFLP partner Koski Management, Inc. (solely owned by Beverly Koski), (v) 91,967 shares held directly by KFLP partner, Thomas Koski, and (vi) 53,086 shares held in trusts which Robert Koski serves as sole trustee (See Note 6 below), (vii) 27,333 option shares able to be acquired upon the exercise of currently exercisable stock options granted pursuant to our Director Compensation program to Robert Koski through June 22, 2018, (viii) 300,000 shares able to be acquired by the KFLP upon conversion of Series B Convertible Preferred Stock, and (ix) 241,936 shares able to be acquired by the KFLP upon exercise of warrants. Christine L. Koski, Robert C. Koski, Thomas L. Koski and Beverly Koski (as sole owner of Koski Management, Inc.) share voting and investment powers as general partners of the KFLP. The address for the KFLP is 3525 Turtle Creek Boulevard, Unit 19-B, Dallas, Texas 75219.

(5) Includes: 30,500 option shares able to be acquired upon the exercise of currently exercisable stock options granted pursuant to our Director Compensation program.

(6) The information is based upon the Securities Purchase Agreement dated April 6, 2018, which included Hudson Bay Master Fund Ltd. as one of the investors participating in the registered direct offering of our common stock and simultaneous private placement of warrants to acquire common stock, as well as information provided directly by Hudson Bay Master Fund Ltd. Pursuant to the Purchase Agreement, Hudson Bay Master Fund Ltd. acquired 450,000 shares of our common stock on April 10, 2018 in a registered direct offering and has indicated to us that as of April 26, 2018 it owned 76,779 shares. In addition to the acquisition of common stock, Hudson Bay Master Fund Ltd. also acquired in a separate private placement a warrant to purchase 450,000 shares of our common stock which is not exercisable for six months from the date of issuance and therefore excluded from the table. The warrant is also subject to a 4.99% ownership blocker, pursuant to which shares of our common stock may not be issued to the extent such issuance would cause Hudson Bay Master Fund Ltd. to beneficially own more than 4.99% of our outstanding common stock. Hudson Bay Capital Management LP, the investment manager of Hudson Bay Master Fund Ltd., has voting and investment power over these securities. Sander Gerber is the managing member of Hudson Bay Capital GP LLC, which is the general partner of Hudson Bay Capital Management LP. Each of Hudson Bay Master Fund Ltd. and Sander Gerber disclaims beneficial ownership over these securities.

(7) Consists of shares of common stock underlying warrants that are exercisable beginning October 10, 2018 and will expire on April 10, 2023

PLAN OF DISTRIBUTION

Each selling securityholder of the shares of the securities and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the NYSE American or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling securityholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the selling securityholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling securityholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act of 1933, as amended (the "Securities Act"), if available, rather than under this prospectus.
Broker-dealers engaged by the selling securityholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling securityholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the selling securityholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The selling securityholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The selling securityholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling securityholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling securityholder has informed the Company that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the selling securityholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the selling securityholders without registration and without regard to any volume or manner-of-sale limitations by

reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect.

The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling securityholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the selling securityholders or any other person. We will make copies of this prospectus available to the selling securityholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

DESCRIPTION OF SECURITIES

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 the registration statement of which this prospectus is a part, and by the provisions of applicable law.

Overview

Authorized Capital Stock

As of April 12, 2018, our authorized capital stock consisted of 45,000,000 shares of common stock, par value $0.001, and 50,000,000 shares of preferred stock, without par value and there were 6,086,635 shares of our common stock issued and outstanding and 9,417,000 shares of Series A Preferred, 6,600,000 shares of Series B Preferred and 101.733 shares of Series C Preferred stock issued and outstanding. On April 19, 2018 our board of directors approved an Amendment to our Amended and Restated Articles of Incorporation to increase the authorized shares of common stock from 45,000,000 to 200,000,000 subject to the approval of our shareholders at our annual meeting to be held on June 22, 2018 for shareholders of record on May 8, 2018.

Authorized but Unissued Capital Stock

Florida law does not require shareholder approval for any issuance of authorized shares other than in connection with certain mergers to which we may be a party. These additional shares may be used for a variety of corporate purposes, including future public offerings to raise additional capital or to facilitate corporate acquisitions.

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.

Distributions

Our Board of Directors, subject to any restrictions contained in (i) the Florida Business Corporation Act, or FBCA; or (ii) our amended and restated articles of incorporation, as amended, or Articles of Incorporation, may make distributions upon our securities. Distributions may be paid in cash, in property, or in our securities.

We have not declared or paid any distributions on our common stock. We presently intend to retain our future earnings, if any, to fund the development and growth of our business and, therefore, do not have plans to pay any dividends in the foreseeable future.

Other Rights

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 will be entitled to receive a pro rata distribution of all of our assets and funds legally available for distribution.

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.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

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, Series B Convertible Preferred Stock and Series C Non-Convertible Preferred Stock and 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 April 12, 2018 we have 9,417,000 shares of Series A Preferred, 6,600,000 shares of Series B Preferred and 101.733 shares of Series C Preferred issued and outstanding.

Series A Convertible Preferred Stock

As of July 25, 2017, we issued 12,000,000 shares of convertible preferred stock, designated as the Series A Convertible Preferred Stock pursuant to the certificate of designation and rights filed by us with the Secretary of State of the State of Florida, with an aggregate original purchase price and initial liquidation preference of $3.0 million. Each share of Series A Convertible Preferred Stock was issued for an amount equal to $0.25 per share, which we refer to as the original purchase price. On March 9, 2018, an investor converted a portion of its Series A Preferred to common stock and as a result of the conversion 9,417,000 shares of Series A Preferred are issued and outstanding as of April 12, 2018.

The following description is a summary of the material provisions of the Series A Convertible Preferred Stock and the certificate of designation and rights and does not purport to be complete. This summary is subject to and is qualified by reference to all the provisions of the Series A Convertible Preferred Stock and certificate of designation and rights of Series A Convertible Preferred Stock, including the definitions of certain terms used in the certificate of designation and rights. We urge you to read this document because it, and not this description, defines the rights of a holder of the Series A Convertible Preferred Stock. A copy of the form of certificate of designation and rights that we filed with the Secretary of State of the State of Florida effective May 10, 2017 as amended and restated effective November 8, 2017 has been incorporated by reference as an exhibit to the registration statement of which this prospectus forms a part.

No Mandatory Redemption Date or Sinking Fund

The shares of Series A Convertible Preferred Stock do not have a mandatory redemption date and are not subject to any sinking fund. The shares of Series A Convertible Preferred Stock will remain outstanding indefinitely unless we elect to redeem them under the circumstances described below in “Redemption” or we otherwise repurchase them or they are converted into shares of our common stock as described below under “Conversion Rights.”

Dividends

The shares of Series A Convertible Preferred Stock are entitled to participate in all dividends declared and paid on shares of company common stock on an “as if” converted basis.

Liquidation Preference

Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary that is not a Fundamental Transaction (as defined in the certificate of designation), the holders of Series A Convertible 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.

Ranking

The Series A Convertible Preferred Stock ranks (i) on par with the Common Stock and Series B Convertible Preferred Stock and junior to Series C Non-Convertible Preferred Stock as to dividend rights and (ii) senior to Common Stock and on par with Series B Convertible Preferred Stock, junior to Series C Non-Convertible Preferred Stock and senior to Common Stock as to rights upon liquidation, dissolution or winding up of the Company, whether voluntarily or involuntarily.

See "Voting Rights—Matters Requiring Approval of Holders of Series A Convertible Preferred Stock" for a description of the types of issuances of equity securities and other securities of our company requiring approval of holders of a majority of shares of Series A Convertible Preferred Stock then outstanding, voting together as a class.

Redemption

To the extent we have funds legally available therefor, at any time after the fifth anniversary of the original issue date of the Series A Convertible Preferred Stock, we have the right to redeem all or any portion of the outstanding shares of Series A Convertible Preferred Stock at the original issue price by providing at least seventy five (75) days written notice of such redemption to all holders of the then outstanding shares of Series A Convertible Preferred Stock.

Conversion Rights

The holders of shares of Series A Convertible Preferred Stock will, at any time, be entitled to convert some or all of their Series A Convertible Preferred Stock into the number of shares of our common stock obtained by dividing the aggregate original purchase price of the shares to be converted by the aggregate original purchase price of the shares to be converted, which amount we refer to as the conversion price.

The conversion price will be adjustable upon the occurrence of certain events and transactions to prevent dilution as described under "Adjustments to Conversion Price to Prevent Dilution." Any shares of our common stock issued upon conversion of the shares of Series A Convertible Preferred Stock shall be validly issued, fully paid and non-assessable. The Company shall either pay cash in lieu of fractional shares or round up to the next whole share.

Adjustments to Conversion Price to Prevent Dilution

The Series A Convertible Preferred Stock is subject to provisions that protect the holders against dilution by adjustment of the conversion price and/or number of shares of common stock issuable upon conversion in certain events such as a subdivision, combination or reclassification of our outstanding common stock.

Voting Rights—Matters Requiring Approval of Holders of Series A Convertible Preferred Stock

Except as otherwise required by law, the Series A Convertible Preferred Stock shall have no voting rights. However, as long as any shares of Series A Convertible 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 Convertible Preferred Stock, (a) alter

or change adversely the powers, preferences or rights given to the Series A Convertible 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 Convertible Preferred Stock, (c) increase the number of authorized shares of Series A Convertible Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing.

Registration Rights

The holders of the Series A Convertible Preferred Stock were 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 exercise of their associated warrants, subject to customary cutbacks, blackout periods and other exceptions.

Series B Convertible Preferred Stock

On November 8, 2017, we issued 6,600,000 shares of convertible preferred stock, designated as the Series B Convertible Preferred Stock pursuant to the certificate of designation and rights filed by us with the Secretary of State of the State of Florida, with an aggregate original purchase price and initial liquidation preference of $3.3 million. Each share of Series B Convertible Preferred Stock was issued for an amount equal to $0.50 per share, which we refer to as the original purchase price.

The following description is a summary of the material provisions of the Series B Convertible Preferred Stock and the certificate of designation and rights and does not purport to be complete. This summary is subject to and is qualified by reference to all the provisions of the Series B Convertible Preferred Stock and certificate of designation and rights of Series B Convertible Preferred Stock, including the definitions of certain terms used in the certificate of designation and rights. We urge you to read this document because it, and not this description, defines the rights of a holder of the Series B Convertible Preferred Stock. A copy of the form of certificate of designation and rights that we filed with the Secretary of State of the State of Florida effective November 8, 2017 has been incorporated by reference as an exhibit to the registration statement of which this prospectus forms a part.

No Mandatory Redemption Date or Sinking Fund

The shares of Series B Convertible Preferred Stock do not have a mandatory redemption date and are not subject to any sinking fund. The shares of Series B Convertible Preferred Stock will remain outstanding indefinitely unless we elect to redeem them under the circumstances described below in “Redemption” or we otherwise repurchase them or they are converted into shares of our common stock as described below under “Conversion Rights.”

Dividends

The shares of Series B Convertible Preferred Stock are entitled to participate in all dividends declared and paid on shares of company common stock on an “as if” converted basis.

Liquidation Preference

Upon any liquidation, dissolution or winding-up of the Company (any such event, a “Liquidation”), whether voluntary or involuntary, each holder of shares of Series B Convertible Preferred Stock shall be entitled to receive, after payment to the Series C Non-Convertible Preferred Stock as provided in the Certificate of Designation of Series C Non-Convertible 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 Convertible 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 Convertible Preferred Stock if all outstanding shares of Series B Convertible Preferred Stock were converted into Common Stock immediately prior to the Liquidation (disregarding for this purpose any and all limitations of any kind on such conversion).

Ranking

The Series B Convertible Preferred Stock ranks (i) on par with the Common Stock and Series A Convertible Preferred Stock and junior to Series C Non-Convertible Preferred Stock as to dividend rights and (ii) junior to Series C Non-Convertible Preferred Stock, on par with Series A Convertible Preferred Stock and senior to the Common Stock as to distributions of assets upon liquidation, dissolution or winding up of the Corporation, whether voluntarily or involuntarily.

See "Voting Rights—Matters Requiring Approval of Holders of Series B Convertible Preferred Stock" for a description of the types of issuances of equity securities and other securities of our company requiring approval of holders of a majority of shares of Series B Convertible Preferred Stock then outstanding, voting together as a class.

Redemption

To the extent we have funds legally available therefor, at any time after the fifth anniversary of the original issue date of the Series B Convertible Preferred Stock, we have the right to redeem all or any portion of the outstanding shares of Series B Convertible Preferred Stock at the original issue price by providing at least seventy five (75) days written notice of such redemption to all holders of the then outstanding shares of Series B Convertible Preferred Stock.

Conversion Rights

The holders of shares of Series B Convertible Preferred Stock will, at any time, be entitled to convert some or all of their Series B Convertible Preferred Stock into the number of shares of our common stock obtained by dividing the aggregate original purchase price of the shares to be converted by the aggregate original purchase price of the shares to be converted, which amount we refer to as the conversion price and then multiplying such product by two (2).

The conversion price will be adjustable upon the occurrence of certain events and transactions to prevent dilution as described under "Adjustments to Conversion Price to Prevent Dilution." Any shares of our common stock issued upon conversion of the shares of Series B Convertible Preferred Stock shall be validly issued, fully paid and non-assessable. The Company shall either pay cash in lieu of fractional shares or round up to the next whole share.

Adjustments to Conversion Price to Prevent Dilution

The Series B Convertible Preferred Stock is subject to provisions that protect the holders against dilution by adjustment of the conversion price and/or number of shares of common stock issuable upon conversion in certain events such as a subdivision, combination or reclassification of our outstanding common stock.

Voting Rights—Matters Requiring Approval of Holders of Series B Convertible Preferred Stock

Except as otherwise required by law, the Series B Convertible Preferred Stock shall have no voting rights. However, as long as any shares of Series B Convertible 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 Convertible Preferred Stock, (a) amend, alter, repeal, restate or supplement (in each case, whether by reclassification, merger, consolidation, reorganization or otherwise) the certificate of designation in any manner that would adversely affect the holders of the Series B Convertible Preferred Stock, (b) authorize or agree to authorize any increase in the number of shares of Series B Convertible Preferred Stock or issue any additional shares of Series B Convertible Preferred Stock, (c) amend, alter or repeal any provision of the Certificate of Incorporation or Bylaws of the Company which would adversely affect any right, preference, privilege or voting power of the Series B Convertible Preferred Stock or the holders thereof or (d) agree to take any of the foregoing actions.

Registration Rights

The holders of the Series B Convertible Preferred Stock were 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 exercise of their associated warrants, subject to customary cutbacks, blackout periods and other exceptions.

Series C Non-Voting, Non-Convertible Preferred Stock

On November 8, 2017, we issued 100 shares of non-convertible preferred stock, designated as the Series C Non-Voting, Non-Convertible Preferred Stock pursuant to the certificate of designation and rights filed by us with the Secretary of State of the State of Florida, with a stated value and liquidation preference equal to $33,847.9874 per share, which we refer to as the Stated Value. The shares of Series C Non-Voting, Non-Convertible Preferred Stock are entitled to (payment-in-kind ("PIK") dividends thereon at the annual rate of twelve percent (12%) (the "Initial Rate") of its Stated Value, payable by issuing additional shares of Series C Non-Voting, Non-Convertible Preferred Stock within thirty days after the end of each calendar year, pro-rata for partial years. On January 25, 2018 we paid a dividend on our Series C Preferred Stock to Intrexon of 1.733 shares for the portion of the 2017 fiscal year the Series C Preferred was outstanding.

The following description is a summary of the material provisions of the Series C Non-Voting, Non-Convertible Preferred Stock and the certificate of designation and rights and does not purport to be complete. This summary is subject to and is qualified by reference to all the provisions of the Series C Non-Voting, Non-Convertible Preferred Stock and certificate of designation and rights of Series C Non-Voting, Non-Convertible Preferred Stock, including the definitions of certain terms used in the certificate of designation and rights. We urge you to read this document because it, and not this description, defines the rights of a holder of the Series C Non-Voting, Non-Convertible Preferred Stock. A copy of the form of certificate of designation and rights that we filed with the Secretary of State of the State of Florida effective November 8, 2017 has been incorporated by reference as an exhibit to the registration statement of which this prospectus forms a part.

No Mandatory Redemption Date or Sinking Fund

The shares of Series C Non-Voting, Non-Convertible Preferred Stock do not have a mandatory redemption date and are not subject to any sinking fund. The shares of Series C Non-Voting, Non-Convertible Preferred Stock will remain outstanding indefinitely unless we elect to redeem them under the circumstances described below in "Redemption" or we otherwise repurchase them.

Dividends

The shares of Series C Non-Voting, Non-Convertible Preferred Stock are entitled to receive dividends thereon at the annual rate of twelve percent (12%) (the "Initial Rate") of its Stated Value, payable by issuing additional shares of Series C Non-Voting, Non-Convertible Preferred Stock within thirty days after the end of each calendar year pro-rata for partial years. The Initial Rate shall be subject to increase to twenty percent (20%) automatically after

May 10, 2019. On January 25, 2018 we paid a dividend on our Series C Non-Voting, Non-Convertible Preferred Stock to Intrexon of 1.733 shares for the portion of the 2017 fiscal year the Series C Non-Voting, Non-Convertible Preferred Stock was outstanding.

Liquidation Preference

Upon any liquidation, dissolution or winding-up of the Company (any such event, a "Liquidation"), whether voluntary or involuntary, each holder of shares of Series C Non-Voting, Non-Convertible Preferred Stock shall be entitled to receive, in preference to the holders of Common Stock, Series A Convertible Preferred Stock, Series B Convertible Preferred Stock and to all other equity securities issued by the Corporation from time to time (the "Junior Securities"), an amount of cash equal to the product of (i) the sum of (a) the number of shares of Series C Non-Voting, Non-Convertible Preferred Stock then held by such holder plus (b) the number of shares of Series C Non-Voting, Non-Convertible Preferred Stock issuable to such holder in connection with any accrued but unpaid dividends, multiplied by (ii) the Stated Value per share of Series C Non-Voting, Non-Convertible Preferred Stock (the "Series C Liquidation Amount") and no distributions or payments shall be made in respect of any Junior Securities unless all Series C Liquidation Amounts, if any, are first paid in full.

Ranking

The Series C Non-Voting, Non-Convertible Preferred Stock ranks (i) senior to the Junior Securities as to dividend rights and (ii) senior to the Junior Securities as to rights upon liquidation, dissolution or winding up of the Corporation, whether voluntarily or involuntarily.

See "Voting Rights—Matters Requiring Approval of Holders of Series C Non-Convertible Preferred Stock" for a description of the types of issuances of equity securities and other securities of our company requiring approval of holders of a majority of shares of Series C Non-Voting, Non-Convertible Preferred Stock then outstanding, voting together as a class.

Redemption

To the extent we have funds legally available therefor, at any time after November 8, 2017, we have the right to redeem all or any portion of the outstanding shares of Series C Non-Voting, Non-Convertible Preferred Stock at the Stated Value by providing at least thirty (30) days written notice of such redemption to all holders of the then outstanding shares of Series C Non-Voting, Non-Convertible Preferred Stock.

No Conversion Rights

The shares of Series C Non-Voting, Non-Convertible Preferred Stock do not have any conversion rights and are not convertible into or exchangeable for any other property or securities of the Company.

Voting Rights—Matters Requiring Approval of Holders of Series C Non-Voting, Non-Convertible Preferred Stock

Except as otherwise required by law, the Series C Non-Voting, Non-Convertible Preferred Stock shall have no voting rights. However, as long as any shares of Series C Non-Voting, Non-Convertible 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 C Non-Voting, Non-Convertible Preferred Stock, (a) amend, alter, repeal, restate or supplement (in each case, whether by reclassification, merger, consolidation, reorganization or otherwise) the certificate of designation in any manner that would adversely affect the holders of the Series C Non-Voting, Non-Convertible Preferred Stock, (b) authorize or agree to authorize any increase in the number of shares of Series C Non-Voting, Non-Convertible Preferred Stock or issue any additional shares of Series C Non-Voting, Non-Convertible Preferred Stock, (c) amend, alter or repeal any provision of the Certificate of Incorporation or Bylaws of the Company which would adversely affect any right, preference, or privilege of the Series C Non-Voting, Non-Convertible Preferred Stock or the holders thereof or (d) agree to take any of the foregoing actions.

Options and Warrants

As of the date of this prospectus there were 3,077,425 shares of common stock issuable upon exercise of warrants to investors at a weighted average exercise price per share of $2.78, 260,633 shares issuable upon exercise of options outstanding at a weighted average exercise price of $9.01 per share, and an additional 264,617 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. Our board has recently approved an increase of 1,500,000 shares available for grant under our 2012 Equity Incentive Plan subject to approval of our shareholders in connection with our annual meeting. 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 private placement and financing transactions, 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. For example, on June 30, 2016, we issued 904,568 restricted shares of our common stock to the KFLP, Intrexon and our Chairman as part of a private placement. The resale of shares acquired from us in private transactions could cause our stock price to decline significantly.

Contingent Share Issuance-Intrexon

On June 9, 2015, we entered into an Oral Mucositis ECC with Intrexon and Actobiotics, a wholly-owned subsidiary of Intrexon, through which we intend to research, develop and commercialize products, including the continued development and commercialization of AG013, for use in the treatment of oral mucositis in humans through the administration of an effector via genetically modified bacteria, but, in any case, excluding the delivery of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer (collectively, the "Program"). Contemporaneously with the Oral Mucositis ECC, we and Intrexon also entered into a Stock Issuance Agreement (the "SIA") which authorized the issuance of the Technology Access Fee and the future stock issuance of our Common Stock to Intrexon upon the achievement of designated milestones. We issued a Convertible Note in the amount of $5,000,000 as payment of the technology access fee associated with the Oral Mucositis ECC which was payable, at our option, in cash or shares of our common stock. The convertible note, including accrued interest, was repaid in December 2015 through the issuance of 338,101 shares of our common stock. Effective January 1, 2018, Intrexon assigned its interest in the Oral Mucositis ECC and related SIA (excluding Intrexon's standstill obligation) to its wholly owned subsidiary, ActoBio Therapeutics, Inc.

In November of 2017, the Stock Issuance Agreement and the Oral Mucositis ECC were amended. Under the terms of the amendment, the Company has agreed to make certain payments to Intrexon upon our achievement of designated milestones in the form of shares of our Common Stock (based upon the fair market value of the shares otherwise required to be issued) unless the issuance of such shares would reasonably likely cause Intrexon to consolidate our financial statements with Intrexon's financial statements, or at our option make a cash payment to Intrexon. The milestone events and amounts payable are as follows:

- a one-time payment of twenty seven million five hundred thousand United States dollars ($27,500,000) 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);
- 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
- 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 that is deemed to be a different drug product that the first Oragenics Product that was clinically pursued under the Lantibiotics Program.

Effective January 1, 2018, Intrexon assigned its interest in the Oral Mucositis ECC and Stock Issuance Agreement (excluding Intrexon's standstill obligation) to its wholly owned subsidiary, ActoBio Therapeutics, Inc.

Equity Participation Right-Intrexon

Pursuant to the Stock Issuance Agreement, Intrexon was 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 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. Intrexon waived their right to participate in the July 2012, June 2016, May 2017 and November 2017 Private Placements.

Registration Rights

Intrexon Corporation. Pursuant to Stock Issuance Agreements with Intrexon dated June 5, 2012 and June 9, 2015, we granted certain registration rights to Intrexon. The registration rights consisted of "piggyback registration" rights which permit Intrexon 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 Intrexon 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 Intrexon the right to include on the registration statement a number of Intrexon's Company shares equal to one half of the number of shares to be registered on behalf of the other holders or prospective holders. Intrexon waived its registration rights in connection with the Company's July 2012, June 2016, May 2017, November 2017 private placements and has elected to exercise registration rights under the Stock Issuance Agreements with respect to the August 2018 private placement. Of the aggregate of 777,344 shares of common stock we issued to Intrexon under the Stock Issuance Agreements, we are registering for resale pursuant to this Registration Statement all of the 439,243 of the shares we issued to Intrexon under the June 5, 2012 Stock Issuance Agreement and 10,757 of the shares we issued to Intrexon under the June 9, 2015 Stock Issuance Agreement. The balance of the 327,344 shares we issued to Intrexon under the June 9, 2015 Stock Issuance Agreement remains subject to the registration rights set forth therein.

Koski Family Limited Partnership, Intrexon Corporation and Dr. Frederick Telling. Pursuant to the June 30, 2016 Stock Purchase Agreement, we granted certain registration rights to the Koski Family Limited Partnership, Intrexon Corporation, and our Chairman, Dr. Frederick Telling. The registration rights consisted of "piggyback registration" rights which permit such shareholders 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 such shareholders 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 such shareholders the right to include on the registration statement such number of shares equal to one half of the number of shares to be registered on behalf of the other holders or prospective holders. The Koski Family Limited Partnership and Dr. Telling waived their registration rights in connection with the Company's May 2017, November 2017 Private Placements and all of the shares of common stock we issued under the Stock Purchase Agreement are registered for resale pursuant to the Registration Statement of which this prospectus forms a part.

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 exercise of the Warrants.

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 exercise of the Warrants. 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.

2018 Registered Direct Offering and Private Placement. Pursuant to the Securities Purchase Agreement dated April 6, 2018 we are required to file as soon as practicable (and in any event within 45 calendar days of the date of the Securities Purchase Agreement), a registration statement on Form S-1 (or other appropriate form if the Company is not then S-3 eligible) providing for the resale by the purchasers of the common stock issuable upon exercise of the Warrants and to keep such registration statement effective at all times until no purchaser owns any Warrants or common stock issuable upon exercise thereof.

Listing

Our common stock is currently listed on the NYSE American under the trading symbol "OGEN."

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, NY 10004-1561, 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.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

LEGAL MATTERS

Shumaker, Loop & Kendrick, LLP will issue a legal opinion as to the validity of the securities offered by this prospectus.

EXPERTS

The audited financial statements of Oragenics, Inc. as of December 31, 2017 and 2016, and for the two-year period ended December 31, 2017, included in our Annual Report on Form 10-K for the year ended December 31, 2017, incorporated by reference in this prospectus have been audited by Mayer Hoffman McCann P.C., an independent registered public accounting firm, as stated in their report dated February 16, 2018, which includes an explanatory paragraph related to Oragenics, Inc.'s ability to continue as a going concern, which is incorporated by reference herein, and has been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL IN FORMATION

We have filed a registration statement on Form S-1 with the SEC under the Securities Act. This prospectus is part of the registration statement but the registration statement includes additional information and exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference. You may read and copy the registration statement and any document we file with the SEC at the public reference room maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a web site that contains reports, proxy and information statements and other information regarding companies, such as ours, that file documents electronically with the SEC. The website address is www.sec.gov. The information on the SEC's website is not part of this prospectus, and any references to this website or any other website are inactive textual references only.

Our Internet address is www.oragenics.com. There we make available free of charge, on or through the investor relations section of our website, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with the Securities and Exchange Commission. The information found on our website is not part of this prospectus and investors should not rely on any such information in deciding whether to invest.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to another document that we have filed separately with the SEC. You should read the information incorporated by reference because it is an important part of this prospectus. We incorporate by reference the following information or documents that we have filed with the SEC, excluding any portions of any Current Report on Form 8-K that are not deemed "filed" pursuant to the General Instructions of Form 8-K:

- Our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on February 16, 2018; and

- Our Current Reports on Form 8-K filed with the SEC on January 8, 2018, January 19, 2018; and April 10, 2018.

Any information in any of the foregoing documents will automatically be deemed to be modified or superseded to the extent that information in this prospectus or in a later filed document that is incorporated or deemed to be incorporated herein by reference modifies or replaces such information.

We also incorporate by reference any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, including those made after the date of filing of the initial registration statement and prior to effectiveness of the registration statement, until we file a post-effective amendment that indicates the termination of the offering of the securities made by this prospectus. Information in such future filings updates and supplements the information provided in this prospectus. Any statements in any such future filings will automatically be deemed to modify and supersede any information in any document we previously filed with the SEC that is incorporated or deemed to be incorporated herein by reference to the extent that statements in the later filed document modify or replace such earlier statements.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, without charge upon written or oral request, a copy of any or all of the documents that are incorporated by reference into this prospectus but not delivered with the prospectus, including exhibits which are specifically incorporated by reference into such documents. You may request a copy of these filings at no cost, by writing to or telephoning us at the following address:

Oragenics, Inc.
4902 Eisenhower Boulevard, Suite 125
Tampa, Florida 33634
Attention: Investor Relations
Phone: (813) 276-7900

You may also access filed documents by accessing the Investors section of our website at www.oragenics.com.

PROSPECTUS