Table of Contents

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

FORM 10-K

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

For the fiscal year ended December 31, 2016

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

For the transition period from _____ to _____

Commission file number 001-32188

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

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

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

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

Title of each class	Name of each exchange on which registered
Common Stock $0.001 par value per share	**NYSE MKT**

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:
None

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this

Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☒

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, was approximately $7,482,815 computed based upon a last sales price of $0.51 as reported by the NYSE MKT as of June 30, 2016.

As of February 10, 2017, there were 49,274,219 shares of the registrant's Common Stock outstanding.

TABLE OF CONTENTS

FORWARD LOOKING STATEMENTS AND CERTAIN CONSIDERATIONS

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

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

- We have incurred significant operating losses since our inception and cannot assure you that we will generate revenues or achieve profitability.
- We will need to raise additional capital to fully implement our business strategy and we may not be able to do so.
- Our inability to achieve success with our lead lantibiotic and oral mucositis candidates.
- The success, timing and expenses of our collaboration efforts with Intrexon and expected clinical trials.
- Our inability to achieve success in our clinical trials of our oral mucositis product candidates.
- Our inability to achieve success in our identification of lantibiotic homologs or the manufacture and nonclinical testing of our lantibiotic product candidates.
- We are subject to extensive and costly regulation by the Food and Drug Administration, which must approve our product candidates in development and could restrict or delay the future commercialization of certain of our product candidates.
- We may be unable to achieve commercial viability and acceptance of our proposed product candidates.
- We may be unable to successfully operate internationally.
- 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.
- 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.
- We are subject to significant competition.
- 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.

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

Table of Contents

PART I

ITEM 1. BUSINESS.

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

Overview

We are focused on 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 affecting up to 500,000 patients annually. OM has a negative effect on patient well-being and if severe, negatively affects 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.

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. As a result of that meeting and subject to the availability of adequate amounts of financing, we expect to file an Investigational New Drug ("IND") update in early 2017 and initiate a Phase 2 study with AG013 in the United States and Europe in 2017.

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. 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 a therapeutic agent 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. The 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.

We had selected a lead candidate, OG253, and we had a pre IND meeting with the FDA in November of 2015 regarding the pursuit of an IND on OG253. Following additional research and development on second generation lantibiotics, in August of 2016, we selected a second generation lantibiotic, OG716, for treatment of *C. diff*. OG716 is a new, orally-active homolog, that has exhibited positive results in an animal model for potential treatment of *C. diff*. Generated from our MU1140 platform, this new lantibiotic showed promising efficacy in reducing clinically relevant *C. diff* infections as measured by increased animal survival and decreased relapse as well as reduced production of *C. diff* spores 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 quarter ended June 30, 2016, we currently expect the IND for a first-in-human clinical study of OG716 to occur in 2017 as we continue to assess the promising properties of the homologs we have identified.

Our Probiotic Products

On June 27, 2016, we completed the sale of our consumer probiotics business to ProBiora Health, LLC, ("ProBiora Health") an entity owned by Ms. Christine L. Koski, a director at the time of the transaction.

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.

Our Products and Product Candidates

We are currently developing our antibiotic product candidate, OG716, as well as other homolog antibiotic product candidates, researching AG013 in connection with the treatment of Oral Mucositis, and have other product candidates for outlicensing or partnering. We seek to protect our products and product candidates through patents and patent applications. Our products and product candidates are protected by six issued U.S. patents and four filed U.S. patent applications, including patents exclusively licensed from the University of Florida Research Foundation, Inc., or UFRF, and patent applications we filed in connection with our exclusive license agreement with Texas A&M University System. We are the exclusive worldwide licensee to the patents for our antibiotic product candidate, MU1140, which is owned by the UFRF. We also have worldwide commercialization rights to each of these product candidates. We co-own the intellectual property for certain homologs of our MU1140 and SMaRT Replacement Therapy product candidates with the Texas A&M University System. We have exclusively licensed the rights of the Texas A&M University System to this intellectual property. We have an exclusive, worldwide license from Intrexon to use its technology to develop lantibiotics. We also have an exclusive worldwide license from Intrexon and its wholly owned subsidiary, Actobiotics NV ("Actobiotics") to use their intellectual property to develop AG013 for the treatment of oral mucositis in patients undergoing treatment for cancer.

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

OG716, Homologs of MU1140 and Other Lantibiotics

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

On June 5, 2012, we entered into the Lantibiotic ECC with Intrexon. Through this collaboration we intend to develop lantibiotics, a novel class of broad spectrum antibiotics, as active pharmaceutical ingredients toward the goal of commercialization for the treatment of infectious diseases in humans. Intrexon is a leader in the field of synthetic biology and we believe a portion of their technologies covered by the Lantibiotic ECC helped to produce sufficient quantities of native MU1140 as well as a potential pipeline of other MU1140 homologs to initiate nonclinical testing.

We previously selected a lead candidate, OG253, and had a pre IND meeting with the FDA in November of 2015 regarding the pursuit of an IND on OG253. Following additional research and development on second generation lantibiotics, in August of 2016, we selected a second generation lantibiotic, OG716, for treatment of *C. diff*. OG716 is a new, orally-active homolog, that has exhibited positive results in an animal model for potential treatment of *C. diff*. Generated from our MU1140 platform, this new lantibiotic showed promising efficacy in reducing clinically relevant *C. diff* infections as measured by increased animal survival and decreased relapse as well as reduced production of *C. diff* spores and toxin levels when compared to a vancomycin positive control. We expect to have a pre-IND meeting with FDA for OG716 during the second quarter of 2017.

Market Opportunity

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

The need for novel antibiotics is increasing as a result of the growing resistance of the targeted pathogens. The CDC has estimated that up to 77% of certain nosocomial pathogenic bacteria are resistant to drugs of last resort (vancomycin-resistant E. faecium and vancomycin, respectively, in this example). HAIs are not exclusively a problem in the United States as the rest of the world has also seen a dramatic rise in HAIs during the last decade. We believe novel antibiotics have become increasingly scarce as major pharmaceutical companies focus more research and development resources on lifestyle drugs and fewer resources on specialty pharmaceuticals such as antibiotics. Between 1983 and 1987, 16 new antibiotics were approved by the FDA. Twenty years later, over an equivalent time period from 2003 to 2007, only five new antibiotics were approved by the FDA, of which only two possessed a novel mechanism of action. Between 2008 and 2012, there were only two new antibiotics approved by FDA.

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

Our Solution

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

Our Strategy

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

Regulatory Status

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

Manufacturing

Through our work with Intrexon, we have been able to produce a significant increase in the fermentation titer of the target compound MU1140 and the discovery of a new purification process for MU1140. We continue to improve on the manufacturing through collaborations with fermentation and purification experts and third party CROs, and through the hire of key personnel who will be able to further optimize and scale up the production/purification scheme internally. Our determination to examine many new homologs of MU1140 resulted in the need to reproduce the fermentation and purification steps on at least 10-15 identified homolog candidates. Each homolog requires different optimizations for both the fermentation and purification steps and in many cases required a new approach. As such, our work on the development of new lantibiotic homologs using genetically modified bacteria continues. We believe these developments represent progress toward our goal of commercial production of sufficient quantities of a MU1140 homolog and deliver a step in validating the lantibiotics platform targeting infectious diseases.

We are working with a third party manufacturer to produce additional quantities of designated homologs, based upon the developments achieved from our work with Intrexon and outside contractors. The production of additional quantities of designated homologs including OG716, that are needed for the consummation and pursuit of our nonclinical testing activities supporting the IND filing are currently underway.

Our Oral Mucositis (OM) – Product Candidate

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 and/or the administration to humans of a trefoil factor via genetically modified bacteria (including *L. lactis*) for the treatment of diseases and conditions of the oral cavity, throat, and esophagus, 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 3,381,004 shares of our common stock.

Market Opportunity

We estimate, based upon our review of historic studies and reports, and an interpolation of data on the incidence of oral mucositis, that oral mucositis occurs in approximately 500,000 patients receiving cancer treatment in the U.S., with a comparable number in Europe. Oral mucositis almost always occurs in patients with head and neck cancer treated with radiation therapy (greater than 80% incidence of severe mucositis) and is common in patients undergoing high dose chemotherapy and hematopoietic cell transplantation, where the incidence and severity of oral mucositis depends greatly on the nature of the conditioning regimen used for myeloablation.

According to Global Data, it is estimated the oral mucositis therapeutics market was valued at $813.2 million in 2010. Further, the oral mucositis therapeutics market is expected to grow at a compound annual growth rate (CAGR) of 5.2% from $813.2 million in 2010 to $1,156.0 million in 2017. We believe the growth would be primarily due to the increase in the number of cancer patients, increased rate of chemotherapy usage and increase in awareness among patients about oral mucositis.

Our Solution

To continue research and development through our collaboration with Intrexon and Actobiotics to develop AG013 as an effective treatment for oral mucositis.

Our Strategy

In collaboration with Intrexon, and subject to our ability to raise additional capital to pursue further development of AG013, we expect to further the research and development of AG013 toward the goal of moving AG013 forward in its clinical development and to assess the data generated and research and development conducted by Actobiotics on our behalf to identify other potential candidates product for the treatment of oral mucositis that could be more effective than AG013.

Regulatory Status

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 secreted protein locally, resulting in homogeneous exposure to the entire mucosal surface up to 24 hours after administration of a rinse. AG013 has been granted Orphan Drug status in the European Union and we believe it may be eligible for Biologic License Application exclusivity. In November 2016, the U.S. FDA granted Fast Track designation for AG013.

Manufacturing

We expect to utilize contract manufacturing firms to produce our investigational product candidate AG013 in accordance with "current good manufacturing practices" (cGMP) guidelines outlined by the International Conference of Harmonization (ICH) and FDA.

ProBiora3 Oral Care Probiotics

On June 27, 2016, we completed the sale of our consumer probiotics business to ProBiora Health, LLC, ("ProBiora Health") an entity owned by Ms. Christine L. Koski, a director at the time of the transaction. The purchase price was $1,700,000 in cash of which $1,250,000 was paid at closing and $450,000 was payable on or before July 31, 2016. The note accrued interest at the rate of 1% per annum and was paid in full on July 29, 2016. In connection with the sale ProBiora Health assumed certain liabilities. ProBiora Health is obligated to pay the Company contingent consideration annually over a 10 year period based on a percentage of sales of products using the Purchased Assets, with a maximum obligation to the Company of $2,000,000.

Other Product Candidates and Technologies

LPT3-04 Weight Loss Product

In the course of our research efforts, our scientific team also discovered that consumption of a significant amount of LPT3-04, a naturally occurring compound which is normally consumed in the human diet in small amounts, resulted in dose-dependent weight loss in experimental animal models. In December 2013 we entered into an exclusive licensing arrangement of our LPT3-04 weight-loss product candidate for further development to LPThera LLC ("LPThera"). LPThera LLC was a newly formed entity that needs to raise capital to further pursue the opportunity presented by our LPT3-04 product candidate. LPThera LLC was formed by a former consultant to the Company who became an employee effective in April 2014 and subsequently ceased his employment in March 2016. The exclusive license agreement we granted to LPThera, provides LPThera the exclusive worldwide royalty bearing license to develop, make or have made, use, sell, offer for sale, market and promote the LPT3-04 for use under our technology. LPThera may sublicense the rights described without our written consent, but shall provide notice to us of any sublicense granted.

Under the LPT3-04 license agreement, as amended in March 2014, LPThera has agreed to achieve the following development milestones within the following time frames:

Development Milestones	Completion date
1. Fundraising to support nonclinical and animal studies	Q2 2015
2. Formulation development	Q3 2015
3. Complete required nonclinical, exploratory animal and GLP animal studies	Q3 2018
4. Complete required Investigational New Drug ("IND") human clinical studies	Q3 2020
5. First Regulatory Approval (as defined in the LPT3-04 license agreement)	Q3 2021
6. First Commercial Sale (as defined in the LPT3-04 license agreement)	Q3 2021

The milestones set forth above for 2015 for fundraising and formulation development were satisfactorily achieved on a timely basis in 2015. Our licensee is pursuing a strategy of weight loss in companion pets in order to be in position to commercialize a product candidate on a more accelerated basis than would apply to use in humans.

LPThera is responsible for commercializing the products containing LPT3-04 using commercially reasonable efforts. If at any time after the second anniversary of the effective date of the LPT3-04 license agreement, we believe in our reasonable opinion that LPThera has not satisfied the development milestones or commercialization responsibility, designated representatives of each party will meet to discuss areas of concern and any additional actions that should be taken to remedy the cause for our concern and we may require LPThera to take certain actions for it to comply with its diligence obligations under the LPT3-04 license agreement.

LPThera has agreed to pay us 5% of the aggregate net sales derived from the sale of products containing LPT3-04, where the manufacture, use, promotion or sale of such products is protected by a valid claim of one of our patents covered by the LPT3-04 license agreement in such country. If we do not obtain a US patent with a valid claim, LPThera has agreed to pay us 2.5% of aggregate net sales derived from the sale of products containing LPT3-04 in the US. LPThera has likewise agreed to pay us 20% of license income obtained from a sublicensee in the event of a sublicensing arrangement.

Under the LPT3-04 license agreement, LPThera has agreed to make certain payments to us upon its achievement of designated sales levels. The sales levels and amounts payable are as follows:

Calendar Year Net Sales	Sales Milestone
$ 1,000,000	$ 50,000
$ 10,000,000	$ 500,000
$ 100,000,000	$ 5,000,000

LPThera has agreed to indemnify and hold us harmless from any damages caused as a result of the development, manufacture, distribution, marketing, promotion or sale of the products containing LPT3-04 or its breach of a representation, warranty or obligation under the LPT3-04 license agreement.

We have agreed to indemnify and hold LPThera harmless from any damages caused as a result of the development, manufacture, distribution, marketing, promotion or sale of the products containing LPT3-04 prior to the effective date of the LPT3-04 license agreement or our breach of a representation, warranty or obligation under the LPT3-04 license agreement.

The term of the LPT3-04 license agreement expires upon the expiration of our patents covered by the LPT3-04 license agreement that contain one or more valid claims. After expiration of the royalty term for products containing LPT3-04 in each country, LPThera shall have a royalty-free, non-exclusive license to develop, make, have made, use, import, market, promote, distribute, sell, and offer for sale and otherwise exploit such products containing LPT3-04 in such country.

LPThera may voluntarily terminate the LPT3-04 license agreement upon 60 days written notice to us. Either party may terminate the LPT3-04 license agreement if one party materially breaches the LPT3-04 license agreement and fails to cure such breach within 60 days or in the case of payment defaults, 30 days. After the effective date of termination of the LPT3-04 license agreement (unless terminated by LPThera as a result of our material breach), (i) all licenses granted by us to LPThera shall terminate, (ii) LPThera will assign and transfer to us all regulatory filings related to products containing LPT3-04, (iii) LPThera will license to us on a royalty-free basis all rights to all trademarks for the products containing LPT3-04 for use with such products, (iv) LPThera shall assign to us all inventions controlled by LPThera that relate to solely the development, manufacture, use or sale of the products containing LPT3-04, but if such inventions are not solely related to, but are necessary for, the development, manufacture, use or sale of the products containing LPT3-04, then LPThera shall grant to us the exclusive, worldwide, royalty-free license (with right to sublicense) to develop, manufacture, sell and use solely the products containing LPT3-04. In the event that the LPT3-04 license agreement is terminated following completion of development milestones 1, 2 and 3 described above, we have agreed to pay LPThera (i) during the royalty term a royalty on our net sales of the products containing LPT3-04 at a rate of 3% and (ii) 10% of any license income obtained from a sublicensee.

Replacement Therapy

Our SMaRT Replacement Therapy is based on the creation of a genetically modified strain of bacteria that colonizes in the oral cavity and replaces native bacteria that cause tooth decay. Our SMaRT Replacement Therapy product candidate is designed to be a painless, one-time, five-minute topical treatment applied to the teeth that has the potential to offer lifelong protection against dental caries, or tooth decay. While we commenced a Phase 1b clinical trial for SMaRT Replacement Therapy during the first quarter of 2011, the very restrictive study enrollment criteria required by the FDA made the enrollment of candidates meeting the restrictive criteria difficult. This enrollment difficulty was also present in our Phase 1a clinical trial. Due to the enrollment difficulties we encountered with our initial Phase 1a clinical trial and with our phase 1b clinical trial, we determined to discontinue pursuit of our Phase 1b clinical trial. Our focus for the SMaRT Replacement Therapy technology is on possible partnering opportunities that may exist.

Our Replacement Therapy technology was exclusively licensed from the University of Florida Research Foundation, Inc. (“UFRF”). The UFRF license terminated in June 2015 when the patent covered by the license expired. The Company, however, had a new patent issue, patent number 9,260,488, through its research and development undertaken with Texas A&M. (See discussion of Texas A&M license below). The Company believes the issuance of the patent could support or enable future potential partnership opportunities for this technology.

Our In-Licensed Technology Agreements

The University of Florida Research Foundation Licenses

We hold exclusive licenses from the University of Florida Research Foundation, Inc. (“UFRF”) for our MU1140 product candidates.

MU1140 –We have exclusively licensed the intellectual property for our MU1140 lantibiotic technology from the UFRF. The original license agreement was dated June 22, 2000 and was subsequently amended on September 15, 2000, July 10, 2002, September 25, 2002, March 17, 2003 and April 19, 2013. The amended license agreement provides us with an exclusive worldwide license to make, use and sell products and processes covered by Patent No. 5,932,469 entitled "Antimicrobial Polypeptide, Nucleic Acid and Methods of Use" and includes U.S. patent numbers 6,964,760; 7,067,125; 6,391,285; 6,475,771 and the following foreign patents based on the technology in the '469 patent: Australian patent number 7488871, Canadian patent number 2295986, European patent number 1019084 validated in France, Germany, Ireland, Italy, Spain, Sweden and United Kingdom. Our license is for the period of the patents, which expire between 2017 and 2019 subject to the performance of terms and conditions contained therein.

Additional Terms of UFRF License Agreements - In the amended license agreement MU1140, 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 that are dedicated 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. 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 for the license agreement. The annual payments are required to be paid in advance on a quarterly basis which amounts to $2,500 per quarter for the license. We must also pay all patent costs and expenses incurred by the UFRF for the preparation, filing, prosecution, issuance and maintenance of the patent. We have agreed to indemnify and hold UFRF and other affiliated parties harmless from any damages caused as a result of the production, manufacture, sale, use, lease, consumption or advertisement of the licensed product.

The terms of the UFRF amended license agreement expire upon the earlier of (i) the date that no patents covered by the license agreement remain enforceable or (ii) the payment of earned royalties under the amended license agreement, once begun, ceases for more than three calendar quarters. We may voluntarily terminate the amended license agreement upon 90 days written notice to UFRF. UFRF may terminate the amended license agreement if we breach our obligations to timely pay any amounts due under the amended license agreement, 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.

Texas A&M License Agreement

In December 2011, we entered into an exclusive licensing agreement with Texas A&M University System (College Station, TX) ("Texas A&M") for access to new homologs of the lantibiotic Mutacin 1140 (MU1140) and other lantibiotics with improved pharmacological properties and structural features. These novel antibiotics may be useful to treat or prevent colonization and/or infections by one or more types of bacteria. The structural changes available to us from this license agreement may improve the bioactivity of MU1140. Under the terms of the Texas A&M license agreement, we filed two patent applications with the US Patent Office to secure the intellectual property related to these new lantibiotic homologs on February 27, 2012, entitled "Variants of the Lantibiotic MU1140 and Other Lantibiotics with Improved Pharmacological Properties and Structural Features" and "Replacement Therapy for Dental Carries." The patent filed for Replacement Therapy for Dental Carries was issued on February 16, 2016, No. 9,260,488 and will expire on February 16, 2036. We have had a longstanding relationship with Dr. James Leif Smith, one of the co-authors of the patent application. Dr. Smith is an Associate Professor in the Department of Biology at Texas A&M University and the Founder and Chair of Biotech Analyst Group, LLC, since 2006.

Under the terms of the license agreement, we made an initial payment of five thousand dollars ($5,000) to Texas A&M. We must also pay to Texas A&M a royalty of five percent (5%) of net sales of products that include the licensed technology, subject to royalty stacking provisions with a two percent (2%) minimum royalty. Additionally, in order to maintain the exclusive license, commencing in 2014 and each year thereafter prior to the calendar year of the first sale of products using the licensed technology), we must pay Texas A&M $15,000 as minimum consideration for the continuation of the license agreement. Once we commence the sale of products that include the technology we license from Texas A&M we must pay a minimum annual amount of $100,000 to Texas A&M and every year thereafter through the expiration of the Agreement. However, once sales begin, any royalty payments we make on net sales will be credited against the $100,000 required maintenance payment.

We must also pay all patent costs and expenses for the preparation, filing, prosecution, issuance and maintenance of the patent rights. We have agreed to indemnify and hold the Texas A&M harmless from any damages caused as a result of alleged infringement of a third party's intellectual property rights or as a result of the production, manufacture, sale, use, lease, consumption or advertisement of the product. Sales by sublicensees are subject to the royalty rate above, and we shall be responsible for certain payments to Texas A&M for any other consideration received that is not in the form of a royalty.

Pursuant to the Texas A&M license agreement, we are obligated to meet the following milestones and make milestone payments: (i) enrollment of first patient in a Phase 1 clinical trial using the licensed technology, to occur on or before June 1, 2015, with a milestone achievement payment of $50,000 , (ii) completion of Phase 2 clinical trial of a product using the licensed technology to occur on or before June 1, 2019, with a milestone achievement payment of $100,000, (iii) completion of Phase 3 clinical trial of a product using the licensed technology to occur on or before June 1, 2022, with a milestone achievement payment of $150,000, and (iv) first sale of a product using the licensed technology to occur on or before June 1, 2025 with a milestone achievement payment of $400,000. If we fail to accomplish the milestones or fail to achieve net sales of products including the licensed technology for two consecutive calendar years once sales begin, Texas A&M, at its sole option may waive the requirement, negotiate the missed milestones or terminate the license agreement. In addition, products using the licensed technology must be substantially manufactured in the United States. We expect to seek an amendment to extend the enrollment milestones.

On July 11, 2012 the Texas A&M license agreement was amended to add references to replacement therapy in the defined terms “Licensed Technology” and “Patent Rights”. All other terms of the Texas A&M license agreement remain unchanged.

On May 18, 2015, the Texas A&M license agreement was amended to extend the enrollment of first patient in a Phase 1 clinical trial using the licensed technology, from on or before June 1, 2015, to on or before June 1, 2016. All other terms of the Texas A&M license agreement as amended remained unchanged. The term of the Texas A&M license agreement expires upon (i) the expiration of the applicable patent rights covered by the license agreement, (ii) the failure of any patent filed pursuant to the license agreement to issue, or (iii) the final and unappealable determination by a court that the patent rights are invalid. We may voluntarily terminate the license agreement upon 90 days written notice to Texas A&M. Texas A&M can terminate the license agreement if we materially breach the license agreement and do not cure such breach within 60 days of receiving notice of such breach from Texas A&M.

In October of 2016, the Texas A&M license agreement was amended to extend the enrollment of first patient in a Phase 1 clinical trial using the licensed technology, from on or before June 1, 2016, to on or before June 1, 2019 and provides for a payment of $25,000 commencing in 2017 and each year thereafter prior to the calendar year of the first sale of products using the licensed technology, as minimum annual consideration for the continuation of the license agreement. All other terms of the Texas A&M license agreement as amended remained unchanged.

Our Worldwide Exclusive Channel Collaboration (“ECC”) Agreements with Intrexon

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.

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

Subject to certain expense allocations and other offsets provided in the Lantibiotic ECC, we will pay Intrexon on a quarterly basis 25% of gross quarterly profits derived in that quarter from the sale of products developed from the Lantibiotic ECC, calculated on an Oragenics Product-by-Oragenics Product basis. We have likewise agreed to pay Intrexon on a quarterly basis 50% of revenue obtained in that quarter from a sublicensor in the event of a sublicensing arrangement.

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

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

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

- commercialized by us;
- approved by regulatory authorities;
- a subject of an application for regulatory approval that is pending before the applicable regulatory authority; or
- the subject of at least an ongoing Phase 1, Phase 2 or Phase 3 clinical trial in the Field (in the case of a termination by Intrexon due to an uncured material breach by the Company or a voluntary termination by us).

Our obligation to pay 25% of gross profits or revenue and the milestone payments described above with respect to these "retained" products as well as to use diligent efforts to develop and commercialize these "retained" Oragenics Products will survive termination of the Lantibiotic ECC.

In addition, in partial consideration for each party's execution and delivery of the Lantibiotic ECC, we entered into a Stock Issuance Agreement with Intrexon. Pursuant to the Stock Issuance Agreement, we issued to Intrexon 4,392,425 shares of our common stock as an initial technology access fee, in consideration for the execution and delivery of the Lantibiotic ECC and granted Intrexon certain equity participation rights and registration rights.

The registration rights granted to Intrexon in the Stock Issuance Agreement by us 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.

Pursuant to the Stock Issuance Agreement, Intrexon is also entitled, at its election, to participate in future securities offerings by us that constitute "qualified financings" and purchase securities equal to 30% of the number of shares of common stock or other securities sold in such offering (exclusive of 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.

Under the Stock Issuance Agreement and as part of the Lantibiotic ECC, the Company has also agreed to make certain payments to Intrexon upon our achievement of designated milestones in the form of shares of our common stock or, at our option, make a cash payment to Intrexon (based upon the fair market value of the shares otherwise required to be issued). The milestone events and amounts payable are as follows:

(i) upon filing of the first Investigational New Drug application with the U.S. Food and Drug Administration for an Oragenics Product, that number of shares equal to the number of shares of common stock comprising 1.0% of the Base Shares (as defined below);

(ii) upon the dosing of the first patient in the first Phase 2 clinical study with an Oragenics Product, that number of shares equal to the number of shares of common stock comprising 1.5% of the Base Shares;

(iii) upon the dosing of the first patient in the first Phase 3 clinical study with an Oragenics Product, that number of shares equal to the number of shares of common stock comprising 2% of the Base Shares;

(iv) upon the filing of the first New Drug Application ("NDA") or Biologics License Application ("BLA") with the U.S. Food and Drug Administration for an Oragenics Product, or alternatively the filing of the first equivalent regulatory filing with a foreign regulatory agency, that number of shares equal to the number of shares of Common Stock comprising 2.5% of the Base Shares; and

(v) upon the granting of the first regulatory approval of an Oragenics Product, that number of shares equal to the number of shares of Common Stock comprising 3% of the Base Shares.

Base Shares is defined in the Stock Issuance Agreement to mean (i) the number of shares of our common stock together with any securities or instruments convertible or exercisable for shares of common stock issued and outstanding at the time of the applicable milestone event, (ii) minus any shares issuable upon conversion of Capital Inducement Securities. Capital Inducement Securities is defined in the Stock Issuance Agreement to mean warrants or other convertible securities of the Company issued to investors in connection with a debt or equity investment in us that are issued in addition to the primary investment securities and in an amount not to exceed 10% of the overall number of shares issued in the investment (on an as-converted to common stock basis).

On July 21, 2016, the Lantibiotics ECC was amended to revise the definition of Field in view of a provisional patent application filing between Intrexon and Oragenics and to further clarify Oragenics' rights under the Lantibiotic ECC to genetically modified *Streptococcus mutans* that express Lantibiotic(s).

None of the Lantibiotic ECC milestones had been achieved as of December 31, 2016.

The Oral Mucositis ECC

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 and/or the administration to humans of a trefoil factor via genetically modified bacteria (including *L. lactis*) for the treatment of diseases and conditions of the oral cavity, throat, and esophagus, 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 3,381,004 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 and/or the administration to humans of a trefoil factor via genetically modified bacteria (including *L. lactis*) for the treatment of diseases and conditions of the oral cavity, throat, and esophagus, 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.

Under the Oral Mucositis ECC, and subject to certain exceptions, we are responsible for, among other things, funding the further anticipated development of products toward the goal of commercialization, conducting preclinical and clinical development of candidate products, as well as for other aspects of manufacturing and the commercialization of the product(s). Among other things, Intrexon is responsible for technology discovery efforts, cell-engineering development, and certain aspects of the manufacturing process.

We will pay Intrexon on a quarterly basis 12% of the net sales derived from the sale of products developed from the exclusive channel collaboration. We likewise agreed to pay Intrexon on a quarterly basis 50% of revenue obtained in that quarter from a sublicensor in the event of a sublicensing arrangement.

We also 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 Commercialization Milestone Events and amounts payable are as follows:

(i) two million United States dollars ($2,000,000) within thirty (30) days of the first instance of the achievement of the Phase 2 Milestone Event meaning the first dosing of a patient by or on our behalf, or our Affiliate or permitted sublicensee, in a Phase 2 clinical trial, whether such occurs in the United States of America under the jurisdiction of the FDA or elsewhere under the jurisdiction of a foreign regulatory agency, for each different Oragenics Product;

(ii) five million United States dollars ($5,000,000) within thirty (30) days of the first instance of the achievement of the Phase 2b/3 Milestone Event meaning meeting of the primary endpoint by or on our behalf, or our Affiliate or permitted sublicensee of Oragenics, in a Phase 3 clinical trial, whether such occurs in the United States of America under the jurisdiction of the FDA or elsewhere under the jurisdiction of a foreign regulatory agency, for each different Oragenics Product;

(iii) five million United States dollars ($5,000,000) within thirty (30) days of the first instance of the achievement of the Regulatory Approval Application Milestone Event for each different Oragenics Product which Regulatory Approval Application Milestone Event meaning for a given Oragenics Product, the first to occur of (a) the filing by us, our Affiliate, or a permitted sublicensee thereof, of a FDA New Drug Application or a Biologics License Application with the FDA seeking approval of such Oragenics Product, or (b) the filing of an equivalent approval or marketing application for such Oragenics Product with an equivalent regulatory authority in a foreign jurisdiction;

(iv) ten million United States dollars ($10,000,000) within thirty (30) days of the first instance of the achievement of the Approval Milestone Event for each different Oragenics Product which Approval Milestone Event meaning the first to occur of (a) the First Commercial Sale of an Oragenics Product anywhere in the Territory, or (b) 90th day after the approval of a FDA New Drug Application for an Oragenics Product by the FDA or equivalent regulatory action in a foreign jurisdiction;

(v) We shall pay Intrexon a milestone payment of five million United States dollars ($5,000,000) within thirty (30) days of the first instance of the achievement of the New Indication Milestone Event meaning the filing by or on our behalf, our Affiliate, or a permitted sublicensee a Supplemental FDA Application with the FDA or with another equivalent regulatory agency seeking approval of an indication for use of the product AG013 other than the current regulatory-approved indication; and

(vi) We shall pay Intrexon a milestone payment of five million United States dollars ($5,000,000) within thirty (30) days of the first instance of the achievement of the New Product Milestone Event meaning the filing of a regulatory package filed with the FDA or with another equivalent regulatory agency by or on our behalf, our Affiliate, or a permitted sublicensee, that is deemed (according to relevant FDA guideline) to be a different drug product than AG013.

None of the Oral Mucositis ECC milestones had been achieved as of December 31, 2016.

We may voluntarily terminate the Oral Mucositis ECC upon 90 days written notice to Intrexon. Intrexon may also terminate the Oral Mucositis ECC if we breach and fail to cure the breach within 60 days or we do not pursue development of the Superior Therapy under the probiotics identified by Intrexon that is a “Superior Therapy” as defined in the Oral Mucositis ECC. Upon termination of the ECC, we may continue to develop and commercialize any Company Product that, at the time of termination that satisfies at least one of the following criteria:

(i) the particular Company Product is being sold by the Company triggering profit sharing payments under the Oral Mucositis ECC to Intrexon;

(ii) the particular Company Product has received regulatory approval;

(iii) the particular Company Product is a subject of an application for regulatory approval in the Field covered by the ECC that is pending before the applicable regulatory authority;

(iv) the particular Company Product is AG013, and such Company Product has been the subject of at least one completed Phase 2 clinical trial (as such is defined by relevant FDA guidelines) during the Term; or

(v) the particular Company Product other than AG013 and such Oragenics Product is the subject of at least an ongoing Phase 1, Phase 2 or Phase 3 clinical trial in the Field.

Government Regulations

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

FDA Regulation of Drugs-New Drug Approval Process

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

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

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

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

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

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

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

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

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

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

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

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

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

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

After completion of the required clinical testing, an NDA or BLA is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before marketing of the product may begin in the U.S. The NDA or the BLA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs and BLAs is additionally subject to a substantial application user fee, currently exceeding $2,038,000 for fiscal year 2017, and the manufacturer and/or sponsor under an approved NDA or BLA are also subject to annual product and establishment user fees, currently exceeding $97,000 per product and $512,000 per establishment for fiscal year 2017. Although these fees were reduced from fiscal year 2016, they are typically increased annually.

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

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee – typically a panel that includes clinicians and other experts – for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMPs is satisfactory and the NDA or BLA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

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

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

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

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

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

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

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

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

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

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

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

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs, BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

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

Disclosure of Clinical Trial Information

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

The Hatch-Waxman Amendments

Orange Book Listing

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

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

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

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

Exclusivity

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

Patent Term Extension

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

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

Section 505(b)(2) New Drug Applications

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

505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

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

Post-Approval Requirements

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

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

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

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

Biologics

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

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

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

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

Regulation Outside the United States

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

Regulation and Marketing Authorization in the European Union

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

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

Preclinical Studies

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

Clinical Trial Approval

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

In April 2014, the EU legislators passed the new Clinical Trials Regulation, (EU) No 536/2014, which will replace the current Clinical Trials Directive 2001/20/EC. To ensure that the rules for clinical trials are identical throughout the European Union, the new EU clinical trials legislation was passed as a regulation that is directly applicable in all EU member states. All clinical trials performed in the European Union are required to be conducted in accordance with the Clinical Trials Directive 2001/20/EC until the new Clinical Trials Regulation (EU) No 536/2014 becomes applicable, which will be no earlier than May 28, 2016.

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

- A streamlined application procedure via a single entry point, the EU portal.
- A single set of documents to be prepared and submitted for the application as well as simplified reporting procedures that will spare sponsors from submitting broadly identical information separately to various bodies and different member states.

- A harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed jointly by all member states concerned. Part II is assessed separately by each member state concerned.
- Strictly defined deadlines for the assessment of clinical trial application.
- The involvement of the ethics committees in the assessment procedure in accordance with the national law of the member state concerned but within the overall timelines defined by the Regulation (EU) No 536/2014.

Marketing Authorization

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

Centralized Authorization Procedure

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

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

- medicinal products developed by means of one of the following biotechnological processes:
- recombinant DNA technology;
- controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells; and
- hybridoma and monoclonal antibody methods;
- advanced therapy medicinal products as defined in Article 2 of Regulation (EC) No. 1394/2007 on advanced therapy medicinal products;
- medicinal products for human use containing a new active substance that, on the date of effectiveness of this regulation, was not authorized in the European Union, and for which the therapeutic indication is the treatment of any of the following diseases:
- acquired immune deficiency syndrome;
- cancer;
- neurodegenerative disorder;
- diabetes;
- auto-immune diseases and other immune dysfunctions; and
- viral diseases;
- medicinal products that are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

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

Administrative Procedure

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

Conditional Approval

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

Marketing Authorization under Exceptional Circumstances

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

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

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

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

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

Pediatric Studies

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

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

Periods of Authorization and Renewals

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

Regulatory Data Protection

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

Regulatory Requirements After a Marketing Authorization has been Obtained

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

Pharmacovigilance and other requirements

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

Manufacturing

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

Marketing and Promotion

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

Patent Term Extension

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

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

Pharmaceutical Coverage, Pricing and Reimbursement

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

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

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

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

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

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

Healthcare Law and Regulation

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

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

- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Health Care Reform Law requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Our Intellectual Property

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

Patents

We attempt to protect our technology and products through patents and patent applications. We have a portfolio of patents and patent applications covering certain of our product candidates and other technologies. As of December 31, 2016, we held one U.S. issued patent, one U.S. patent application pending, and sixteen foreign patent applications pending. In addition, as of December 31, 2016, we have licenses for approximately five U.S. issued patents, three U.S. patent applications pending, and eleven foreign issued patents. We reassess the value of each patent at the time maintenance fees are due, and in cases where maintaining the patent is judged to be of no significant strategic value we decline to pay the fee.

The following table sets forth information regarding each of our currently held or licensed United States patents:

Antibiotics

Patent No.	Patent Expiration	Title/Product	Ownership	Jurisdiction Where Granted
5,932,469	2017	Antimicrobial Polypeptide, Nucleic Acid and Methods of Use (MU1140)	Exclusive License	USA
6,391,285	2017	Antimicrobial Polypeptide, Nucleic Acid and Methods of Use (MU1140)	Exclusive License	USA
6,475,771	2017	Antimicrobial Polypeptide, Nucleic Acid Modification Enzyme and Methods of Use (MU1140)	Exclusive License	USA
6,964,760	2018	Antimicrobial Polypeptide, Nucleic Acid and Methods of Use (MU1140)	Exclusive License	USA
7,067,125	2019	Antimicrobial Polypeptide, Nucleic Acid Modification Enzyme and Methods of Use (MU1140)	Exclusive License	USA

Replacement Therapy

Patent No.	Patent Expiration	Title/Product	Ownership	Jurisdiction Where Granted
9,260,488	2033	Replacement Therapy for Dental Carries	Owned	USA

We have exclusively licensed the intellectual property for our MU1140 antibiotic product candidate from the UFRF. Our exclusive license agreement extends through to the patent expiration dates. See "Our In-Licensed Technology Agreements." We co-own the intellectual property for certain homologs of our MU1140 product candidate with the Texas A&M University System. We have exclusively licensed the rights of the Texas A&M University System to this intellectual property. We have an exclusive, worldwide license from Intrexon to use its technology to develop lantibiotics. We also have an exclusive worldwide license from Intrexon and its wholly owned subsidiary, Actobiotics NV to use their intellectual property to develop AG013 for the treatment of oral mucositis.

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

Our pending patent applications cover a range of technologies, including specific embodiments and applications for treatment of various medical indications, improved application methods and adjunctive utilization with other therapeutic modalities. The coverage claimed in a patent application can be significantly reduced before the patent is issued. Accordingly, we do not know whether any of the applications we acquire or license will result in the issuance of patents, or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because unissued U.S. patent applications are maintained in secrecy for a period of eighteen months and U.S. patent applications filed prior to November 29, 2000 are not disclosed until such patents are issued, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in opposition proceedings in a foreign patent office, or for United States patent applications filed before March 16, 2013, in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, or in United States *inter partes* review or post-grant review procedures, any of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that the patents, if issued, would be held valid by a court of competent jurisdiction. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology.

We have patents and patent applications in other countries, as well as in the European Patent Office that we believe provide equivalent or comparable protection for our product candidates in jurisdictions internationally that we consider to be key markets. Because of the differences in patent laws and laws concerning proprietary rights, the extent of protection provided by U.S. patents or proprietary rights owned by us may differ from that of their foreign counterparts.

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

Trademarks

Our trademarks are important to our business. We currently use the following unregistered trademarks: SMaRT Replacement Therapy™, MU1140™, IVIAT™ and CMAT™, LPT3-04™, and DPOLT™. We currently have pending with the U.S. PTO, applications for registration of the mark of ORAGENICS™ (therapeutic products; anti-infectives).

We also have rights to use other names essential to our business. Federally registered trademarks have a perpetual life, as long as they are maintained and renewed on a timely basis and used properly as trademarks, subject to the rights of third parties to seek cancellation of the trademarks if they claim priority or confusion of usage. We regard our trademarks and other proprietary rights as valuable assets and believe they have significant value to us.

Protection of Trade Secrets

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

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

Government Grants

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

Research and Development Costs

We have spent $4,754,650 and $8,733,510 on research and development of our technologies during the years ended December 31, 2016 and 2015, respectively. Approximately $5,000,000 of the 2015 research and development costs consisted of a one-time up front Technology Access Fee we paid to Intrexon in connection with the Oral Mucositis ECC in the form of our common stock.

Employees

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

Available Information

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

ITEM 1A. RISK FACTORS.

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

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 $7.0 million and $11.7 million for the years ended December 31, 2016, and 2015, respectively. As of December 31, 2016 our accumulated deficit was approximately $94.7 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 areas of lantibiotics ("Lantibiotics Program") and 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, 2016 will be sufficient to fund our operations as presently structured through May 2017. 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 may 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;
- sustain or achieve broader commercialization of our products;
- acquire or license products or technologies; 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, if needed, 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, 2016 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 May 2017. 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 products 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. To date, it has been produced only in laboratory cultures. 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. While preliminary results from these efforts have demonstrated progress in the increase in production of MU1140, we will need to contract with a third party manufacturer to produce additional quantities of each homolog in order to be able to pursue further nonclinical testing. If we are not able to 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 or any other possible antibiotic product candidates based on lantibiotics, is a highly exacting and complex process. Manufacturing MU1140 homologs 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 or any homologs thereof 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 2017. Provided sufficient capital is raised, we expect to conduct a phase 2 clinical trial on our AG013 product candidate in early 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 are based on early stage technologies in their fields.

Our exclusive channel collaboration agreements with Intrexon 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. 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. 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 new products and services by us and 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 commercialization and sale of our ProBiora3 products, 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 revenues may be materially adversely affected.

We do not have the internal capability to manufacture MU1140, 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.

There are a limited number of manufacturers that operate under GMPs that are capable of manufacturing MU1140 or our other potential lantibiotic product candidates. Manufacturing on a commercial scale has not yet been undertaken and there are additional technical skills needed for the manufacture of MU1140 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 and other 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 or our inability to successfully hire a permanent CEO 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 and nutraceutical 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 and homologs has been undertaken solely in the laboratory and in animals. We have not yet conducted human studies with any MU1140 and homolog. To date, testing of 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 and 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 pay the majority 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 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 product candidate, or any other product candidates 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 hundreds of 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 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 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.

Risks Related to Our Common Stock

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

The listing of our common stock on the NYSE MKT is contingent on our compliance with the NYSE MKT's continued listing standards. On May 10, 2015, we were notified by the NYSE MKT that we were no longer in compliance with the NYSE MKT 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 MKT 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 MKT exchange's continued listing standards set forth in Sections 1003(a)(ii) and 1003(a)(iii) of the NYSE MKT Company Guide (the "Company Guide") by November 10, 2017, subject to periodic review by the NYSE MKT for compliance with the initiatives set forth in the plan. If the Company is not in compliance with the continued listing standards by November 10, 2017, or if it does not make progress consistent with the plan during the plan period, the NYSE Regulation staff may initiate delisting proceedings as appropriate.

A delisting of our common stock from the NYSE MKT 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 December 31, 2016, the KFLP, together with members of the Koski family, beneficially owns approximately 34.5% of our outstanding shares of common stock and Intrexon, together with its CEO, beneficially owns approximately 31.5% 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.

The issuance of additional equity securities by us in the future could result in dilution to our existing 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 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 shareholders. These issuances would dilute the percentage ownership interest of our existing 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 have increased from 27,382,830 shares as of December 31, 2012 to 49,114,219 shares as of December 31, 2016.

In connection with the Lantibiotic ECC that we entered into on June 20, 2012, we could be required to issue up to additional 10% of our then outstanding shares of common stock to Intrexon upon meeting all designated commercialization milestones.

In connection with the new Oral Mucositis ECC we entered into on June 9, 2015, we will be required, at our option, to pay up to $32.0 million cash to Intrexon or issue up to $32.0 million of additional shares of our common stock to Intrexon upon meeting certain commercialization milestones. We also 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. In December of 2015, we issued 3,381,004 shares of our common stock in payment of this Convertible Note and accrued interest.

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 727,090 shares of our common stock to our executive officers and non-employee directors pursuant to performance awards under our long term incentive program which expired on December 31, 2014. During the quarter ended March 31, 2015, as part of our non-employee director compensation program we issued an aggregate of 200,000 restricted shares of our common stock to our non-employee directors under the Company's 2012 Equity Incentive Plan. During the quarter ended March 31, 2016, as part of our non-employee director compensation program we issued an aggregate of 200,000 restricted shares of our common stock 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 MKT will increase the liquidity of our common stock or that our shares will continue to be listed on the NYSE MKT.

Our common stock commenced trading on the NYSE MKT (formerly the NYSE Amex and the American Stock Exchange) on April 10, 2013, and we are subject to certain NYSE MKT 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 MKT. We may also incur costs that we have not previously incurred for expenses for compliance with the rules and requirements of the NYSE MKT. We cannot provide any assurance that we will be able to continue to satisfy the requirements of the NYSE MKT'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 27,382,830 shares as of December 31, 2012 to 49,114,219 as of December 31, 2016.

As of December 31, 2016, there were 49,114,219 shares of our common stock outstanding, with another 175,584 shares of common stock issuable upon exercise of warrants to investors, 1,621,523 shares issuable upon exercise of options outstanding and an additional 291,015 shares available for option grants under our 2012 Equity Incentive Plan. The issuance of shares of our common stock under our 2012 Equity Incentive Plan is covered by Form S-8 registration statements we filed with the Securities and Exchange Commission, or SEC, and upon exercise of the options, such shares may be resold into the market. We have also issued shares of common stock and warrants in connection with previous private placements. Such shares are available for resale as well as certain of the shares of common stock issuable upon exercise of the warrants. We have also issued shares of our common stock in the private placement and financing transaction, which are deemed to be "restricted securities," as that term is defined in Rule 144 promulgated under the Securities Act of 1933, as amended, or Securities Act, and such shares may be resold pursuant to the provisions of Rule 144. For example, on June 30, 2016 we issued 9,045,679 restricted shares of our common stock to three accredited investors (Intrexon, the KFLP and our Chairman Dr. Telling) in a private placement. The resale of shares acquired from us in private transactions could cause our stock price 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 MKT.

As a public company listed on the NYSE MKT, 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 MKT, 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 MKT.

If securities or industry analysts do not continue to 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. If one or more of the analysts who 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 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

Not applicable.

ITEM 2. PROPERTIES.

In November 2012 we entered into a new one year lease for executive offices located at 4902 Eisenhower Blvd., Suite 125, Tampa, Florida 33634. The new lease location became our principal executive office. The office space was for approximately 4,168 square feet. In October 2013 we renewed this lease through February 2017. The 12-month lease costs for the year ended December 31, 2016 were approximately $77,000 which includes insurance, taxes and utilities. Lease payments are capped during the term.

In November of 2016, the Company entered into an amendment for the leased office space in Tampa, FL. The amended lease is for approximately 2,207 square feet. The lease period for the office space is for thirty-six months commencing on March 1, 2017. Lease payments range from $4,138 per month to $4,392 per month inclusive of insurance, taxes and utilities. The lease expires on February 29, 2020.

In addition to our Tampa location we continue to lease our research facility located at 13700 Progress Boulevard, Alachua, Florida 32615. The facility is approximately 5,300 square feet of which approximately 60% is laboratory space and the remainder is office space and common areas. The 12-month lease costs for the year ended December 31, 2015 were $122,922 which includes insurance, taxes and utilities. Lease payments are capped during the term which expires in November 2019. We expect the location in Alachua, Florida to continue to be used primarily as our research and laboratory space. There were $-0- in leasehold improvements in 2015 and 2014. On July 13, 2014 we amended the lease for our Alachua, Florida facility. The lease term was extended from an expiration date of December 1, 2014 to an expiration date of November 30, 2019. The monthly lease payments are initially $10,219 per month with annual rent increases of 3%. We may terminate the lease for this facility prior to November 30, 2019 upon the payment of nine months' rent in advance. All other terms of the original lease are unchanged and remain in effect.

ITEM 3. LEGAL PROCEEDINGS.

We are not a party to any material legal proceedings and there are no material legal proceedings pending with respect to our property. We are not aware of any legal proceedings contemplated by any governmental authorities involving either us or our property. None of our Directors, officers or affiliates is an adverse party in any legal proceedings involving us, or has an interest in any proceeding which is adverse to us.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

Our common stock is quoted on the NYSE MKT under the ticker symbol "OGEN". The following table sets forth the high and low bid quotations of our common stock reflected on the NYSE MKT. 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 MKT on February 10, 2017 was $0.73 per share. As of February 10, 2017, 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.

	2016		2015	
Period	High	Low	High	Low
First quarter	$1.54	$0.75	$1.78	$0.70
Second quarter	$1.04	$0.50	$2.64	$0.66
Third quarter	$1.06	$0.43	$3.87	$1.32
Fourth quarter	$1.10	$0.33	$2.12	$1.02

Dividends

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

Stock Repurchases in the Fourth Quarter

There were no purchases of our common stock during the three months ended December 31, 2016. The Company has no publicly announced share repurchase programs.

ITEM 6. SELECTED FINANCIAL DATA.

Not applicable.

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

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

Overview

We are focused on 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 affecting up to 500,000 patients annually. OM has a negative effect on patient well-being and if severe, negatively affects 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.

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. As a result of that meeting and subject to the availability of adequate amounts of financing, we expect to file an Investigational New Drug ("IND") update in early 2017 and initiate a Phase 2 study with AG013 in the United States and Europe in 2017.

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. 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 a therapeutic agent 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. The 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.

We had selected a lead candidate, OG253, and we had a pre IND meeting with the FDA in November of 2015 regarding the pursuit of an IND on OG253. Following additional research and development on second generation lantibiotics, in August of 2016, we selected a second generation lantibiotic, OG716, for treatment of *C. diff*. OG716 is a new, orally-active homolog, that has exhibited positive results in an animal model for potential treatment of *C. diff*. Generated from our MU1140 platform, this new lantibiotic showed promising efficacy in reducing clinically relevant *C. diff* infections as measured by increased animal survival and decreased relapse as well as reduced production of *C. diff* spores 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 quarter ended June 30, 2016, we currently expect the IND for a first-in-human clinical study of OG716 to occur in 2017 as we continue to assess the promising properties of the homologs we have identified.

Our Probiotic Products

On June 27, 2016, we completed the sale of our consumer probiotics business to ProBiora Health, LLC, ("ProBiora Health") an entity owned by Ms. Christine L. Koski, a director at the time of the transaction.

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.

About Us

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 as well as to the commercialization of our consumer ProBiora3 products. We have generated limited revenues from grants and from our recently disposed of consumer ProBiora3 product business through June 30, 2016, and have principally funded our operations through the sale of debt and equity securities, including the exercise of warrants issued in connection with these financing transactions. Prior to 2008, our revenues were derived solely from research grants. Since 2008, our revenues have also included sales from our recently disposed of consumer probiotics business, which we initiated in late 2008. Our net revenues were $464,048 and $1,175,841, for the years ended December 31, 2016 and 2015, respectively. 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.

As of December 31, 2016 we had an accumulated deficit of $94,669,272 and we have yet to achieve profitability. We incurred net losses of $7,013,304 and $11,711,333 for the years ended December 31, 2016 and 2015, 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. 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 May, 2017 in order to continue to fund our operations, raise substantial doubt about our ability to continue as a going concern. There can be no assurance that additional capital will be available to us on acceptable terms, if at all. Adequate additional funding may not be available to us on acceptable terms, or at all. We expect that research and development expenses will increase along with general and administrative costs, as we grow and operate our business.

Financial Overview

Net Revenues

Our revenues were historically derived from sales of our ProBiora3 products and were $464,048 and $1,175,841 for the years ended December 31, 2016 and 2015, respectively. In June of 2016, we completed the sale of our consumer probiotics business to ProBiora Health, LLC and as a result we do not expect to generate any future revenue from sales of consumer probiotic products. These revenues are not included in net revenue but rather are reflected as part of "Discontinued Operations" for the periods presented.

Research and Development Expenses

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

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

Our research and development expenses were $4,754,650 and $8,733,510 for the years ended December 31, 2016 and 2015, respectively. Included in research and development expense for 2015 is the non-cash expense of $5,000,000 associated with an up-front payment of a technology access fee, consisting of the issuance of a convertible note to Intrexon for $5,000,000 in connection with the establishment of the Oral Mucositis ECC with Intrexon. The convertible note, including accrued interest, was repaid in December 2015 through the issuance of 3,381,004 shares of our common stock.

Our current strategy is to increase our research and development expenses in the future as we continue the advancement of our clinical trials and nonclinical product development programs for our MU1140 product candidate and with respect to our oral mucositis product candidate. The lengthy process of completing clinical trials; seeking regulatory approval for our product candidates; and expanding the claims we are able to make, requires expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenues and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Our current antibiotic product development candidate is not expected to be commercially available until we are able to obtain regulatory approval from the FDA.

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

General and Administrative Expenses

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

We anticipate that our general and administrative expenses may continue to increase for, among others, the following reasons:

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

Other Income (Expense)

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

Income Taxes

As of December 31, 2016 and 2015, we have net operating loss carryforwards of approximately $87,663,000 and $81,059,000, respectively, to offset future federal and state income taxes. We also have research and development tax credit carryforwards of approximately $1,875,000 and $1,708,000 as of December 31, 2016 and 2015, respectively, to offset future federal and state income taxes. Our net operating loss and research and development tax credit carryforwards will expire if not used by 2036 and 2026, respectively. Our ability to utilize our net operating loss and tax credit carryforwards may be limited in the event a change in ownership, as defined in Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, has occurred or may occur in the future. The private placement transaction with the KFLP in June 2009 (the "June 2009 Private Placement") constituted such an event and our historical loss carryforwards up to such point in time were limited. Furthermore, our transactions with Intrexon during 2013 constituted a second such event, and our historical loss carryforwards up to December 2013 were further limited. See "Tax Loss Carryforwards." In each period since our inception, we have recorded a 100% valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal tax benefit in our statements of operations.

Critical Accounting Estimates and Policies

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

- It requires us to make an assumption because information was not available at the time or it included matters that were highly uncertain at the time we were making the estimate; and
- Changes in the estimate or different estimates that we could have selected may have had a material impact on our financial condition or results of operations.

The principal areas of estimation reflected in the financial statements are anticipated milestone payments, stock-based compensation, valuation of warrants, and income tax.

Revenue Recognition

During the quarter ended June 30, 2016, we sold our consumer probiotic business from which we had historically generated revenues. We had recognized revenues from the sales of our consumer probiotics products when title and risk of loss had passed to the customer, which is generally when the product was shipped.

We recorded allowances for discounts and product returns at the time of sale as a reduction of revenues as such allowances can be reliably estimated based on historical experience or known trends. We maintained a return policy that allowed customers to return product within a specified period of time prior to and subsequent to the expiration date of the product. The estimate of the provision for returns was analyzed quarterly and was based upon many factors, including industry data of product return rates, historical experience of actual returns, analysis of the level of inventory in the distribution channel, if any, and reorder rates. If the history or product returns changes, the reserve would have been adjusted.

We had granted guaranteed rights of return at various times to two dental distributors for which the Company deferred recognition of revenue until the customer provided notification to us that the product had been sold to the end consumer. Once notification was received and verified, we recorded revenue in that accounting period.

Accounts Receivable

During the quarter ended June 30, 2016, we sold our consumer probiotic business. Accounts receivable had been recorded at their net realizable value and consisted of trade receivables from the sale of product to customers. We had analyzed accounts receivable on a monthly basis and determined the collectability based on the facts and circumstances relating to each customer. We had estimated the allowance for doubtful accounts based on sales trends and specific review of the creditworthiness of each customer.

Inventory

During the quarter ended June 30, 2016, we sold our consumer probiotic business. Inventories had been stated at the lower of cost or market. Cost, which had included material, labor and overhead, had been determined on a first-in, first-out basis. On a quarterly basis, we had analyzed our inventory levels and we had reserved for the following: inventory that had been expected to expire prior to being sold, inventory that had a cost basis in excess of its expected net realizable value, inventory that had been excess of expected sales requirements, or inventory that had failed to meet commercial sale specifications. Expired inventory had been disposed of and the related costs are written off to the reserve for inventory obsolescence. The inventory reserve at December 31, 2016 and 2015 was $-0- and $60,660, respectively.

Stock-Based Payment Arrangements

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

Stock-Based Compensation

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

Warrants

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

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rate is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced to estimated amounts expected to be realized by the use of a valuation allowance. Based on our historical operating losses, a valuation allowance has been recognized for all deferred tax assets.

Under US GAAP, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, GAAP provides guidance on derecognition, classification, interest and penalties, accounting for interim periods, disclosure and transition.

New Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board issued guidance on Compensation—Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting, to simplify the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Some of the areas for simplification apply only to nonpublic entities. The guidance is effective for annual and interim periods beginning after December 15, 2016. The Company is currently evaluating the effects, if any; the adoption of this guidance will have on the Company's financial statements.

In February 2016, the FASB issued guidance to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Previous leases accounting was criticized for failing to meet the needs of users of financial statements because it did not always provide a faithful representation of leasing transactions. In particular, it did not require lessees to recognize assets and liabilities arising from operating leases on the balance sheet. The guidance is effective for annual and interim periods beginning after December 15, 2018.

The Company is currently evaluating the effects, if any; the adoption of this guidance will have on the Company's financial statements.

There are no additional accounting pronouncements issued or effective during the twelve months ended December 31, 2016 that have had or are expected to have an impact on our financial statements.

Table of Contents

Results of Operations:

	Year Ended December 31,		Three Months Ended December 31,	
	2016	2015	2016	2015
Revenue, net	$ —	$ —	$ —	$ —
Cost of revenue	—	—	—	—
Gross profit	—	—	—	—
Operating expenses:				
Research, and development	4,754,650	8,733,510	1,775,875	1,340,971
General and administrative	3,787,855	3,047,354	932,033	854,880
Total operating expenses	8,542,505	11,780,864	2,707,908	2,195,851
Loss from continuing operations	(8,542,505)	(11,780,864)	(2,707,908)	(2,195,851)
Other income (expense):				
Interest income	40,090	21,378	17,536	3,983
Interest expense	(4,116)	(76,668)	(1,169)	(26,467)
Local business tax	(4,798)	(4,700)	(1,220)	(900)
Other income	14,013	776	8,578	—
Total other income (expense), net	45,189	(59,214)	23,725	(23,384)
Loss from continuing operations before income taxes	(8,497,316)	(11,840,078)	(2,684,183)	(2,219,235)
Income tax benefit	—	—		
Net loss from continuing operations	$(8,497,316)	$(11,840,078)	$ (2,684,183)	$ (2,219,235)
Discontinued operations				
Profit from operations of discontinued component	30,268	128,745	9,386	(174)
Gain on sale of discontinued operations	1,453,744	—	—	—
Income tax benefit	—	—	—	—
Profit (Loss) from discontinued operations	1,484,012	128,745	9,386	(174)
Net Loss	$(7,013,304)	$(11,711,333)	$ (2,674,797)	$ (2,219,409)

For the Three Months Ended December 31, 2016 and 2015

Research and Development. Research and development expenses were $1,775,875 for the three months ended December 31, 2016 compared to $1,340,971 in the same period in 2015; an increase of $434,904, or 32.47%. This increase was primarily due to increases in costs associated with work under the ECC's, of $644,788. These increases were partially offset by decreases in stock based compensation costs, and bonus costs of $171,062 and $54,715, respectively.

General and Administrative. General and administrative expenses were $932,033 for the three months ended December 31, 2016 compared to $854,880 in the same period in 2015; an increase of $77,153, or 9.0%. This increase was primarily due to increases in bonus costs, legal costs, and salary and salary related cost of $207,109, $83,649, and $32,766. These increases were partially offset by a decrease in consultant costs, board fees, non-employee stock based compensation, and accounting fees of $126,434, $55,499, $35,213, and $31,073 respectively.

Other Income (Expense). Other income (expense) was $23,725 for the three months ended December 31, 2016 compared to $(23,384) in the same period in 2015; a change of $47,109. The net change was primarily attributable to an increase in interest income of $13,553 due to interest on the stock subscription receivable, a decrease in interest expense of $25,298 due to decreased levels of borrowing in 2016 and an increase in miscellaneous income of $8,579.

Discontinued Operations. On June 22, 2016, we sold the assets constituting our consumer probiotic business and as such have accounted for such business as a discontinued operation. Profit (Loss) from discontinued operations was $9,386 for the three months ended December 31, 2016 compared to $(174) for the three months ended December 31, 2015, resulting in a net change of $9,560. The net change was primarily attributable to decreases in net revenues and cost of sales of $229,131 and $92,369 respectively and decreases in salary and salary related costs, selling expense costs, contract manufacturing costs, advertising and promotion costs, supplies and equipment costs, bank fees, and patents costs of $72,607, $18,451, $18,240, $11,372, $10,432, $8,872, and $2,745, respectively.

For the Years Ended December 31, 2016 and 2015

Research and Development. Research and development expenses were $4,754,650 for the year ended December 31, 2016 compared to $8,733,510 for the year ended December 31, 2015; a decrease of $3,978,860, or 45.6%. This decrease was primarily due to the payment of a $5.0 million technology access fee through the issuance of a Convertible Note Payable to Intrexon pursuant to the terms of the our new Oral Mucositis ECC during the twelve months ended December 31, 2015. There was no such payment of a Technology Access Fee to Intrexon during the twelve month period ending December 31, 2016. In addition, there was an increase costs associated with work under the ECC's of $1,513,218. This increase was partially offset by decreases in stock based compensation costs and salary and salary related costs of $434,865 and $46,873 respectively.

General and Administrative. General and administrative expenses were $3,787,855 for the year ended December 31, 2016 compared to $3,047,354 for the year ended December 31, 2015; an increase of $740,501 or 24.3%. This increase is due to increases in salary and salary related costs, legal fees, bonus costs, filing fees, non-employee stock option expense, and supplies and equipment costs of $258,263, $246,711, $207,109, $149,508, $73,256, and $21,189 respectively. These increases were partially offset by decreases in, board fees, consulting, and accounting costs of $116,250, $73,066, and $25,407, respectively.

Other Income (Expense). Other income (expense) was $45,189 for the year ended December 31, 2016 compared to $(59,214) for the year ended December 31, 2015; a change of $104,403. The net change was primarily attributable to an increase in interest income of $18,712 due to interest on the stock subscription receivable, a decrease in interest expense of $72,552 due to decreased levels of borrowing in 2016 and an increase in miscellaneous income of $17,644.

Discontinued Operations. On June 22, 2016, we sold the assets constituting our consumer probiotic business and as such have accounted for such business as a discontinued operation. Profit from discontinued operations was $30,268 for the year ended December 31, 2016 compared to $128,745 for the year ended December 31, 2015, resulting in a decrease of $98,477. The net change was primarily attributable to decreases in net revenues and cost of sales of $711,793 and $329,392 respectively and decreases in salary and salary related costs, contract manufacturing costs, clinical trial costs, selling expenses, supplies and equipment costs, bank fees, stock based compensation costs, patent costs, and travel and entertainment costs of $151,916, $29,353, $21,341, $20,139, $16,161, $14,018, $13,377, $11,025 and $7,280 respectively.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through the sale of equity securities in our initial public offering, the sale of equity securities and warrants in private placements, debt financing and grants. The following table sets forth the primary sources and uses of cash for each of the periods indicated:

	Years ended December 31,	
	2016	2015
Net cash provided by (used in) operating activities	$(7,075,085)	$(5,189,490)
Net cash provided by (used in) investing activities	1,675,019	(101,231)
Net cash provided by (used in) financing activities	4,451,484	(159,950)
Net decrease in cash and cash equivalents	$ (948,582)	$(5,450,671)

During the years ended December 31, 2016 and 2015, our operating cash flows from discontinued operations used cash of $54,155 and provided cash of $85,105 respectively. The use of cash in all periods primarily resulted from our net losses adjusted for non-cash items and changes in operating assets and liabilities. We had working capital surplus of $2,878,261 and $4,590,374 as of December 31, 2016 and 2015, respectively.

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

Financings

The June 30, 2016 Private Placement

One June 30, 2016, we closed on a private placement of 9,045,679 shares of our common stock to three accredited investors. The investors in the private placement included some of our current shareholders, the Koski Family Limited Partnership ("KFLP"), Intrexon Corporation, as well as our Chairman, Dr. Frederick Telling. Approximately $4.667 million was raised of which $2 million was payable under a note payable by the KFLP which was due on or before September 30, 2016. The note accrued interest at 3% per annum. The purchase price per share of the common stock sold in the private placement was $0.5159, which was the midpoint of the closing quote on the Company's primary exchange, NYSE MKT, on June 29, 2016 as required by NYSE listing standards. We will use the net proceeds, after payment of offering expenses, for the funding of research and development activities related to the Intrexon Exclusive Channel Collaborations and for general corporate purposes.

On September 15, 2016, the note payable with the KFLP was amended. Under the terms of the amendment, the KFLP paid $1,000,000 on September 30, 2016 which was first applied to accrued interest and then to the outstanding principal balance. The amendment extended the maturity date on the remaining balance of the note payable to, on or before, December 31, 2016 and increased the interest rate on the note payable from 3% per annum to 6% per annum commencing on the date of the amendment. On December 29, 2016, the KFLP made a payment of $1,000,000 which was applied to accrued interest and then to the outstanding principal balance. The remaining balance of the Note was paid in full in January of 2017.

The June 2015 Convertible Note Payable

On June 9, 2015, we entered into an unsecured short-term Convertible Promissory Note in the principal amount of $5,000,000 bearing interest at 3.00% as consideration for the Technology Access Fees associated with the Oral Mucositis ECC entered into with Intrexon. The Convertible Promissory Note was payable, at the Company's option, in cash or shares of the Company's common stock. Principal and accrued interest were due on December 31, 2015. On December 1, 2015, the outstanding principal and accrued interest under the Convertible Note Payable was repaid through the issuance of 3,381,004 shares of our common stock.

Other Financings

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

On March 20, 2014, we entered into a short-term note payable for $50,694 bearing interest at 6.57% per annum to finance the product liability insurance. Principal and interest payments on this note began April 10, 2013 and are made evenly based on a straight line amortization over a 10-month period with the final payment being made on January 10, 2015.

On July 24, 2014, we entered into a short-term note payable for $108,306 bearing interest at 4.64% to finance the director and officers and employment practices liability insurance premiums. Principal and interest payments on this note began August 24, 2014 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on June 24, 2015.

On March 19, 2015, we entered into a short-term note payable for $49,395 bearing interest at 5.68% per annum to finance the product liability insurance. Principal and interest payments on this note began April 16, 2015 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on January 16, 2016.

On July 28, 2015, the Company entered into a short-term note payable for $109,067 bearing interest at 4.64% to finance a portion of the directors' and officers' liability insurance and employment practices liability insurance premiums. Principal and interest payments on this note began August 24, 2015 and are made evenly based on a straight line amortization over an 11-month period with the final payment due on June 24, 2016.

On March 1, 2016, we entered into a short-term note payable for $49,395 bearing interest at 5.93% per annum to finance the product liability insurance. Principal and interest payments on this note began April 10, 2016 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on January 10, 2017.

On July 24, 2016, we entered into a short-term note payable for $111,730 bearing interest at 4.89% per annum to finance a portion of the directors' and officers' liability insurance and employment practices liability insurance premiums. Principal and interest payments on this note begin August 24, 2016 and are made evenly based on a straight line amortization over an 11-month period with the final payment being due June 24, 2017.

Future Capital Requirements

Our capital requirements for 2017 will depend on numerous factors, including the success of our commercialization efforts and of our research and development, the resources we devote to develop and support our technologies and our success in pursuing strategic licensing and funded product development relationships with external partners. Subject to our ability to raise additional capital including through possible joint ventures and/or partnerships, we expect to incur substantial expenditures to further commercialize or develop our technologies including continued increases in costs related to research, nonclinical testing and clinical studies, as well as costs associated with our capital raising efforts and being a public company. We will require substantial funds to conduct research and development and nonclinical and Phase 1 and Phase 2 clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase 2 and 3 clinical testing and manufacture and marketing of any products that are approved for commercial sale. Our plans include seeking both equity and debt financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to ensure continuation of our operations and research and development programs.

Our current available cash and cash equivalents are insufficient to satisfy our liquidity requirements. We believe our existing cash and cash equivalents will allow us to only fund our operating plan through May 2017. We expect to continue to seek additional funding for our operations. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned clinical testing, research and development and commercialization activities, which could harm our business. The sale of additional equity or debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We also will require additional capital beyond our currently forecasted amounts. For example, as we continue to work with Intrexon under the Lantibiotic ECC for the development of MU1140 homologs and in our Oral Mucositis ECC, we will require additional capital.

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

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting nonclinical and clinical trials including the research and development expenditures we expect to make in connection with our collaboration agreements with Intrexon;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- our ability to maintain current research and development licensing agreements and to establish new strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- our ability to achieve our milestones under our ECC agreements and licensing arrangements and the payment obligations we may have;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our products and future products, if any.

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

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Tax Loss and Credit Carryforwards

As of December 31, 2016 and 2015, we have net operating loss carryforwards of approximately $87,663,000 and $81,059,000, respectively, to offset future federal and state income taxes. We also have research and development tax credit carryforwards of approximately $1,875,000 and $1,708,000 as of December 31, 2016 and 2015, respectively, to offset future federal and state income taxes. Our net operating loss and research and development tax credit carryforwards will expire if not used by 2036 and 2026, respectively. Any greater than 50% change in ownership under Section 382 of the Internal Revenue Code, or the Code, places significant annual limitations on the use of such net operating loss carryforwards and we exceeded the 50% threshold when we consummated the June 2009 private placement transaction with the Koski Family Limited Partnership, or KFLP, in June 2009. Subsequent to this event, we again exceeded the 50% threshold when we executed transactions with Intrexon in December 2013. As a result, our loss carryforwards incurred from July 2009 through December 2013 will be limited to approximately $3,540,000 per year. Our historical loss carryforwards through June 2009 will be limited to approximately $417,000 per year. We anticipate that this will effectively limit our ability to utilize our historical loss carryforwards through June 2009 to an aggregate amount of approximately $6,285,000 over such period of time, and the remaining balance of our historical loss carryforwards prior to June 2009 will expire unused. We also anticipate that this limitation will effectively cause all of our tax credit carryforwards through June 2009 to expire unused. We do not anticipate that the December 2013 limitation will cause any of our loss carryforwards or tax credits incurred July 2009 through December 2013 to expire unused. Provided that there are no future ownership changes that would trigger the limitations on loss carryforwards provided under the Code, the operating losses we experience after December 2013 are expected to add to our loss carryforwards and to be fully available to us.

At December 31, 2016 and 2015, we recorded a 100% valuation allowance against our deferred tax assets of approximately $33,787,000 and $31,199,000, respectively, as our management believes it is uncertain that they will be fully realized. If we determine in the future that we will be able to realize all or a portion of our net operating loss carryforwards, an adjustment to our net operating loss carryforwards would increase net income in the period in which we make such a determination.

Inflation

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

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

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

The Financial Statements are incorporated herein by reference to pages F-1 to F-22 at the end of this report and the supplementary data is not applicable.

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

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures

Management's evaluation of the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act was performed under the supervision and participation of our senior management, including our Chief Executive Officer and Chief Financial Officer. The purpose of disclosure controls and procedures is to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures. Based upon that evaluation, our Chief Executive Officer and Chief Financial; Officer concluded that, as of the end of such period, our disclosure controls and procedures were effective as of December 31, 2016 in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported with the time periods specified in the Securities and exchange Commission's rules and forms. Management believes that, existing controls were effective and operating properly as designed. During 2016, management believes that the Company maintained a consistent and verifiable financial reporting organization and internal control procedures.

Changes in Internal Controls over Financial Reporting

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

Limitations on the Effectiveness of Controls

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

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

Chief Executive Officer and Chief Financial Officer Certification

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

Management's Report on Internal Control over Financial Reporting

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

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

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

Our management, under the supervision of the Chief Executive Officer and the Chief Financial Officer, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2016. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework (1992)* as updated in May of 2013, (the "2013 COSO Framework"). We integrated the changes prescribed by the 2013 COSO Framework into our internal controls over financial reporting during the year ending December 31, 2015. We also used SEC guidance on conducting such assessments. Based on our assessment, we believe that, as of December 31, 2016, the Company's internal control over financial reporting was effective.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

ITEM 9B. OTHER INFORMATION.

ITEM 9B Other Events INSERT

The disclosure set forth below is provided in lieu of a separate Form 8-K filing.

Annual Meeting - Shareholder Director Nominations. The Board of Directors of the Company has established May 4, 2017, as the date of the Company's 2017 Annual Meeting of Shareholders (the "2017 Annual Meeting"). Because the date of the 2016 Annual Meeting has advanced by more than 30 days from the anniversary date of the Company's 2016 Annual Meeting of Stockholders (the "2016 Annual Meeting"), in accordance with Rule 14a-5(f) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Company is informing shareholders of such change. The record date, time and location of the 2017 Annual Meeting will be as set forth in the Company's proxy statement for the 2017 Annual Meeting.

Because the date of the 2017 Annual Meeting has been changed by more than 30 days from the anniversary of the 2016 Annual Meeting of Shareholders, a new deadline has been set for submission of proposals by Shareholders intended to be included in the Company's 2017 proxy statement and form of proxy. Proposals to be included in the Company's proxy statement for the 2017 Annual Meeting in accordance with Rule 14a-8 under the Exchange Act, must be received by the Company on or before March 10, 2017, which the Company believes is a reasonable time before it expects to begin to print and send its proxy materials. Shareholders must deliver the proposals or nominations to the Company's principal executive offices at the following address: Oragenics, Inc., Attn: Corporate Secretary, 4902 Eisenhower Boulevard, Suite 125, Tampa, Florida 33634.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Management

Our Board of Directors, executive officers, and key employees are as follows:

Name	Age	Position
Dr. Frederick W. Telling, Ph.D.	65	Chairman and Director
Robert C. Koski	57	Director
Alan Joslyn, Ph.D	57	President, Chief Executive Officer and Director
Charles L. Pope	64	Director
Dr. Alan W. Dunton, M.D.	62	Director
Michael Sullivan	60	Chief Financial Officer, Secretary and Treasurer
Dr. Martin Handfield	45	Senior Vice President of Discovery Research

Directors of the Company

Dr. Frederick W. Telling. Dr. Telling was elected Chairman of the Board of Directors on February 4, 2011. He has served as a Director since June 2010. Dr. Telling retired from Pfizer Inc. in June 2007 after 30 years of service. At Pfizer Dr. Telling served as its Corporate Vice President and Vice President of Corporate Strategic Planning and Policy. Dr. Telling also serves as a director, the Chair of the Compensation Committee and a member of the Audit Committee at CTI BioPharma, Inc. (NASDAQ: CTIC), a public company based in Seattle, Washington. Dr. Telling also serves on the boards of various civic and non-profit organizations. Dr. Telling holds a B.A. degree in History and Economics from Hamilton College and a MA degree in Industrial and Labor Relations and a PhD in Economics and Public Policy from Cornell University.

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

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

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

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

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

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

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

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

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

Executive Management

Alan F. Joslyn, Ph.D. The biography of Dr. Joslyn is included above under Directors of the Company.

Michael Sullivan. Mr. Sullivan, age 60, has served as our Interim Principal Executive Officer from October 30, 2014 until June 5, 2016 and served as our Chief Financial Officer, Secretary and Treasurer since February 6, 2012. Mr. Sullivan has held senior level financial positions for several publicly and privately held businesses including Utek Corporation, eANGLER, and HSN Direct International Limited. Most recently, he was the Group Financial Officer for the Investigative Services and Litigation Consulting Services segment of First Advantage Corporation a firm specializing in talent acquisition solutions where he streamlined the employee recruitment process. Mr. Sullivan is a Florida Certified Public Accountant. He graduated from the Florida State University with a Bachelor of Science in Accounting and a Master of Business Administration.

Key Employee

Dr. Martin Handfield. Dr. Handfield, age 45, is, the Company's Senior Vice President of Discovery Research and previously has served as our Director of Research and Development. Dr. Handfield has served the Company since January 2009. Prior to joining our Company, Dr. Handfield held a position as Tenured Associate Professor at the Center for Molecular Microbiology and the Department of Oral Biology at the University of Florida College of Dentistry, where he co-invented IVIAT and co-founded *ivi* Gene Corp. and Epicure Corp. to commercialize this and related technologies. Dr. Handfield holds a B.S. degree in Biochemistry, and a MS degree and PhD in Microbiology and Immunology from the Université Laval College of Medicine in Canada, and did postdoctoral training at the University of Florida.

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

Board of Directors and Committees

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

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

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

Independence of Directors

Our common stock is listed on a national securities exchange, the NYSE MKT. Accordingly, in determining whether our Directors are independent, we are required to comply with the rules of the NYSE MKT. We also expect to continue to comply with securities and other laws and regulations regarding the independence of directors, including those adopted under Section 301 of the Sarbanes-Oxley Act and Rule 10A-3 under the Securities and Exchange Act of 1934 with respect to the independence of Audit Committee members. The NYSE MKT listing standards define an "independent director" generally as a person, other than an officer of a company, who does not, in the view of the company's Board of Directors, have a relationship with the company that would interfere with the director's exercise of independent judgment. As of June 24, 2016, the Board has affirmatively determined that each of the following directors, constituting a majority of the Board, is independent within the meaning of the NYSE MKT listing standards:

Dr. Frederick W. Telling
Charles L. Pope
Dr. Alan Dunton

As of June 24, 2016 the Board also determined that Robert Koski was no longer independent as a result of the consumer probiotic transaction with Christine Koski, his sister. Such independence definition includes a series of objective tests, including that the director is not an executive officer employee of the company and has not engaged in various types of business dealings with the company. In addition, as further required by the NYSE MKT listing standards, the Board has made a subjective determination as to each independent director that no relationships exist which, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit Committee Financial Expert

The Audit Committee members currently consist of Mr. Charles Pope, Dr. Frederick Telling and Dr. Alan Dunton with Mr. Pope serving as Chairman. The Board has affirmatively determined that each such person met the independence requirements for audit committee purposes based on the more stringent independence standards imposed by applicable NYSE MKT and SEC rules. In addition, the Board of Directors has determined that Mr. Pope is an "audit committee financial expert" as that term is defined in Item 407(d)(5) of Regulation S-K promulgated under the Securities and Exchange Act of 1934. In March 2004, the Audit Committee adopted a written charter which was modified on April 24, 2007 and on December 29, 2009. The Company believes that its Audit Committee Charter complies with the requirements related to Sarbanes-Oxley and a current copy of the Audit Committee Charter is available on our website http://ir.oragenics.com/governance-docs. The Audit Committee met unanimously or consented to resolutions four times during Fiscal 2016.

Code of Ethics

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

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires the Company's officers and Directors and any persons who beneficially own more than ten percent of the Company's Common Stock to file reports of ownership and changes in ownership of such securities with the Securities and Exchange Commission Officers, Directors and beneficial owners of more than ten percent of the Common Stock are required by applicable regulations to furnish the Company with copies of all Section 16(a) forms they file. Based solely on its review of copies of forms furnished to the Company and written representations from the executive officers, directors and holders of ten percent or more of the Company's Common Stock, the Company believes, all persons subject to the reporting requirements with regard to the Common Stock complied with the applicable filing requirements during 2016.

ITEM 11. EXECUTIVE COMPENSATION

Director Compensation

The Director compensation program for 2016 consisted of the following:

Non-employee directors

Cash Compensation. The Director compensation program for 2016 provided that all non-employee Directors would receive an annual base fee for service on the Board of $45,000. In addition, the Chairperson of the Board and of our Audit Committee, Compensation Committee and Nominating Committee would also receive annual fees of $40,000, $20,000, $15,000 and $10,000, respectively. All non-employee Directors serving on our Audit Committee, Compensation Committee and Nominating Committee (other than as the Chairperson) would receive an annual fee of $10,000, $7,500, and $5,000, respectively, in connection with such committee service. In addition, from time to time, the Board may establish special committees and in connection therewith determine the cash compensation that would be paid to the directors serving on a special committee at the time of the establishment of such committee. All fees for Board service are to be paid on or before the last business day of each quarter.

The Board is expecting to meet in-person for a minimum of six meetings each year. To the extent, the Board meets in excess of six in-person meetings an additional per meeting fee would also be considered to be paid to each director by the Board for such additional in-person meeting. To the extent the Board determines to establish a special committee or a special committee was previously established and continues to function, the Board would determine the cash compensation payable to each director serving on any such special committee.

Equity Compensation. Equity compensation is issued to Directors upon joining our Board. Non-employee Directors receive a stock option for the purchase of 5,000 shares of our common stock at an exercise price per share equal to the fair market value per share on date they became a Director, which will immediately vest and be exercisable for ten years, subject to early termination under the terms of the 2012 Equity Incentive Plan. As part of the Director compensation program, the Board may also make discretionary equity based awards from time to time under the Company's 2012 Equity Incentive Plan.

On February 15, 2016, the Board approved stock option awards in the amount of 80,000, to each of the Company's non-employee directors, under the Company's 2012 Equity Incentive Plan at an exercise price of $0.84 per share, the closing price on the February 16, 2016, the date of grant. In addition, each of the Company's non-employee directors were also awarded 40,000 restricted shares of Company common stock under the Company's 2012 Equity Incentive Plan of which 10,000 restricted shares vested at the end of each calendar quarter in 2016. The options are subject to time-based vesting in equal annual installments over a two-year period on the first and second anniversaries of the date of the grant, provided that the recipient remains a director of the Company through the vesting dates. The stock option and restricted stock awards are subject to the standard terms and conditions of the Company's form of stock option and restricted stock agreements which include earlier vesting upon a change in control of the Company.

Minimum dollar value stock ownership requirements. Each non-employee director receiving the above equity based awards will be subject to a minimum dollar value stock ownership holding requirement with respect to the awards received as well as all prior equity awards under the 2012 Equity Incentive Plan which requirement is intended to align the ability to sell shares with the performance of the Company's stock price. The non-employee Directors will each be subject to a minimum dollar value stock ownership requirement equal to six times the annual Board retainer ($270,000) below which dollar threshold they would be precluded from selling shares of Company stock acquired from the Company under its 2012 Equity Incentive Plan.

Reimbursement of Expenses. Non-employee Directors are also reimbursed for expenses incurred in connection with their attendance at Board or committee meetings and reasonable out-of-pocket business expenses associated with their Board service.

Long-term Incentive Compensation. The Company did not have a Long Term Incentive Compensation plan in place performance in 2016 for its Non-Employee Directors.

The following table sets forth the compensation of our non-employee Directors in 2016.

Director Compensation Table

Name	Fees earned or paid in cash(1)	Stock Awards(2)	Option awards(3)	All other compensation(4)	Total
Dr. Frederick W. Telling	$ 142,970	$ 33,600	$ 78,059	$ —	$254,629
Robert C. Koski	$ 47,498	$ 33,600	$ 78,059	$ —	$159,157
Charles L. Pope	$ 106,250	$ 33,600	$ 78,059	$ —	$217,909
Dr. Alan W. Dunton	$ 74,781	$ 33,600	$ 78,059	$ —	$186,440
Christine L. Koski(5)	$ 26,250	$ 16,800	$119,321	$ —	$162,371

(1) Amounts represent cash compensation earned by Directors during 2016 in connection with their Board service including service in connection with special committees established by the Board. The amount of fees earned by Director's Telling, Dunton, and Pope in connection with special committee service was $36,094, $1,031, and $28,125, respectively.

(2) As part of the Company's non-employee Director compensation program each non-employee was granted an award of 40,000 restricted shares of Company common stock under the Company's 2012 Equity Incentive Plan, of which 10,000 restricted shares vested at the end of each calendar quarter in 2016. The grant date fair value of these shares was $0.84 per share.

(3) As part of the Company's non-employee Director compensation program each non-employee was awarded 80,000 stock options, under the Company's 2012 Equity Incentive Plan at an exercise price of $0.84 per share, the closing price on the March 16, 2016, the date of grant. The options are subject to time-based vesting in equal annual installments over a two-year period on the first and, second anniversaries of the date of the grant, provided that the recipient remains a director of the Company through the vesting dates.

(4) No other compensation was paid to the non-employee Directors except for reimbursement for travel expenses to Board meetings and other Board related meetings.

(5) Ms. Koski resigned from our Board in connection with the consummation of the sale of our consumer probiotic business to an entity she wholly owned. See Certain Relationships and Related Party Transactions — Sale of Consumer Probiotic Business.

Employee Directors

The Director Compensation program provides that employee Directors receive no additional compensation in connection with their board service.

Executive Compensation

Compensation Practices and Risk

The following "Compensation Discussion and Analysis" section describes generally our compensation policies and practices that are applicable for executive and management employees. We use common variable compensation designs across all of our business units and divisions, with a significant focus on corporate and business financial performance as generally described in this Proxy Statement.

Table of Contents

Compensation Discussion and Analysis

The Compensation Committee of the Company's Board of Directors is responsible for establishing and evaluating the Company's policies governing the compensation of its executive officers, including its named executive officers. The Compensation Committee reviews and proposes recommendations to the Board of Directors regarding the compensation to be paid to the Chief Executive Officer. In addition, the Compensation Committee reviews and approves the compensation to be paid to all other executive officers. The Compensation Committee ensures that the total compensation paid to the Company's executive officers is fair, reasonable and competitive.

Compensation Objective

The Company's executive compensation programs are designed to achieve the following objectives:

- Attract and retain talented and experienced executive officers;
- Motivate and reward executive officers whose knowledge, skills, performance and business relationships are critical to the Company's success;
- Align the interests of the Company's executive officers and shareholders by motivating executive officers to ultimately increase shareholder value;
- Compensate the Company's executive officers to manage the Company's business to meet its short term and long-range goals;
- Ensure fairness among the executive officers by recognizing the contributions each executive officer makes to the Company's success; and
- Provide a competitive compensation package which includes some pay for performance factors.

Role of Others in Compensation Decisions

The Compensation Committee makes all of the decisions with respect to the compensation received by the Company's executive officers other than the Company's chief executive officer which the Committee reviews and proposes recommendations to the Board of Directors. The Compensation Committee meets outside the presence of all of the Company's executive officers to consider appropriate compensation recommendations for the Company's chief executive officer. For all other executive officers, the Compensation Committee meets outside the presence of all executive officers except for the Company's chief executive officer. The Company's chief executive officer periodically reviews each of the other executive officers' performance with the Compensation Committee and makes recommendations to the Compensation Committee with respect to any appropriate changes in base salary, bonus and grants of long-term equity incentive awards for the executive officers, excluding himself. Based in part on these recommendations and other considerations, the Compensation Committee reviews and approves such compensation arrangements of the Company's executive officers other than the Company's chief executive officer. The Compensation Committee also annually analyzes the chief executive officer's performance and determines his salary, annual cash bonus and grants of long-term equity incentive awards and makes recommendations to the Board of Directors. The Compensation Committee reviews and makes recommendation to the Board of Directors regarding all new equity related incentive plans for senior management.

Consideration of Most Recent Shareholder Advisory Vote on Executive Compensation

The Compensation Committee also considers the results of the Company's most recent shareholder advisory vote on executive compensation. At the 2016 Annual Meeting, the Company's shareholders voted overwhelmingly in favor of the compensation of our named executive officers: approximately 85.4% of the shares outstanding voted in favor of the program. In light of these results, the Compensation Committee decided to continue to include in the 2016 executive compensation program all of the features previously approved by the Company's shareholders. The Board of Directors previously determined that future shareholder advisory votes on executive compensation will be submitted to shareholders of the Company annually until the next required advisory vote on the frequency of conducting advisory votes on executive compensation.

Clawback Policy

In order to further align management's interests with those of shareholders and to support the Company's governance practices, the Board of Directors adopted a recoupment policy applicable to annual bonuses and other short-term and long-term incentive compensation based on financial targets ("Incentive Compensation") received by current and former executive officers of the Company and such other senior executives/employees of the Company who may from time to time be deemed subject to the policy by the Board of Directors ("Covered Executive"). The policy provides that if, as a result of a restatement of the Company's financial statements due to the Company's material noncompliance with any financial reporting requirement under the securities laws, a Covered Executive received more Incentive Compensation than the Covered Executive would have received absent the incorrect financial statements, the Company shall recover said excess Incentive Compensation (defined as the excess of (i) the actual amount of Incentive Compensation paid to the Covered Executive over (ii) the Incentive Compensation that would have been paid based on the restated financial results during the three-year period preceding the date on which the Company is required to prepare such restatement). The policy also provides that if the Board of Directors makes a determination in its sole discretion that a Covered Executive engaged in Misconduct (as defined below), the Board of Directors may require reimbursement or forfeiture of all or part of the Incentive Compensation received by the Covered Executive. The Board of Directors may use its judgment in determining the amount to be recovered. Misconduct is defined as (i) conviction of a felony, (ii) material breach of any agreement with the Company, (iii) material breach of any Company policy or code, (iv) act of theft, embezzlement or fraud, (v) misrepresentation or misstatement of financial or performance results, and (vi) any other act or event that the Board of Directors has determined that recoupment is appropriate.

2016 Executive Compensation Components

For the fiscal year ended December 31, 2016, the principal components of compensation for the Company's executive officers were:

- Annual base salary;
- Bonus;
- Long-term equity based incentive compensation;
- Other benefits.

Annual Base Salary

Base salary is designed to attract and retain experienced executive officers who can drive the achievement of the Company's goals. While the initial base salary for the Company's executive officers was determined by an assessment based upon the responsibilities of the position, the expected contribution of the position to our business, the experience and skill required for the position, and competition in the marketplace for the talent; the factors used in determining increases in base salary include individual performance, changes in role and/or responsibility and changes in the competitive market environment. The Compensation Committee periodically reviews the base salary for each executive officer.

Bonus

The Company established a formal performance based bonus for its named executive officers. See "Bonus Plan 2016" below for a description of the bonus program for 2016. Discretionary bonuses for executive officers and employees may also be considered by the Compensation Committee and recommended at the discretion of the Compensation Committee for approval by our Board of Directors.

Long-Term Equity Incentive Compensation

The Company awards long-term equity incentive awards to executive officers, including the named executive officers, as part of its total compensation package. These awards are consistent with the Company's pay for performance principles and align the interests of the executive officers to the interests of the Company's shareholders. The Compensation Committee reviews and approves the amount of each award to be granted to each named executive officer. Long-term equity incentive awards are made pursuant to the 2012 Equity Incentive Plan.

The Company's long-term equity incentives are currently in the form of options to acquire its common stock. Stock option awards provide the Company's executive officers with the right to purchase shares of its common stock at a fixed exercise price for a period of up to ten years under the 2012 Equity Incentive Plan. Stock options are granted under the 2012 Equity Incentive Plan at a price not less than the prevailing market value at the time of grant and will have realizable value only if the Company's stock price increases. Stock options are earned on the basis of continued service to the Company and generally vest over a number of years or based upon other specific performance based criteria.

The Company's long-term equity incentive also can be in the form of restricted share awards of the Company's common stock under the 2012 Equity Incentive Plan. Restricted stock awards provide the Company's executive officers with the shares of its common stock subject to certain restrictions and/or vesting requirements. Restricted stock shares will be earned on the basis of continued service to the Company and will vest as set forth in the separate award agreements.

The Compensation Committee determines the amount and features of the stock options and/or restricted stock, if any, to be awarded to executive officers. The Compensation Committee evaluates a number of criteria, including the past service of each such executive officer to the Company, the present and potential contributions of such executive officer to the Company's success and such other factors as the Compensation Committee shall deem relevant in connection with accomplishing the purposes of the 2012 Equity Incentive Plan, including the executive officer's current stock holdings, years of service, position with the Company and other factors. The Compensation Committee may apply a formula assigning specific weights to any of these factors when making its determination.

Other Benefits

Retirement Benefits. The Company maintains a Simple Individual Retirement Arrangement plan in which all full-time employees, including the Company's named executive officers, are eligible to participate. The Company provides this plan to help its employees save some amount of their cash compensation for retirement in a tax efficient manner. The Company does not provide an option for its employees to invest in the Company's stock under the 401k plan. The Company matches 100% of the employee's contribution up to a maximum of 3% of the employee's compensation.

Health and Welfare Benefits. All full-time employees, including our named executive officers, may participate in the Company's health and welfare benefit programs, including medical, dental and vision care coverage as may be provided and applicable to all employees.

Perquisites. Because the Company provides limited perquisites to certain executive officers, the Company does not believe these perquisites and other personal benefits constitute a material component of the executive officers' compensation packages.

Employment Agreements

During 2016, the Company had employment agreements in effect with Dr. Alan Joslyn, Mr. Michael Sullivan, and Dr. Martin Handfield. The Company entered into employment agreements with these officers to ensure that they would perform their respective roles with the Company for an extended period of time. In addition, the Company also considered the critical nature of each of their positions and the Company's need to retain them when the Company committed to these agreements. See "Employment Contracts and Change in Control Arrangements."

Bonus Plan 2016

On August 25, 2016, the Board of Directors (the "Board")of Oragenics, Inc. (the "Company") approved the 2016 cash bonus program for Dr. Joslyn, Mr. Sullivan, and Dr. Handfield recommended by the Compensation Committee. Under such cash bonus program Dr. Joslyn, Mr. Sullivan, and Dr. Handfield are eligible for cash bonuses of up to $102,083, $76,650, and $48,900 respectively, equaling up to 50%, 35%, and 25% of their respective base salaries (each a "Bonus Target"). In the case of Dr. Joslyn his bonus amount represents a portion of his base salary for the time since he joined the Company

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

(i) Up to 40% of the Bonus Target for meeting budgeted operational objectives and developing corporate organizational strategy;

(ii) Up to 30% of the Bonus Target for financial performance objectives related to the Company's raising capital;

(iii) Up to 10% of the Bonus Target for objectives related to AG013 clinical trial;

(iv) Up to 10% of the Bonus Target for research and development objectives related to lantibiotics; and

(v) Up to 10% of the Bonus Target designated to be discretionary as determined by the Board.

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

(i) Up to 40% of the Bonus Target for meeting budgeted operational objectives including as to the consumer probiotic business;

(iii) Up to 40% of the Bonus Target for financial performance objectives related to the Company's raising capital and finalizing an approved budget and incentive plan for 2017;

(iii) Up to 10% of the Bonus Target related to investor relations and securities compliance matters; and

(iv) Up to 10% of the Bonus Target designated to be discretionary as determined by the Board.

Each of Dr. Joslyn and Mr. Sullivan were also eligible for an additional 10% of Bonus Target should capital raise thresholds be exceeded.

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

(i) Up to 20% of the Bonus Target for meeting operational objectives tied to management of staff for approved budgets and timelines;

(ii) Up to 12.5% of the Bonus Target for financial performance objectives related to the Company's intellectual property;

(iii) Up to 50% of the Bonus Target for various research and development objectives related to lantibiotics including manufacturing and compound identification;

(iv) Up to 2.5% of the Bonus Target for additional research projects; and

(v) Up to 10% of the Bonus Target designated to be discretionary as determined by the Board.

Dr. Handfield was also eligible for an additional 10% of Bonus Target should the manufacturing run be completed by a designated time as well as certain request for proposal and protocols being in place.

2016 Compensation Decisions

The Company believes that the total compensation paid to its named executive officers for the fiscal year ended December 31, 2016 achieved the overall objectives of its executive compensation program. In accordance with its overall objectives, executive compensation for 2016 was competitive with other similarly-sized companies. The Compensation Committee took the following key compensation actions in 2016:

- ***Determination of Annual Base Salaries***

The Compensation Committee did not authorize or approve any changes in the annual salary for any of the Company's named executive officers during 2016.

- ***Determination of Equity Awards*:**

During the year ended December 31, 2016, we made no stock awards to our named executive officers other than Dr. Joslyn upon commencement of his services to us as President and Chief Executive Officer.

- ***Determination of Cash Bonus***:

The Compensation Committee established a performance based 2016 bonus plan for the named executive officers pursuant to the terms of their employment agreements. The Committee subsequently approved bonus awards to the named executive officers based on such bonus plan in the amounts set forth in the Summary Compensation Table below:

Summary Compensation Table

The following table sets forth the aggregate compensation in 2016 and 2015 for services in all capacities paid or accrued by the Company to Dr. Alan Joslyn, Mr. Michael Sullivan, our Chief Financial Officer who also served as our interim principal executive officer through June of 2016, and our two next most highly compensated officers who earned more than $100,000 in total salary and bonus during the fiscal year ended December 31, 2016 (the "Named Executive Officers").

Name and principal position	Year	Salary	Bonus	Stock Awards(4)	Option Awards(4)	All Other Compensation(5)	Total
Dr. Alan Joslyn(1)	2016	$200,353	$ 91,500	$ 14,038	$ 79,666	$ 4,812	$390,369
President and Chief Executive Officer	2015	$ —	$ —	$ —	$ —	$ —	$ —
Michael O. Sullivan(2)	2016	$219,000	$100,000	$ —	$ 73,366	$ 6,570	$398,936
Chief Financial Officer Interim Principal Executive Officer	2015	$219,000	$ 41,391	$ —	$ 152,199	$ 6,570	$419,160
Dr. Martin Handfield(3)	2016	$195,600	$ 57,500	$ —	$ 54	$ 5,868	$259,022
Senior Vice President of Discovery Research	2015	$195,600	$ 20,783	$ —	$ 228,288	$ 5,508	$450,179

(1) Dr. Joslyn became our President and Chief Executive Officer on June 6, 2016. Pursuant to the terms of Dr. Joslyn's employment agreement, the Board of Directors adopted a bonus plan for the achievement of certain financial and other performance objectives. See "Employment Agreements – Dr. Joslyn, Mr. Sullivan, and Dr. Handfield" and "Bonus Plan 2016" for discussion of the bonus plan. Under the bonus plan Dr. Joslyn was awarded a bonus of $66,500 for 2016. In addition, and pursuant to the terms of Dr. Joslyn's employment agreement Dr. Joslyn was awarded and paid a signing bonus of $25,000.

(2) Mr. Sullivan became our Chief Financial Officer on February 6, 2012 and served as our Interim Principal Executive Officer between October 30, 2014 and the time Dr. Joslyn was appointed as our Chief Executive Officer in June 2016. Pursuant to the terms of Mr. Sullivan's employment agreement, the Board of Directors adopted a bonus plan for the achievement of certain financial and other performance objectives. See "Employment Agreements – Mr. Sullivan, and Dr. Handfield" and "Bonus Plan 2016" for discussion of the bonus plan. Under the bonus plan Mr. Sullivan was awarded a bonus of $50,000 for 2016. In addition, Mr. Sullivan was awarded and paid a bonus of $50,000 for his increased responsibilities and duties while serving as the Company's Interim Principal Executive Officer.

(3) Under the bonus plan Dr. Handfield was awarded a bonus of $57,500 for 2016.

(4) The amounts in this column represent the aggregate grant date fair value computed in accordance with Financial Accounting Standards Board Accounting Standards Codification, Topic 718, Compensation—Stock Compensation (ASC 718). On June 6, 2016, Dr. Joslyn was awarded stock options of 300,000 shares under the 2012 Equity Plan. The exercise price for these options was $0.55 per share and was based on the closing price on the grant date. These options are subject to vesting in six installments of 50,000 shares every six months after June 6, 2016, provided that Dr. Joslyn has continued his employment with the Company through such dates. In addition, on June 6, 2016, Dr. Joslyn was awarded 30,000 shares of restricted stock, vesting in two installments on the six month and twelve month anniversaries of June 6, 2016. Under SEC rules relating to executive compensation disclosure, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Fair values relating to share grants have been determined under ASC 718 and were calculated using the common stock closing price on the date of grant and multiplying that price by the number of shares subject to the share grant. The equity-based compensation expense relating to the stock grants is recognized over the requisite service period of the grant. For option awards, we utilize the Black-Scholes option pricing model to determine the fair value on the date of the grant multiplied by the number of options subject to the option grants in accordance with ASC 718. The stock-based compensation expense relating to the stock option grants is recognized over the requisite service period of the grant and the amounts included in the Option Awards column do not reflect compensation actually received by the named executive officers. For information on the assumptions used to calculate the fair value of stock option grants, refer to Footnote 9 - "Stock Compensation Plan" in our financial statements for the year ended December 31, 2015.

(5) Amounts in this column for Dr. Joslyn, Mr. Sullivan and Dr. Handfield represent the Company's matching contributions to our Simple IRA retirement plan. The retirement plan requires us to match employee contributions up to the first 3% of compensation earned.

Current Executive Officers and Key Employee

We are led by a team of executives that are chosen by the Board of Directors. Currently, we have three executive officers, set forth below is biographical information for executive officers and certain identified key employees.

Executive Officers

Alan F. Joslyn, Ph.D. The biography of Dr. Joslyn is included above under "Directors of the Company."

Michael Sullivan. Mr. Sullivan, age 60, has served as our Interim Principal Executive Officer from October 30, 2014 until June 5, 2016 and served as our Chief Financial Officer, Secretary and Treasurer since February 6, 2012. Mr. Sullivan has held senior level financial positions for several publicly and privately held businesses including Utek Corporation, eANGLER, and HSN Direct International Limited. Most recently, he was the Group Financial Officer for the Investigative Services and Litigation Consulting Services segment of First Advantage Corporation a firm specializing in talent acquisition solutions where he streamlined the employee recruitment process. Mr. Sullivan is a Florida Certified Public Accountant. He graduated from the Florida State University with a Bachelor of Science in Accounting and a Master of Business Administration.

Key Employee

Dr. Martin Handfield. Dr. Handfield, age 45, is, the Company's Senior Vice President of Discovery Research and previously has served as our Director of Research and Development. Dr. Handfield has served the Company since January 2009. Prior to joining our Company, Dr. Handfield held a position as Tenured Associate Professor at the Center for Molecular Microbiology and the Department of Oral Biology at the University of Florida College of Dentistry, where he co-invented IVIAT and co-founded *ivi* Gene Corp. and Epicure Corp. to commercialize this and related technologies. Dr. Handfield holds a B.S. degree in Biochemistry, and a MS degree and PhD in Microbiology and Immunology from the Université Laval College of Medicine in Canada, and did postdoctoral training at the University of Florida.

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

The Compensation Committee believes that our future success depends, in large part, upon our ability to maintain a competitive position in attracting, retaining and motivating key personnel. The Compensation Committee utilizes the 2012 Equity Incentive Plan to provide incentives to employees. We do not have any separate long-term incentive plans that provide compensation intended to serve as incentives for performance other than awards contemplated under, or pursuant to, our 2012 Equity Incentive Plan.

Outstanding Equity Awards

The following table provides information concerning unexercised options outstanding as of December 31, 2016:

Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date
Dr. Alan Joslyn **President and Chief Executive Officer**	50,000	250,000(1)	0.55	06/06/2026
Michael O. Sullivan **Chief Financial Officer**	40,000		0.88	12/08/2024
	25,000		0.86	10/30/2024
	45,000		1.20	02/10/2022
	66,666	133,334(2)	1.32	03/16/2025
Dr. Martin Handfield **Senior Vice President of Discovery Research**	40.000		0.88	12/08/2024
	15,000		10.40	09/18/2018
	12,500		5.40	12/12/2019
		4,275	5.40	12/12/2019
	2,500		5.40	12/12/2019
	16,800		1.50	09/27/2021
	150,000		1.32	03/16/2025

(1) Represents awards that are time vested with each award vesting evenly on a six month basis over three years, subject to earlier vesting upon a change in control as defined in the award agreements.

(2) Represents awards that are time vested with each award vesting evenly on an annual basis over three years, subject to earlier vesting upon a change in control as defined in the award agreements.

Employment Contracts and Change in Control Arrangements

Employment Agreements—Dr. Joslyn

We have entered into an Executive Employment Agreement dated as of June 6, 2016, with Dr. Alan Joslyn pursuant to which Dr. Joslyn serves as our President and Chief Executive. The employment term is a one-year term with an automatic 12 month extension thereafter unless either party provides the other 30 days' prior written notice of its intention not to renew the employment agreement.

Dr. Joslyn received a one-time signing bonus of $25,000 upon execution of the employment agreement and is currently entitled to receive an annual base salary of $350,000 which is subject to annual review and adjustment by the Company's Board of Directors. He is eligible to receive annual performance bonus from the Company of up to fifty percent (50%) of his annual base salary based upon appropriate Company-based and individual-based targets specified by the Compensation Committee of the Board, in its discretion, as approved by the full Board of Directors. Dr. Joslyn is also entitled to participate in our employee benefit plans on terms comparable to other full time employees as well as four weeks paid vacation annually.

The employment agreement also provided for Dr. Joslyn to be granted equity awards under the Company's 2012 Amended and Restated Equity Incentive Plan consisting of (i) stock options to purchase 300,000 shares of the Company's common stock at an exercise price equal to $0.55 per share which stock options shall vest is six installments of 50,000 shares each every six months after June 6, 2016, provided that he has continued his employment with the Company through such dates, and (ii) 30,000 shares of restricted stock of the Company, vesting in two installments on the six month and twelve month anniversaries of June 6, 2016. All of the performance bonuses, as well as any equity awards which are granted to Dr. Joslyn or which become vested as a result of the satisfaction of financial performance goals of the Company, are subject to the Company's policy on recoupment or clawback of executive incentive compensation.

Dr. Joslyn is subject to a covenant not to disclose our confidential information during his employment term and an assignment of intellectual property rights. Also, during his employment term and for a period of 12 months thereafter, Dr. Joslyn covenants not to compete with us and not to solicit any of our customers, vendors or employees. If Dr. Joslyn breaches any of these covenants, the Company will be entitled to injunctive relief.

If Dr. Joslyn's employment is terminated by us for Cause (as defined in his employment agreement) or by Dr. Joslyn during the term of the agreement, he will be entitled to receive his (i) his then-current annual base salary through the date of termination; (ii) any reimbursable expenses for which he has not yet been reimbursed as of the date of termination; and (iii) any other rights and vested benefits (if any) provided under employee benefit plans and programs of the Company, determined in accordance with the applicable terms and provisions of such plans and programs ("Accrued Compensation").

If Dr. Joslyn's employment is terminated by us without "Cause", subject to his execution of a release of claims against us, and in addition to the payment of the Accrued Compensation, the Company is obligated to make payments to Dr. Joslyn within 60 days after his termination date equal to six months of his annual base salary, as in effect at the termination date, plus any earned but unpaid bonus (the "Additional Severance Payments").

The employment agreement also contains change of control provisions providing that if Dr. Joslyn's employment with the Company is terminated by the Company without Cause during the period of ninety (90) days following a Change in Control (as that term is defined below) of the Company, in lieu of the Additional Severance Payments described above, Dr. Joslyn will be entitled to receive a severance payment equal to the sum of (i) six (6) months of his annual base salary, at the higher of the base salary rate in effect on the date of termination or the base salary rate in effect immediately before the effective date of the Change of Control, and (ii) his Performance Bonus for the year which includes the effective date of the Change in Control, payable at the target level of performance, which will be paid in a single lump sum after his execution and non-revocation of the Release. In addition, he will also receive in the same payment the amount of any performance bonus that, as of the date of termination, has been earned by Dr. Joslyn but has not yet been paid by the Company. If Dr. Joslyn holds any stock options or other stock awards granted under the Company's 2012 Equity Incentive Plan which are not fully vested at the time his employment with the Company is terminated by the Company without Cause during the period of ninety (90) days following a Change in Control, such equity awards shall become fully vested as of the termination date. For purposes of the employment agreement, the term "Change in Control" means a transaction or series of transactions which constitutes a sale of control of the Company, a change in effective control of the Company, or a sale of all or substantially all of the assets of the Company, or a transaction which qualifies as a "change in ownership" or "change in effective control" of the Company or a "change in ownership of substantially all of the assets" of the Company under the standards set forth in Treasury Regulation section 1.409A-3(i)(5).

Dr. Joslyn's employment agreement also provides that each of the payments and benefits under the agreement are subject to compliance with Section 409A of the Code and it includes time of payment language intended to comply with Section 409A requirements.

Employment Agreements—Mr. Sullivan and Dr. Handfield

We have entered into employment agreements with our Chief Financial Officer, Mr. Michael Sullivan and Dr. Martin Handfield, our Senior Vice-President of Research and Development (the "Employment Agreements"). The annual base salaries provided in the Employment Agreements are payable in installments consistent with our normal payroll practices. Mr. Sullivan and Dr. Handfield are also eligible under the Employment Agreements to receive annual bonuses during the term at the discretion of the Compensation Committee and the Board of Directors with Mr. Sullivan's employment agreement providing for such a discretionary bonus of up to 35% of his base salary and with Dr. Handfield's employment agreement providing for such a discretionary bonus of up to 25% of his base salary.

The Employment Agreements are terminable at any time by either party and if the executive officer is involuntarily terminated by us he shall receive his base salary and vacation pay each accrued through the date of termination, and any nonforfeitable benefits earned and payable to him under the terms of the employee handbook (which applies to all employees) and benefits available under any applicable incentive plan in which the executive participates. In addition, if the executive officer's separation from employment is not voluntary and without cause, we would be obligated to pay the executive officer six months of his annual base salary as severance and the executive shall be entitled to out placement services. If the executive officer is terminated for cause, he shall be entitled to receive his base salary and accrued vacation due through the date of termination and any nonforfeitable benefits already earned and payable to the executive under the terms of the employee handbook or other applicable incentive plans maintained by us. Cause is defined in the Employment Agreements as any action that is illegal, immoral, or improper that reflects on the Company, the employee, or the ability of either to function optimally. If the executive officer voluntarily resigns, he shall be entitled to this base salary and accrued vacation due through the date of termination (including any mutually agreed upon notice period) and any nonforfeitable benefits already earned and payable to the executive officer employee under the terms of the employee handbook or other incentive plans maintained by us.

If the executive officer dies during the term of employment with us, his estate shall be paid his salary as it would have accrued over a period of thirty days after the executive officer's death. We shall also extend the executive officer's right to exercise vested stock options for six months. In the event the executive officer becomes disabled (as defined in the then applicable short and long-term disability insurance policies) we shall pay to the executive officer his salary as it would have accrued over a period of 30 days after the executive became so disabled and we shall extend the executive officer's right to exercise vested stock options for six months.

The Employment Agreements also each include non-disclosure and Company ownership of invention provisions, as well as a provision providing for the Company to defend and indemnify the executive if the executive is named as a defendant in any lawsuit regarding any action taken within the scope of employment.

In the event of a change in control, any stock options or other awards granted (other than performance awards) under our Stock Incentive Plan shall become immediately vested in full and, in the case of stock options, exercisable in full. If the change in control results in an involuntary separation from employment of the executive officer within 180 days following a change in control, the executive officer would be entitled to (i) receive six months of salary and the extension of his benefits (excluding vacation time and paid time off) and (ii) exercise vested options for six months from the date of separation. Under the Employment Agreements, "involuntary separation of employment" means (i) termination without cause, (ii) any reduction in responsibilities of office altering the status of the executive officer as an employee, or (iii) the duplication of the executive officer's position by an equivalent executive in an acquiring entity; and "change in control" means the sale of the entire company, or substantially all of its assets, or the sale of the business unit employing an individual which results in the termination of employment or subsequent transfer of the employment relationship to another legal entity, or entity, or single party acquiring more shares than are owned by the Koski Family Limited Partnership, including its members and their immediate families, including spouses and their children.

On February 20, 2015, we entered into an amended and restated employment agreement, effective January 1, 2015, with Mr. Sullivan . The terms of Mr. Sullivan's amended and restated employment agreement were substantially similar to those of the previous agreement disclosed above except for:

1. The percentage of base salary eligible for bonus awards was set as previously disclosed for Mr. Sullivan at up to 35% of base salary.
2. A provision was added in Mr. Sullivan's agreement to provide for the clawback of bonuses pursuant to the Board's adoption of a clawback policy. In the A&R Employment Agreement Mr. Sullivan acknowledges and agrees that any incentive-based compensation paid to him will be subject to clawback or repayment to the extent such clawback or repayment is required by the terms of the Company's recoupment, clawback or similar policy as may be in effect from time to time, or as required by law.
3. A provision was added whereby Mr. Sullivan would be required to release the Company as a condition to receiving any severance benefit provided by his A&R Employment Agreement with the form of release added and attached as an exhibit to his A&R Employment Agreement.
4. The definition of a change of control in the prior agreement was revised to align it with the definition of a change in control set forth in the Company's 2012 Equity Incentive Plan as follows:

    (i) Any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) becomes the "beneficial owner" (as defined in Rule 13d 3 of the Exchange Act), directly or indirectly, of securities of the Company representing fifty percent (50%) or more of the total voting power represented by the Company's then outstanding voting securities;

    (ii) The consummation of the sale or disposition by the Company of all or substantially all of the Company's assets;

    (iii) A change in the composition of the Board occurring within a two-year period, as a result of which fewer than a majority of the directors are Incumbent Directors. "Incumbent Directors" means directors who either (A) are Directors as of the effective date of this Agreement, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company); or

    (iv) The consummation of a merger or consolidation of the Company with any other corporation, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its parent) at least fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity or its parent outstanding immediately after such merger or consolidation.

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

The following table sets forth information about beneficial ownership of our Common Stock as of February 10, 2017 (unless otherwise noted) by (i) each shareholder that has indicated in public filings that the shareholder beneficially owns more than five percent of the Common Stock, (ii) each of the Company's directors and named officers and (iii) all directors and officers as a group. Except as otherwise noted, each person listed below, either alone or together with members of the person's family sharing the same household, had, to our knowledge, sole voting and investment power with respect to the shares listed next to the person's name.

Name and address(1)	Number of shares beneficially owned	Percentage of ownership(2)
5% shareholders		
Koski Family Limited Partnership(3)	17,057,174	34.5%
Randall J. Kirk (4)	15,481,644	31.5%
Directors and officers		
Alan Joslyn (5)	80,000	*
Robert C. Koski(3)(6)	14,536,885	29.5%
Charles L. Pope(7)	389,397	*
Dr. Alan Dunton(7)	320,922	*
Dr. Frederick W. Telling(7)	1,503,688	3.0
Michael Sullivan(8)	385,877	*
(All Directors and officers as a group 6 persons) (9)	17,216,769	34.2%

* Beneficial ownership percentage is less than 1%.

(1) Except as indicated, the address of the person named in the table is c/o Oragenics, Inc., 4902 Eisenhower Blvd., Suite 125, Tampa, Florida 33634.

(2) In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of the Common Stock subject to options or warrants held by that person that are currently exercisable or will become exercisable within 60 days after December 31, 2016, are deemed outstanding, while the shares are not deemed outstanding for purposes of computing percentage ownership of any other person. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of the Common Stock held by them. Applicable percentage ownership is based on 49,274,219 shares of the Common Stock outstanding as of February 10, 2017. 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 January 23, 2015 and Form 4 filing of July 1, 2016, includes (i) 12,864,822 shares held directly by the KFLP, and (ii) 1,572,523 shares held directly by KFLP partner Christine Koski, (iii) 1,007,878 shares held directly by KFLP partner Robert Koski, (iv) 28,000 shares held directly by KFLP partner Koski Management, Inc. (solely owned by Beverly Koski), (v) 919,666 shares held directly by KFLP partner, Thomas Koski, and (vi) 530,851 shares held in trusts which Robert Koski serves as sole trustee (See Note 6 below), (vii) 93,334 option shares able to be acquired upon the exercise of currently exercisable stock options granted pursuant to our Director Compensation program to Robert Koski and (viii) 40,000 restricted shares of common stock that vest quarterly during 2017, awarded as part of our Director Compensation program. 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 and December 26, 2013 and Form 4 dated July 5, 2016 the number of shares includes (i) 14,481,089 shares owned directly by Intrexon Corporation ("Intrexon") that is controlled by Mr. Randal J. Kirk, and (ii) 1,000,555 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 1,000,555 shares of common stock owned by NRM Holdings and the 14,481,089 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) Includes (i) 30,000 shares of restricted stock subject to vesting; and (ii) 50,000 shares able to be acquired pursuant to currently exercisable stock options and excludes 250,000 shares subject to options that have not yet vested.

(6) In addition to the shares reflected as directly owned by the KFLP, described in Note 3, the share amounts also includes: (i) 1,007,878 shares owned directly by Mr. Koski, (ii) 530,851 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 (107,600 shares); The Robert Clayton Koski Trust for the benefit of Hunter Buchanan Koski (107,600 shares); The Robert Clayton Koski Trust for the benefit of Clayton Ward Bennett (100,000 shares); and The Robert Clayton Koski Trust for the benefit of Robert Edward Koski (107,600 shares) and the Robert Clayton Koski Trust for the benefit of Elyse Margaux Koski (108,051 shares), (iii) 93,334 option shares able to be acquired upon the exercise of currently exercisable stock options granted pursuant to our Director compensation program and (iv) 40,000 restricted shares of common stock that vest quarterly during 2017, awarded as part of our Director Compensation program. Excludes 66,666 shares subject to options that have not yet vested.

(7) Includes: (i) 148,334 option shares able to be acquired upon the exercise of currently exercisable stock options granted pursuant to our Director Compensation program and (ii) 40,000 restricted shares of our common stock awarded under our Director Compensation program that vest quarterly during 2017. Excludes 66,666 shares subject to options that have not yet vested.

(8) Includes 243,334 shares able to be acquired pursuant to currently exercisable stock options and excludes 66,666 shares subject to options that have not yet vested.

(9) Excludes 1,572,523 shares owned directly by Christine Koski, 28,000 shares owned directly by Koski Management, Inc. (solely owned by Beverly Koski), and 919,666 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 39.2%.

Securities Authorized for Issuance under Equity Compensation Plans

Our 2012 Equity Incentive Plan, which is currently our only equity compensation plan, has been approved by our stockholders. The following table sets forth certain information as of December 31, 2016 with respect to the 2012 Equity Incentive Plan:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options (A)	Weighted-Average Exercise Price of Outstanding Options (B)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A)) (C)
Equity compensation plans approved by stockholders:			
2012 Equity Incentive Plan	1,621,523	$ 1.28	291,015
Equity compensation plans not approved by stockholders: (1)			
None	—	$ —	—
Total:	1,621,523	$ 1.28	291,015

(1) The Company does not have any equity compensation plans that have not been approved by security holders. The Company does have warrants to acquire 175,584 shares of common stock outstanding at a weighted average exercise price of $1.50 per share.

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

The Audit Committee of the Board of Directors (or, to the extent applicable, our disinterested directors) is responsible for reviewing all transactions between the Company and any officer or Director of the Company or any entity in which an officer of Director has a material interest. Any such transactions must be on terms no less favorable than those that could be obtained on an arms-length basis from independent third parties.

Financing Transactions

The Lantibiotic Exclusive Channel Collaboration Agreement with Intrexon Corporation ("Intrexon")

On June 5, 2012, the Company entered into an ECC with Intrexon that governs a "channel partnering" arrangement in which the Company 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 ECC establishes committees comprised of Company 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.

The ECC grants the Company 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, the Company may not sublicense the rights described without Intrexon's written consent.

Under the ECC, and subject to certain exceptions, the Company is responsible for, among other things, funding the further anticipated development of lantibiotics toward the goal of commercialization, conducting preclinical and clinical development of candidate lantibiotics, as well as for other aspects of manufacturing and the commercialization of the product(s). Among other things, Intrexon is responsible for technology discovery efforts, cell-engineering development, certain aspects of the manufacturing process, and costs of filing, prosecution and maintenance of Intrexon's patents.

Subject to certain expense allocations and other offsets provided in the ECC, the Company will pay Intrexon on a quarterly basis 25% of gross quarterly profits derived in that quarter from the sale of products developed from the ECC, calculated on an Oragenics Product-by-Oragenics Product basis. The Company has likewise agreed to pay Intrexon on a quarterly basis 50% of revenue obtained in that quarter from a sublicensor in the event of a sublicensing arrangement.

During the first 18 months of the agreement, neither the Company nor Intrexon may terminate the ECC, except under limited circumstances, including in the event of a material breach by the other party and Intrexon may terminate the ECC under certain circumstances if the Company assigns its rights under the ECC without Intrexon's consent. Following the first 12 months of the agreement, Intrexon may also terminate the ECC if the Company fails to use diligent efforts to develop and commercialize Oragenics Products or if the Company elects not to pursue the development of a Lantibiotics Program identified by Intrexon that is a "Superior Therapy" as defined in the ECC. Following the first 18 months of the agreement, the Company may voluntarily terminate the ECC at any time upon 90 days written notice to Intrexon.

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

- commercialized by the Company;
- approved by regulatory authorities;
- a subject of an application for regulatory approval that is pending before the applicable regulatory authority; or
- the subject of at least an ongoing Phase 1, Phase 2 or Phase 3 clinical trial in the Field (in the case of a termination by Intrexon due to an uncured material breach by the Company or a voluntary termination by the Company).

The Company's obligation to pay 25% of gross profits or revenue described above with respect to these "retained" products as well as to use diligent efforts to develop and commercialize these "retained" Oragenics Products will survive termination of the ECC.

In addition, in partial consideration for each party's execution and delivery of the ECC, the Company entered into a Stock Issuance Agreement with Intrexon. Pursuant to the Stock Issuance Agreement the Company issued to Intrexon 4,392,425 shares of the Company common stock as an initial technology access fee, in consideration for the execution and delivery of the ECC and granted Intrexon certain equity participation rights and registration rights.

Under the Stock Issuance Agreement and as part of the ECC, the Company has also agreed to make certain payments to Intrexon upon the Company's achievement of designated milestones in the form of shares of Company Common Stock or at the Company's option make a cash payment to Intrexon (based upon the fair market value of the shares otherwise required to be issued). The milestone events and amounts payable are as follows:

(i) upon filing of the first Investigational New Drug application with the U.S. Food and Drug Administration for an Oragenics Product, that number of shares equal to the number of shares of Common Stock comprising 1.0% of the Base Shares ;

(ii) upon the dosing of the first patient in the first Phase 2 clinical study with an Oragenics Product, that number of shares equal to the number of shares of Common Stock comprising 1.5% of the Base Shares;

(iii) upon the dosing of the first patient in the first Phase 3 clinical study with an Oragenics Product, that number of shares equal to the number of shares of Common Stock comprising 2% of the Base Shares;

(iv) upon the filing of the first New Drug Application ("NDA") or Biologics License Application ("BLA") with the U.S. Food and Drug Administration for an Oragenics Product, or alternatively the filing of the first equivalent regulatory filing with a foreign regulatory agency, that number of shares equal to the number of shares of Common Stock comprising 2.5% of the Base Shares; and

(v) upon the granting of the first regulatory approval of an Oragenics Product, that number of shares equal to the number of shares of Common Stock comprising 3% of the Base Shares.

Base Shares is defined in the Stock Issuance Agreement to mean (i) the number of shares of Company common stock together with any securities or instruments convertible or exercisable for shares of common stock issued and outstanding at the time of the applicable milestone event, (ii) minus any shares issuable upon conversion of Capital Inducement Securities. Capital Inducement Securities is defined in the Stock Issuance Agreement to mean warrants or other convertible securities of the Company issued to investors in connection with a debt or equity investment in the Company that are issued in addition to the primary investment securities and in an amount not to exceed 10% of the overall number of shares issued in the investment (on an as-converted to common stock basis).

During the year ended December 31, 2016 and 2015, we paid $548,994 and $298,581, respectively, to Intrexon relating to work performed under the Lantibiotics ECC.

September 2013-The Probiotics Exclusive Channel Collaboration Agreement with Intrexon

On September 30, 2013, the Company entered into the Probiotics ECC with Intrexon that governs a "channel collaboration" arrangement in which the Company will use Intrexon's proprietary technology relating to the identification, design and production of genetically modified cells, DNA vectors and in vivo control of expression (the "Technology") for the development and commercialization of probiotics, specifically the direct administration to humans of genetically modified probiotics for the treatment of diseases of the oral cavity, throat, sinus and esophagus, including, but not limited to, aphthous stomatitis and Behcet's disease (collectively, the "Probiotics Program"). The Probiotics ECC establishes committees comprised of Company and Intrexon representatives that will govern activities related to the Probiotics Program in the areas of project establishment, chemistry, manufacturing and controls matters, clinical and regulatory matters, commercialization efforts and intellectual property matters.

The Probiotics ECC grants the Company an exclusive worldwide license to utilize Intrexon's Technology to develop and commercialize probiotics, specifically the direct administration to humans of genetically modified probiotics for the treatment of diseases of the oral cavity, throat, sinus and esophagus ("Company Products"). Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of Company Products, and otherwise is non-exclusive. Subject to limited exceptions, the Company may not sublicense the rights described without Intrexon's written consent.

Under the Probiotics ECC, and subject to certain exceptions, the Company is responsible for, among other things, funding the further anticipated development of probiotics toward the goal of commercialization, conducting preclinical and clinical development of candidate probiotics, as well as for other aspects of manufacturing and the commercialization of the product(s). Among other things, Intrexon is responsible for technology discovery efforts, cell-engineering development, and certain aspects of the manufacturing process.

The Company will pay Intrexon 10% of the net sales derived from the sale of products developed from the exclusive channel collaboration relating to the Probiotics Program. The Company has likewise agreed to pay Intrexon a percentage of revenue obtained from a sublicensee in the event of a sublicensing arrangement. The percentage of the revenue to be paid will be determined at the time that a sublicense agreement is negotiated.

The Company may voluntarily terminate the Probiotics ECC upon 90 days written notice to Intrexon. Intrexon may also terminate the Probiotics ECC if the Company breaches the Probiotics ECC and fails to cure the breach within 60 days or the Company does not pursue development of the Superior Therapy under the probiotics identified by Intrexon that is a "Superior Therapy" as defined in the Probiotics ECC.

Upon termination of the Probiotics ECC, the Company may continue to develop and commercialize any Company Product that, at the time of termination, satisfies at least one of the following criteria:

- commercialized by the Company;
- approved by regulatory authorities;
- a subject of an application for regulatory approval that is pending before the applicable regulatory authority; or
- the subject of at least an ongoing Phase 1, Phase 2 or Phase 3 clinical trial in the field of the Probiotics Program.

In addition, in partial consideration for each party's execution and delivery of the Probiotics ECC, on September 30, 2013 the Company entered into a Stock Purchase and Issuance Agreement and a First Amendment to the Stock Purchase and Issuance Agreement (collectively the "SPIA") with Intrexon. Pursuant to the SPIA, the Company paid Intrexon an up-front technology access fee of $6,000,000 (the "Technology Access Fee") in consideration for the execution of the Probiotics ECC. The Technology Access Fee was paid to Intrexon by the Company through the (i) issuance of 1,348,000 (at $3.00 per share) shares of the Company's common stock (the "Technology Access Shares"), and (ii) a convertible promissory note in the amount of $1,956,000 which is payable, at the Company's option, in cash or shares of Company common stock (the "Convertible Note"). The Convertible Note matured on December 31, 2013 and required the Company to obtain shareholder approval prior to conversion of the Convertible Note. The conversion price is equal to the closing price per share of the Company's common stock on the last trading day immediately prior to the date of conversion.

- Under the SPIA and as part of the Probiotics ECC, the Company has also agreed to make certain payments to Intrexon upon the Company's achievement of designated milestones. The milestone payments are each payable to Intrexon, at the Company's election (subject to an election right of Intrexon if the milestone is achieved by a sublicensee), either in cash or in shares of Company common stock (using the fair market value of the shares to calculate the number of shares to be issued to Intrexon in lieu of cash). The Commercialization Milestone Events and amounts payable are as follows:

- $2,000,000 within thirty (30) days of the dosing of a patient by or on behalf of the Company, or an Affiliate (as that term is defined in the Probiotics ECC) or permitted sublicensee of the Company, in a phase II clinical trial, whether such occurs in the United States of America under the jurisdiction of the United States Food and Drug Administration ("FDA") or elsewhere under the jurisdiction of a foreign regulatory agency, for a Company Product;
- $5,000,000 within thirty (30) days of the first meeting of the primary endpoint by or on behalf of the Company, or an Affiliate or permitted sublicensee of the Company, in a phase III clinical trial, whether such occurs in the United States of America under the jurisdiction of the FDA or elsewhere under the jurisdiction of a foreign regulatory agency, for a Company Product;
- $10,000,000 within thirty (30) days of the first to occur of (a) the First Commercial Sale (as that term is defined in the Probiotics ECC) of a Company Product, or (b) the approval of a New Drug Application (as that term is defined in the Probiotics ECC) for a Company Product by the FDA or equivalent regulatory action in a foreign jurisdiction.

On September 30, 2013 the Company also sold to Intrexon 1,300,000 shares of the Company's common stock at a price per share of $3.00 for gross proceeds of $3,900,000. The Company intends to use the proceeds from this sale of common stock towards development of the Company's key initiatives relating to the Probiotics Program, and general corporate purposes.

During the year ended December 31, 2016 and 2015, we paid $0 and $195, respectively, to Intrexon relating to work performed under the Probiotics ECC.

On September 30, 2015, the Company and Intrexon mutually agreed to terminate the Exclusive Channel Collaboration Agreement dated September 30, 2013 regarding the development and commercialization of probiotics (the "Live Biotherapeutic Products ECC"). The termination of the Live Biotherapeutic Products ECC was to enable Oragenics to focus its resources on the lantibiotic and oral mucositis programs.

Participation in Underwritten Public Offering-November 2013

On November 20, 2013, the Company completed an underwritten public offering of 4,400,000 shares of common stock at a public offering price of $2.50 per share resulting in gross proceeds of $11,000,000. Intrexon participated in this public offering acquiring 1,242,490 shares of our common stock.

Repayment of Intrexon Convertible Note

On December 18, 2013, the Company issued to Intrexon 698,241 shares of Company common stock in connection with the conversion of the Convertible Note and accrued interest previously issued by the Company to Intrexon on September 30, 2013 as partial consideration for the Technology Access Fee required by the Exclusive Channel Collaboration Agreement entered into with respect to the Company's probiotics research and development. The Note was payable to Intrexon, at the Company's option, in cash or shares of Company common stock prior to the maturity date of December 31, 2013 and the conversion price was equal to the closing price on the NYSE MKT of the Company's common stock on the last trading day immediately prior to the date of conversion which was $2.82 per share.

June 2015-The Oral Mucositis Exclusive Channel Collaboration Agreement with Intrexon and Intrexon Actobiotics NV

On June 9, 2015, the Company entered into an ECC with Intrexon and Intrexon Actobiotics NV ("Actobiotics"), a wholly-owned subsidiary of Intrexon, through which the Company intends to research, develop and commercialize products, including the continued development and commercialization of AG013, for use in the treatment of oral mucositis in humans and/or the administration to humans of a trefoil factor via genetically modified bacteria (including *L. lactis*) for the treatment of diseases and conditions of the oral cavity, throat, and esophagus, 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, the Company and Intrexon also entered into a Stock Issuance Agreement (the "SIA") which authorized the issuance of the Technology Access Fee (as defined below) and the future stock issuance of our Common Stock to Intrexon upon the achievement of designated milestones. The 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 (the "Technology") for the purpose of developing the Program. The 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 ECC grants the Company 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 and/or the administration to humans of a trefoil factor via genetically modified bacteria (including *L. lactis*) for the treatment of diseases and conditions of the oral cavity, throat, and esophagus, 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.

Under the Oral Mucositis ECC, and subject to certain exceptions, we are responsible for, among other things, funding the further anticipated development of products toward the goal of commercialization, conducting preclinical and clinical development of candidate products, as well as for other aspects of manufacturing and the commercialization of the product(s).

The Company will pay Intrexon on a quarterly basis 12% of the net sales derived from the sale of products developed from the exclusive channel collaboration. The Company has likewise agreed to pay Intrexon on a quarterly basis 50% of revenue obtained in that quarter from a sublicensor in the event of a sublicensing arrangement.

The Company may voluntarily terminate the Oral Mucositis ECC upon 90 days written notice to Intrexon. Intrexon may also terminate the ECC if the Company breaches and fails to cure the breach within 60 days or the Company does not pursue development of the Superior Therapy under the probiotics identified by Intrexon that is a "Superior Therapy" as defined in the ECC.

Upon termination of the ECC, the Company may continue to develop and commercialize any Company Product that, at the time of termination that satisfies at least one of the following criteria:

(i) the particular Company Product is being sold by the Company triggering profit sharing payments under the ECC to Intrexon;

(ii) the particular Company Product has received regulatory approval;

(iii) the particular Company Product is a subject of an application for regulatory approval in the Field covered by the ECC that is pending before the applicable regulatory authority;

(iv) the particular Company Product is AG013, and such Company Product has been the subject of at least one completed Phase 2 clinical trial (as such is defined by relevant FDA guidelines) during the Term; or

(v) the particular Company Product other than AGO13 and such Oragenics Product is the subject of at least an ongoing Phase 1, Phase 2 or Phase 3 clinical trial in the Field.

The Company has also agreed to make certain payments to Intrexon upon the Company's achievement of designated milestones in the form of shares of Company 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 the Company's financial statements with Intrexon's financial statements, or at the Company's option make a cash payment to Intrexon. The Commercialization Milestone Events and amounts payable are as follows:

(i) two million United States dollars ($2,000,000) within thirty (30) days of the first instance of the achievement of the Phase 2 Milestone Event meaning the first dosing of a patient by or on behalf of Oragenics, or an Affiliate or permitted sublicensee of Oragenics, in a Phase 2 clinical trial, whether such occurs in the United States of America under the jurisdiction of the FDA or elsewhere under the jurisdiction of a foreign regulatory agency, for each different Oragenics Product;

(ii) five million United States dollars ($5,000,000) within thirty (30) days of the first instance of the achievement of the Phase 2b/3 Milestone Event meaning meeting of the primary endpoint by or on behalf of Oragenics, or an Affiliate or permitted sublicensee of Oragenics, in a Phase 3 clinical trial, whether such occurs in the United States of America under the jurisdiction of the FDA or elsewhere under the jurisdiction of a foreign regulatory agency, for each different Oragenics Product;

(iii) five million United States dollars ($5,000,000) within thirty (30) days of the first instance of the achievement of the Regulatory Approval Application Milestone Event for each different Oragenics Product which Regulatory Approval Application Milestone Event meaning for a given Oragenics Product, the first to occur of (a) the filing by Oragenics, an Affiliate thereof, or a permitted sublicensee thereof, of a FDA New Drug Application or a Biologics License Application with the FDA seeking approval of such Oragenics Product, or (b) the filing of an equivalent approval or marketing application for such Oragenics Product with an equivalent regulatory authority in a foreign jurisdiction;

(iv) ten million United States dollars ($10,000,000) within thirty (30) days of the first instance of the achievement of the Approval Milestone Event for each different Oragenics Product which Approval Milestone Event meaning the first to occur of (a) the First Commercial Sale of an Oragenics Product anywhere in the Territory, or (b) 90th day after the approval of a FDA New Drug Application for an Oragenics Product by the FDA or equivalent regulatory action in a foreign jurisdiction;

(v) Oragenics shall pay Intrexon a milestone payment of five million United States dollars ($5,000,000) within thirty (30) days of the first instance of the achievement of the New Indication Milestone Event meaning the filing by or on behalf of Oragenics, an Affiliate of Oragenics, or a permitted sublicensee of Oragenics a Supplemental FDA Application with the FDA or with another equivalent regulatory agency seeking approval of an indication for use of the product AG013 other than the current regulatory-approved indication; and

(vi) Oragenics shall pay Intrexon a milestone payment of five million United States dollars ($5,000,000) within thirty (30) days of the first instance of the achievement of the New Product Milestone Event meaning the filing of a regulatory package filed with the FDA or with another equivalent regulatory agency by or on behalf of Oragenics, an Affiliate of Oragenics, or a permitted sublicensee of Oragenics, that is deemed (according to relevant FDA guideline) to be a different drug product than AG013.

During the year ended December 31, 2016 and 2015, we paid $932,645 and $263,590, respectively, to Intrexon relating to work performed under the Oral Mucositis ECC.

Repayment of Intrexon Convertible Note

On December 1, 2015, the Company issued to Intrexon 3,381,004 shares of the Company's common stock in connection with the conversion of the Convertible Note and accrued interest previously issued by the Company to Intrexon on June 9, 2015 as partial consideration for the Technology Access Fee required by the Oral Mucositis Exclusive Channel Collaboration Agreement. The Convertible Note was payable to Intrexon, at the Company's option, in cash or shares of Company common stock prior to the maturity date of December 31, 2015 and the conversion price was equal to the closing price on the NYSE MKT of the Company's common stock on the last trading day immediately prior to the date of conversion which was $1.50 per share.

The June 30, 2016 Private Placement

One June 30, 2016, the Company closed on a private placement of 9,045,679 shares of its common stock to three accredited investors. The investors in the private placement included current Company shareholders, KFLP (5,815,080 shares) and Intrexon Corporation ("Intrexon") (2,261,419 shares), as well as the Company's Chairman, Dr. Frederick Telling (969,180 shares). Approximately $4.667 million was raised of which $2,000,000 was payable by the KFLP under a note payable on or before September 30, 2016. On September 15, 2016, the note payable with the KFLP was amended. Under the terms of the amendment, the KFLP paid $1,000,000 on September 30, 2016 which was first applied to accrued interest and then to the outstanding principal balance. In addition, the amendment extended the maturity date on the remaining principal balance of the note payable to December 31, 2016 and increased the interest rate on the note payable from 3% per annum to 6% per annum (See Note 5). On December 29, 2016, the KFLP made a payment of $1,000,000 which was first applied to accrued interest and then to the outstanding principal balance. The private placement was approved by the Company's audit committee and disinterested directors. As of December 31, 2016, including the results of the financing, Intrexon and the KFLP beneficially owned 31.5% and 34.5%, respectively of the Company's common stock.

Sale of Consumer Probiotics Business

On June 27, 2016, the Company completed the sale of its consumer probiotics business to ProBiora Health, LLC, ("ProBiora Health") an entity owned by Ms. Christine L. Koski, a director at the time of the transaction. The purchase price was $1,700,000 in cash of which $1,250,000 was paid at closing and $450,000 was payable on or before July 31, 2016. The note accrued interest at the rate of 1% per annum and was paid in full on July 29, 2016. In connection with the sale, ProBiora Health assumed certain liabilities. ProBiora Health is obligated to pay the Company contingent consideration annually over a 10 year period based on a percentage of sales of products using the Purchased Assets, with a maximum obligation to the Company of $2,000,000.

The transaction was approved by a special committee of the Company's board of directors consisting solely of disinterested directors and Griffin Securities rendered a fairness opinion in connection with the transaction. Ms. Koski, a director since 2009, and a significant shareholder of the Company through the Koski Family Limited Partnership, resigned as a director of the Company upon completion of the sale. In addition, the Company entered into a Transition Services Agreement (the "Agreement") with ProBiora Health. Under the terms of the agreement, the Company will provide accounting, inventory management, shipping, logistics, customer, vendor, supplier, general business support, IT, pharmacovigilance, quality assurance, regulatory, and clinical services to ProBiora Health. In exchange for the services, ProBiora Health is to pay the Company three percent (3%) of is net sales of all ProBiora3 products sold during the term of the Agreement. The term of the Agreement is for a ninety day (90) period but may be terminated earlier at the option of ProBiora Health. The Company is also subletting space to ProBiora Health at the rate of $1,623 per month. The sublease runs through February 2017. The sublease may be terminated prior to February 2017 under certain provisions by either party. The Company will also provide fulfillment services to ProBiora Health during the term that the sublease is in effect. The Company will receive compensation for those services in an amount equal to the direct costs in providing such services.

During the twelve months ended December 31, 2016, we received $26,333 from ProBiora Health under our Transition Services, sublease, and fulfillment services agreements with ProBiora Health.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Audit and Other Fees

The following table provides the aggregate fees billed for professional services rendered by the Company's principal accountants, Mayer Hoffman McCann P.C. ("MHM"), in the categories indicated during each of the past two fiscal years ended December 31:

Services Rendered	2016	2015
Audit Fees(1)	$146,625	$150,000
Audit-Related Fees(2)	—	—
Tax Fees(3)	9,450	10,145
All Other Fees(4)	—	—
	$156,075	$160,145

(1) *Audit Fees*. This category includes fees for professional services provided in conjunction with the audit of the Company's financial statements and with the audit of management's assessment of internal control over financial reporting and the effectiveness of internal control over financial reporting, review of the Company's quarterly financial statements, assistance and review of documents filed with the SEC, consents, and comfort letters and attestation services provided in connection with statutory and other regulatory filings and engagements.

(2) *Audit-Related Fees*. This category includes fees for assurance and related professional services associated with due diligence related to mergers and acquisitions, consultation on accounting standards or transactions, internal control reviews and assistance with internal control reporting requirements, services related to the audit of employee benefit plans, and other attestation services not required by statute or regulation.

(3) *Tax Fees*. This category includes fees for professional services provided related to tax compliance, tax planning and tax advice.

(4) *All Other Fees*. There were no other fees paid to MHM.

MHM leases substantially all of its personnel, who work under the control of MHM shareholders, from wholly owned subsidiaries of CBIZ, Inc., in an alternative practice structure.

Pre-Approval Policy

The Audit Committee approves in advance all audit and non-audit services to be performed by the Company's independent registered public accounting firm. The Audit Committee considers whether the provision of any proposed non-audit services is consistent with the SEC's rules on auditor independence and has pre-approved certain specified audit and non-audit services to be provided by MHM for up to twelve (12) months from the date of the pre-approval. If there are any additional services to be provided, a request for pre-approval must be submitted by management to the Audit Committee for its consideration.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

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

1. The financial statements and accompanying report of independent registered public accounting firm are set forth immediately following the signature page of this report on pages F-1 through F-24.

2. All financial statement schedules are omitted because they are inapplicable, not required or the information is included elsewhere in the financial statements or the notes thereto.

3. The exhibits required to be filed by this report or able to be incorporated by reference are listed in the "Exhibit Index" following the financial statements.

(b) Other Exhibits

Exhibits required by Item 601 of Regulation S-K are submitted (or incorporated by reference) and listed in a separate section herein immediately following the "Exhibit Index" and are incorporated herein by reference by reference. No exhibits in addition to those previously filed or listed in item 15(a) (3) and filed herein.

(c) Not Applicable.

ITEM 16. FORM 10-k SUMMARY

None.

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this amended report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 27, 2017

ORAGENICS, INC.

By: /s/ Alan Joslyn
Alan Joslyn
President and Chief Executive Officer

POWER OF ATTORNEY

Each of the undersigned officers and directors of Oragenics, Inc., hereby constitutes and appoints Michael Sullivan, their true and lawful attorney-in-fact and agent, for them and in their name, place and stead, in any and all capacities, to sign their name to any and all amendments to this Report on Form 10-K, and other related documents, and to cause the same to be filed with the Securities and Exchange Commission, granting unto said attorneys, full power and authority to do and perform any act and thing necessary and proper to be done in the premises, as fully to all intents and purposes as the undersigned could do if personally present, and the undersigned for himself hereby ratifies and confirms all that said attorney shall lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Alan Joslyn Alan Joslyn	President and Chief Executive Officer	February 27, 2017
/s/ Michael O. Sullivan Michael O. Sullivan	Chief Financial Officer (Principal Accounting and Financial Officer)	February 27, 2017
/s/ Robert C. Koski Robert C. Koski	Director	February 27, 2017
/s/ Frederick W. Telling Frederick W. Telling	Chairman and Director	February 27, 2017
/s/ Charles L. Pope Charles L. Pope	Director	February 27, 2017
/s/ Alan W. Dunton Alan W. Dunton	Director	February 27, 2017

Table of Contents

Financial Statements

Oragenics, Inc.

Financial Statements

Years Ended December 31, 2016 and 2015

Index

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Shareholders of Oragenics, Inc.

We have audited the accompanying balance sheets of Oragenics, Inc. (the Company) as of December 31, 2016 and 2015 and the related statements of operations, changes in shareholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion of the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Oragenics, Inc. as of December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming Oragenics, Inc. will continue as a going concern. As more fully described in Note 1, the Company has incurred recurring operating losses, negative operating cash flows and has an accumulated deficit. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

February 27, 2017

/s/ Mayer Hoffman McCann P.C.

Clearwater, Florida

Oragenics, Inc.
Balance Sheets
December 31, 2016 and 2015

	December 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 4,080,618	$ 5,083,355
Prepaid expenses and other current assets	141,086	209,299
Current assets of discontinued operations	—	345,074
Total current assets	4,221,704	5,637,728
Property and equipment, net	87,462	140,651
Total assets	$ 4,309,166	$ 5,778,379
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,277,066	$ 831,029
Short-term notes payable	66,377	63,352
Current liabilities of discontinued operations	—	152,973
Total current liabilities	1,343,443	1,047,354
Shareholders' equity:		
Preferred stock, no par value; 20,000,000 shares authorized; none issued and outstanding	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized 49,114,219 and 39,858,540 shares issued and outstanding at December 31, 2016 and December 31, 2015	49,114	39,859
Stock subscription receivable	(30,563)	—
Additional paid-in capital	97,616,444	92,347,134
Accumulated deficit	(94,669,272)	(87,655,968)
Total shareholders' equity	2,965,723	4,731,025
Total liabilities and shareholders' equity	$ 4,309,166	$ 5,778,379

See accompanying Report of Independent Registered Public Accounting Firm and notes to the financial statements.

Oragenics, Inc.
Statements of Operations
For the Years Ended December 31, 2016 and 2015

	Year Ended December 31,	
	2016	2015
Revenue, net	$ —	$ —
Cost of revenue	—	—
Gross profit	—	—
Operating expenses:		
Research and development	4,754,650	8,733,510
General and administrative	3,787,855	3,047,354
Total operating expenses	8,542,505	11,780,864
Loss from continuing operations	(8,542,505)	(11,780,864)
Other income (expense):		
Interest income	40,090	21,378
Interest expense	(4,116)	(76,668)
Local business tax	(4,798)	(4,700)
Other income	14,013	776
Total other income (expense), net	45,189	(59,214)
Loss from continuing operations before income taxes	(8,497,316)	(11,840,078)
Income tax benefit	—	—
Net loss from continuing operations	$ (8,497,316)	$(11,840,078)
Basic and diluted net loss per share from continuing operations	$ (0.19)	$ (0.32)
Shares used to compute basic and diluted net loss per share from continuing operations	44,600,197	36,656,257
Discontinued operations		
Profit from operations of discontinued component	30,268	128,745
Gain on sale of discontinued operations	1,453,744	—
Income tax benefit	—	—
Profit from discontinued operations	1,484,012	128,745
Basic and diluted net profit per share from discontinued operations	$ 0.03	$ 0.00
Shares used to compute basic and diluted net profit per share from discontinued operations	44,600,197	36,656,257
Net Loss	$ (7,013,304)	$(11,711,333)
Basic and diluted net loss per share	$ (0.16)	$ (0.32)
Shares used to compute basic and diluted net loss per share	44,600,197	36,656,257

See accompanying Report of Independent Registered Public Accounting Firm and notes to the financial statements.

Table of Contents

Oragenics, Inc.
Statements of Changes in Shareholders' Equity
For the Years Ended December 31, 2016 and 2015

	Common Stock		Stock Subscription Receivable	Additional Paid In Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount				
Balances at December 31,2014	36,178,944	$36,179	$ —	$86,244,604	$(75,944,635)	$ 10,336,148
Issuance of common stock and exercise of warrants	3,479,596	3,480	—	5,068,026	—	5,071,506
Compensation expense relating to option issuances	—	—	—	770,704	—	770,704
Issuance of restricted common stock	200,000	200	—	263,800	—	264,000
Net loss	—	—	—	—	(11,711,333)	(11,711,333)
Balances at December 31,2015	39,858,540	$39,859	$ —	$92,347,134	$(87,655,968)	$ 4,731,025
Issuance of common stock	9,045,679	9,045	(2,000,000)	4,631,102	—	2,640,147
Repayment of stock subscription	—	—	1,969,437	—	—	1,969,437
Compensation expense relating to option issuances	—	—	—	472,780	—	472,780
Compensation expense relating to issuance of restricted shares	30,000	30	—	14,408	—	14,438
Issuance of restricted common stock	180,000	180	—	151,020	—	151,200
Net loss	—	—	—	—	(7,013,304)	(7,013,304)
Balances at December 31,2016	49,114,219	$49,114	$ (30,563)	$97,616,444	$(94,669,272)	$ 2,965,723

See accompanying Report of Independent Registered Public Accounting Firm and notes to the financial statements.

Oragenics, Inc.
Statements of Cash Flows
For the Years Ended December 31, 2016 and 2015

	Year Ended December 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(7,013,304)	$(11,711,333)
Adjustments to reconcile net loss to net cash used in operating activities:		
Technology access fee paid in convertible note payable to shareholder	—	5,000,000
Depreciation and amortization	75,044	71,152
(Gain) loss on sale of fixed assets	3,126	(1,280)
Stock issued as compensation to non-employee directors	151,200	264,000
Stock-based compensation expense	487,218	770,704
Gain on sale of discontinued operations	(1,453,744)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	229,338	68,573
Accounts payable and accrued expenses	446,037	348,694
Net cash used in operating activities	(7,075,085)	(5,189,490)
Cash flows from investing activities:		
Proceeds from sale of fixed assets	2,198	1,280
Purchase of property and equipment	(27,179)	(102,511)
Proceeds from payment of note receivable	250,000	—
Proceeds from sale of discontinued operations	1,450,000	—
Net cash provided by or (used in) investing activities	1,675,019	(101,231)
Cash flows from financing activities:		
Payments on short-term notes payable	(158,100)	(159,950)
Proceeds from payment of stock subscription receivable	1,969,437	—
Net proceeds from issuance of common stock	2,640,147	—
Net cash provided by or (used in) financing activities	4,451,484	(159,950)
Net decrease in cash and cash equivalents	(948,582)	(5,450,671)
Operating cash flows from discontinued operations	(54,155)	85,105
Cash and cash equivalents at beginning of period	5,083,355	10,448,921
Cash and cash equivalents at end of period	$ 4,080,618	$ 5,083,355
Supplemental disclosure of cash flow information:		
Interest paid	$ 4,116	$ 5,241
Non-cash investing and financing activities:		
Conversion of convertible note payable and accrued interest to common shares	$ —	$ 5,071,506
Borrowings under short term notes payable for prepaid expense	$ 161,125	$ 158,462
Short-term note receivable from stockholder in exchange for the issuance of common stock	$ 2,000,000	$ —
Par value of restricted shares issued	$ 230	$ 200
Par value of common stock issued for cashless exercise of warrants	$ —	$ 99
Par value of restricted shares forfeited	$ (20)	$ —

See accompanying Report of Independent Registered Public Accounting Firm and notes to the financial statements.

Oragenics, Inc.
Notes to Financial Statements
December 31, 2016 and 2015

1. Basis of Presentation

The Company

Oragenics, Inc. (formerly known as Oragen, Inc.) (the "Company" or "we") was incorporated in November, 1996; however, operating activity did not commence until 1999. We are focused on becoming a leader in developing novel antibiotics against infectious disease and on developing effective treatments for oral mucositis.

Basis of Presentation

The accompanying financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States ("US GAAP") including the assumption of a going concern basis which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business.

The Company has incurred recurring losses and negative cash flows from operations since inception. To date the Company has not generated significant revenues from operations. The Company generated revenues of $464,048 included in discontinued operations, incurred a net loss of $7,013,304 and used cash of $7,075,085 in its operating activities during the year ended December 31, 2016. As of December 31, 2016, the Company had an accumulated deficit of $(94,669,272) and cash flows from operations were negative throughout 2016.

During 2016, 2013 and 2012 the Company raised $4,666,667, $14,900,000 and $13,000,000 in gross proceeds respectively through the sale of its common stock. The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes the working capital at December 31, 2016 will be sufficient to meet the business objectives as presently structured through May 2017.

The Company's ability to continue operations after its current cash resources are exhausted depends on its ability to obtain additional financing or achieve profitable operations, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in the Company's focus and direction of its research and development programs, competitive and technical advances, or other developments. Additional financing will be required to continue operations after the Company exhausts its current cash resources and to continue its long-term plans for clinical trials and new product development. There can be no assurance that any such financing can be realized by the Company, or if realized, what the terms thereof may be, or that any amount that the Company is able to raise will be adequate to support the Company's working capital requirements until it achieves profitable operations.

The Company intends to seek additional funding through sublicensing arrangements, joint venturing or partnering, sales of rights to technology, government grants and public or private financings. The Company's future success depends on its ability to raise capital and ultimately generate revenue and attain profitability. The Company cannot be certain that additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to it or, if available, will be on terms acceptable to the Company. If the Company issues additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of its common stock, and the Company's current shareholders may experience dilution. If the Company is unable to obtain funds when needed or on acceptable terms, the Company may be required to curtail their current development programs, cut operating costs and forego future development and other opportunities.

2. Significant Accounting Policies

New Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board issued guidance on Compensation—Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting, to simplify the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Some of the areas for simplification apply only to nonpublic entities. The guidance is effective for annual and interim periods beginning after December 15, 2016. The Company is currently evaluating the effects, if any; the adoption of this guidance will have on the Company's financial statements.

In February 2016, the FASB issued guidance to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Previous leases accounting was criticized for failing to meet the needs of users of financial statements because it did not always provide a faithful representation of leasing transactions. In particular, it did not require lessees to recognize assets and liabilities arising from operating leases on the balance sheet. The guidance is effective for annual and interim periods beginning after December 15, 2018.

The Company is currently evaluating the effects, if any; the adoption of this guidance will have on the Company's financial statements.

There are no additional accounting pronouncements issued or effective during the twelve months ended December 31, 2016 that have had or are expected to have an impact on our financial statements.

Use of Estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. The principal areas of estimation reflected in the financial statements are anticipated milestone payments, stock based compensation, valuation of warrants, and income tax valuation allowance. Inventory obsolescence reserve, sales returns and allowances and the allowance for doubtful accounts were the principal areas of estimation that had been reflected in the financial statements related to discontinued operations.

Guaranteed Rights of Return

In June of 2016, the Company sold its consumer probiotics business (See Note 5). The Company had granted guaranteed rights of return to two dental distributors in connection with its consumer probiotics business. The Company deferred recognition of revenue on these accounts until either the distributor provided notification to the Company that the product had been sold to the end consumer or the guaranteed right of return period expired. Once notification was received and verified, the Company recorded revenue in that accounting period. As a result of the sale of the consumer probiotics business (See Note 5), no amounts are shown for deferred revenue as of December 31, 2016. The Company had $-0- and $14,215 of revenue deferred under guaranteed rights of return arrangements included in current liabilities of discontinued operations in the balance sheets as of December 31, 2016 and December 31, 2015, respectively.

Cash and Cash Equivalents

Cash and cash equivalents consist of all cash balances and highly liquid investments with an original maturity of three months or less. The Company's cash and cash equivalents are deposited in a financial institution and consist of demand deposits and overnight repurchase agreements and at times deposits are in excess of federally insured limits.

Accounts Receivable

As a result of the Company's sale of its consumer probiotics business (See Note 5), no amounts are shown for accounts receivable as of December 31, 2016. We had analyzed accounts receivable on a monthly basis and had determined the collectability based on the facts and circumstances relating to each customer. We had estimated the allowance for doubtful accounts based on sales trend and specific review of the creditworthiness of each customer. As of December 31, 2016 and 2015, the Company had recorded an allowance for doubtful accounts of approximately $-0- and $1,400, respectively.

Inventory

As a result of the Company's sale of its consumer probiotics business (See Note 5), no amounts are shown for inventory as of December 31, 2016. The inventory reserve was approximately $-0- and $60,660 as of December 31, 2016 and December 31, 2015, respectively. Inventory had been stated at the lower of cost or market. Cost, included material, labor and overhead, was determined on a first-in, first-out basis. On a quarterly basis, we analyzed our inventory levels and reserve for inventory that is expected to expire prior to being sold, inventory that had a cost basis in excess of its expected net realizable value, inventory in excess of expected sales requirements, or inventory that failed to meet commercial sale specifications. Expired inventory was disposed of and the related costs were written off to the reserve for inventory obsolescence. Amounts previously shown for inventory are included in current assets of discontinued operations.

Property and Equipment

Property and equipment is stated at cost less accumulated depreciation and amortization. Depreciation is provided on the straight-line method over the estimated useful lives of the assets (three to seven years). Leasehold improvements are amortized over the shorter of the estimated useful life or the lease term of the related asset (three years).

Business Segments

In accordance with US GAAP, the Company is required to report segment information. As the Company only operates principally in one business segment, no additional reporting is required.

Stock-Based Payment Arrangements

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

Stock-Based Compensation

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

Warrants

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

Net Loss Per Share

During all periods presented, the Company had securities outstanding that could potentially dilute basic earnings per share in the future, but were excluded from the computation of diluted net loss per share, as their effect would have been antidilutive. Because the Company reported a net loss for all periods presented. Basic and diluted net loss per share amounts are the same for the periods presented. Net loss per share is computed using the weighted average number of shares of common stock outstanding.

Revenue Recognition

During the quarter ended June 30, 2016, the Company sold its consumer probiotic business (See Note 5), from which it had historically generated revenues. The Company had recognized revenues from the sales of its consumer probiotics products when title and risk of loss had passed to the customer, which is generally when the product had been shipped.

The Company had recorded allowances for discounts and product returns at the time of sale as a reduction of revenues as such allowances can be reliably estimated based on historical experience or known trends. The Company had maintained a return policy that allowed customers to return product within a specified period of time prior to and subsequent to the expiration date of the product. The estimate of the provision for returns had been analyzed quarterly and had been based upon many factors, including industry data of product return rates, historical experience of actual returns, analysis of the level of inventory in the distribution channel, if any, and reorder rates. If the history or product returns changes, the reserve would have been adjusted.

The Company had granted guaranteed rights of return at various times to two dental distributors for which the Company deferred recognition of revenue until the customer provided notification to the Company that the product had been sold to the end consumer. Once notification was received and verified, the Company had recorded revenue in that accounting period.

Impairment of Long-Lived Assets

The Company periodically reviews their long-lived assets for impairment and reduces the carrying value to fair value whenever events or changes in circumstances indicate that the carrying value may not be recoverable. There were no impairment losses recorded during the years ended December 31, 2016 and 2015.

Advertising Expenses

During the quarter ended June 30, 2016, the Company sold its consumer probiotic business (See Note 5), from which it had historically incurred costs for advertising and marketing. For the years ended December 31, 2016 and 2015, advertising and marketing expense was $36,030 and $35,887, respectively. These amounts are included in profit from operations of discontinued component.

Research and Development Expenses

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

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rate is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced to estimated amounts expected to be realized by the use of a valuation allowance. Based on our historical operating losses, a valuation allowance has been recognized for all deferred tax assets.

Under US GAAP, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, US GAAP provides guidance on derecognition, classification, interest and penalties, accounting for interim periods, disclosure and transition.

Concentrations

In June of 2016, the Company sold its consumer probiotics business (See Note 5), as such the Company is no longer dependent on key suppliers to continue to operate the consumer probiotics business.

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains cash accounts in commercial banks, which may, at times, exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash and cash equivalents. As of December 31, 2016, the uninsured portion of this balance was $3,830,618. As of December 31, 2015, the uninsured portion of this balance was $4,833,355.

3. Inventory, net

As a result of the Company's sale of its consumer probiotics business (See Note 5) no amounts are shown for inventory as of December 31, 2016. Inventory, net consists of the following as of December 31, 2016 and 2015:

	2015	2015
Finished goods	$ —	$153,461
Rights of Return Agreements	—	5,923
Raw materials	—	222,785
Total inventory	—	382,169
Less: inventory reserve	—	(60,660)
Inventory, net	$ —	$321,509

These amounts are included in current assets of discontinued operations.

4. Property and Equipment, net

Property and equipment, net consists of the following as of December 31, 2016 and 2015:

	2016	2015
Furniture and fixtures	$ 20,742	$ 20,742
Laboratory equipment	812,215	794,625
Leasehold improvements	487,871	487,871
Office and computer equipment	285,326	285,326
	1,606,154	1,588,564
Accumulated depreciation and amortization	(1,518,692)	(1,447,913)
Property and equipment, net	$ 87,462	$ 140,651

Depreciation and amortization expense for the years ending December 31, 2016 and 2015 was $75,044 and $71,152, respectively.

5. Related Party Transactions

At December 31, 2016 and 2015 deferred payments totaling $25,500 and $25,500, respectively, were owed to former directors in connection with their service on our Board and are included in the accompanying balance sheets in accounts payable and accrued expenses.

On June 27, 2016, the Company completed the sale of its consumer probiotics business to ProBiora Health, LLC, (“ProBiora Health”) an entity owned by Ms. Christine L. Koski, a director at the time of the transaction. The purchase price was $1,700,000 in cash of which $1,250,000 was paid at closing and $450,000 was payable on or before July 31, 2016. The note accrued interest at the rate of 1% per annum and was paid in full on July 29, 2016. In connection with the sale, ProBiora Health assumed certain liabilities. ProBiora Health is obligated to pay the Company contingent consideration annually over a 10 year period based on a percentage of sales of products using the Purchased Assets, with a maximum obligation to the Company of $2,000,000.

The transaction was approved by a special committee of the Company’s board of directors consisting solely of disinterested directors and Griffin Securities rendered a fairness opinion in connection with the transaction. Ms. Koski, a director since 2009, and a significant shareholder of the Company through the Koski Family Limited Partnership, resigned as a director of the Company upon completion of the sale. In addition, the Company entered into a Transition Services Agreement (the “Agreement”) with ProBiora Health. Under the terms of the agreement, the Company will provide accounting, inventory management, shipping, logistics, customer, vendor, supplier, general business support, IT, pharmacovigilance, quality assurance, regulatory, and clinical services to ProBiora Health. In exchange for the services, ProBiora Health is to pay the Company three percent (3%) of is net sales of all ProBiora3 products sold during the term of the Agreement. The term of the Agreement is for a ninety day (90) period but may be terminated earlier at the option of ProBiora Health. The Company is also subletting space to ProBiora Health at the rate of $1,623 per month. The sublease runs through February 2017. The sublease may be terminated prior to February 2017 under certain provisions by either party. The Company will also provide fulfillment services to ProBiora Health during the term that the sublease is in effect. The Company will receive compensation for those services in an amount equal to the direct costs in providing such services.

During the twelve months ended December 31, 2016, we received $26,333 from ProBiora Health under our Transition Services, sublease, and fulfillment services agreements with ProBiora Health.

One June 30, 2016, the Company closed on a private placement of 9,045,679 shares of its common stock to three accredited investors. The investors in the private placement included current Company shareholders, KFLP (5,815,080 shares) and Intrexon Corporation (“Intrexon”) (2,261,419 shares), as well as the Company’s Chairman, Dr. Frederick Telling (969,180 shares). Approximately $4.667 million was raised of which $2,000,000 was payable by the KFLP under a note payable on or before September 30, 2016. On September 15, 2016, the note payable with the KFLP was amended. Under the terms of the amendment, the KFLP paid $1,000,000 on September 30, 2016 which was first applied to accrued interest and then to the outstanding principal balance. In addition, the amendment extended the maturity date on the remaining principal balance of the note payable to December 31, 2016 and increased the interest rate on the note payable from 3% per annum to 6% per annum. On December 29, 2016, the KFLP made a payment of $1,000,000 which was first applied to accrued interest and then to the outstanding principal balance. The note was paid in full in January of 2017. The private placement was approved by the Company’s audit committee and disinterested directors. As of December 31, 2016, including the results of the financing, Intrexon and the KFLP beneficially owned 31.5% and 34.5%, respectively of the Company’s common stock.

During the years ended December 31, 2016 and 2015, we paid (i) $548,994 and $298,581, respectively, to Intrexon under our exclusive chanal collaborative ("ECC") agreement with Intrexon (See Note 10) to develop and commercialize lantibiotics (the "Lantibiotic ECC") and we paid $932,645 and $263,590, respectively to Intrexon under the ECC agreement to develop and commercialize AG013 (the "Oral Mucositis ECC"). Included in accounts payable and accrued expenses at December 31, 2016 and 2015 are $524,620 and $302,107, respectively, related to unpaid invoices received from Intrexon relating to work performed under the ECC agreements. As of December 31, 2016 and 2015 Intrexon owned approximately 32% and 33% respectively, of our outstanding common stock.

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 and/or the administration to humans of a trefoil factor via genetically modified bacteria (including *L. lactis*) for the treatment of diseases and conditions of the oral cavity, throat, and esophagus, 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 also issued a Convertible Promissory Note (the "Note") in the amount of $5,000,000 with interest at 3% per annum, as payment of the technology access fee associated with this ECC which was payable, at our option, in cash or shares of our common stock.

On December 1, 2015, the Company issued a Notice of Conversion to Intrexon indicating 3,381,004 shares of Company common stock has been issued to Intrexon effective December 1, 2015 in connection with the Note and in satisfaction of the Company's obligations under the Note.

On September 30, 2015, the Company and Intrexon mutually agreed to terminate the Exclusive Channel Collaboration Agreement dated September 30, 2013 regarding the development and commercialization of probiotics (the "Live Biotherapeutic Products ECC"). The termination of the Live Biotherapeutic Products ECC was to enable Oragenics to focus its resources on the lantibiotic and oral mucositis programs.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following as of December 31, 2016 and 2015:

	2016	2015
Accounts payable trade	$ 461,344	$279,997
Intrexon Collaboration Agreements	524,620	302,107
Professional fees	169,239	155,506
Vacation	93,361	67,919
Deferred compensation	25,500	25,500
Consulting fees	3,002	-0-
Total accounts payable and accrued expenses	$1,277,066	$831,029

7. Short Term Notes Payable

The Company had the following short-term notes payable as of December 31, 2016 and 2015:

	2016	2015
Product liability insurance financing of $49,395 and $49,395, due in monthly installments of $5,093 and $5,087 including principal and interest at 5.93% and 5.68% through January 10, 2017 and January 16, 2016, respectively	$ 4,884	$ 4,882
Directors' and officers' liability insurance financing of $111,730 and $109,067 due in monthly installments of $10,407 and $10,147 including principal and interest at 4.89% and 4.64% through June 24, 2017 and June 24, 2016	61,493	58,470
Total short-term notes payable	$66,377	$63,352

8. Shareholders' Equity

Common Stock

Increase in the Number of Authorized Shares and Approval of a Reverse Stock Split

In January of 2017, we filed an amendment to our Amended and Restated Articles of Incorporation which increased the number of authorized shares of all classes of our capital stock from 120,000,000 shares to 270,000,000 shares by increasing the number of authorized shares of common stock from 100,000,000 shares of common stock to 250,000,000 shares of common stock. The amendment to our Amended and Restated Articles of Incorporation was previously approved by a majority of our shareholders. In addition, a majority of shareholders approved an amendment to our Amended and Restated Articles of Incorporation to effect a reverse stock split of our common stock by a ratio of not less than one-for-five and not more than one-for-ten, with the exact number to be set at a whole number within this range to be determined by our board of directors in its sole discretion and to authorize our board of directors to implement the reverse stock split at any time on or prior to December 31, 2017 by filing an amendment to our Amended and Restated Articles of Incorporation.

Issuance of Common Stock

On June 30, 2016, the Company closed on a private placement of 9,045,679 shares of its common stock to three accredited investors. The investors in the private placement included current significant Company shareholders, Koski Family Limited Partnership, or KFLP and Intrexon, as well as the Company's Chairman, Dr. Frederick Telling. Approximately $4.667 million was raised of which $2,000,000 was payable under a note payable by the KFLP on or before September 30, 2016. The note accrued interest at 3% per annum. On September 15, 2016, the note payable with the KFLP was amended. Under the terms of the amendment, the KFLP paid $1,000,000 on September 30, 2016 which was first applied to accrued interest and then to the outstanding principal balance. In addition, the amendment extended the maturity date on the remaining balance of the note payable to December 31, 2016 and increased the interest rate on the note payable from 3% per annum to 6% per annum. On December 29, 2016, the KFLP made a payment of $1,000,000 which was first applied to accrued interest and then to the outstanding principal balance. The note was paid in full in January of 2017. The purchase price per share of the common stock sold in the private placement was $0.5159, which was the midpoint of the closing quote on the Company's primary exchange, NYSE MKT, on June 29, 2016 as required by NYSE listing standards. The Company expects to use the net proceeds, after payment of offering expenses, for the continued funding of its research and development activities related to the Intrexon Exclusive Channel Collaborations and for general corporate purposes.

Award of Shares to Non-employee Directors

On February 15, 2016, in connection with and in furtherance of the equity based award program, the Board approved the award of 40,000 restricted shares of Company common stock to each of the Company's non-employee directors, Frederick Telling, Charles Pope, Alan Dunton, Christine Koski and Robert Koski under the Company's 2012 Plan. A total of 40,000 restricted shares have vested as of December 31, 2016 for directors, Frederick Telling, Charles Pope, Alan Dunton, and Robert Koski and a total of 20,000 restricted shares have vested as of December 31, 2016 for former director Christine Koski. The awards were considered issued and outstanding as of the date of the grant and were eligible to be voted by the recipient. The Company recognized $151,200 in compensation expense relating to these awards.

On March 16, 2015, in connection with and in furtherance of the new equity based award program, the Board approved the award of 40,000 restricted shares of Company common stock to each of the Company's non-employee directors, Frederick Telling, Charles Pope, Alan Dunton, Christine Koski and Robert Koski under the Company's 2012 Plan of which a total of 40,000 restricted shares have vested as of December 31, 2015 for each non-employee director. The awards were considered issued and outstanding as of the date of the grant and were eligible to be voted by the recipient. The Company recognized $264,000 in compensation expense relating to these awards.

Award of Shares to Employee

On June 6, 2016, in connection with the Company's employment of Dr. Alan Joslyn as President and Chief Executive Officer, the Company issued (i) stock options to purchase 300,000 shares of the Company's common stock at an exercise price equal to $0.55 per share which stock options shall vest in six installments of 50,000 shares every six months after June 6, 2016, provided that he has continued his employment with the Company through such dates, and (ii) 30,000 shares of restricted stock of the Company, vesting in two installments on the six month and twelve month anniversaries of June 6, 2016.

Exclusive Channel Collaboration Agreement with Intrexon-Oral Mucositis–Share Issuance

On December 1, 2015, the Company issued a Notice of Conversion to Intrexon indicating 3,381,004 shares of Company common stock has been issued to Intrexon effective December 1, 2015 in connection with the conversion of the Convertible Promissory Note (the "Note") and in satisfaction of the Company's obligations under the Note.

The Note was previously issued by the Company to Intrexon on June 9, 2015 as payment of the technology access fee under the Exclusive Channel Collaboration Agreement entered into with respect to the Company's research, development and commercialization of products, including the continued development and commercialization of AG013, for use in the treatment of oral mucositis in humans and/or the administration to humans of a trefoil factor via genetically modified bacteria (including *L. lactis*) for the treatment of diseases and conditions of the oral cavity, throat, and esophagus, but, in any case, excluding the delivery of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer. The Note was payable to Intrexon, at the Company's option, in cash or shares of Company common stock prior to the maturity date of December 31, 2015 and the conversion price was equal to the closing price on the NYSE MKT of the Company's common stock on the last trading day immediately prior to the date of conversion, December 1, 2015 which was $1.50 per share.

Warrants

The Company's outstanding and exercisable warrants as of December 31, 2016 are presented below:

Exercise Price	Warrants Outstanding	Expiration Dates
$ 1.50	175,584	7/31/17
	175,584	

On March 23, 2015, warrants to acquire 2,170,925 shares of the Company's common stock at a price of $2.00 per share expired.

On August 3, 2015, Griffin Securities Inc. exercised 185,585 of their previously issued warrants on a net issuance basis resulting in the issuance of 98,592 shares of our common stock.

As of December 31, 2016, there are 175,584 warrants and 1,621,523 stock options outstanding. If all warrants and stock options were exercised, the total number of outstanding common shares would be 50,911,326 as of December 31, 2016.

9. Stock Compensation Plan

The Company originally adopted the Oragenics, Inc. 2002 Stock Option and Incentive Plan (the "Stock Incentive Plan") on September 17, 2002. The Stock Incentive Plan was amended to increase the available shares in May 2004, May 2006, April 2008, October 2009, and on August 29, 2011. On October 23, 2012, the Stock Incentive plan was amended and restated as our 2012 Equity Incentive Plan (the "2012 Incentive Plan"). The 2012 Incentive Plan, as amended and restated has authorized 4,000,000 shares for issuance. To date, 2,087,462 shares have been issued under the 2012 Incentive Plan. As a result of such issuances as of December 31, 2016 there is currently an aggregate of 1,912,538 shares available for issuance under the 2012 Incentive Plan, of which 1,621,523 shares are covered by outstanding option awards and 291,015 shares are available for future awards under the 2012 Incentive Plan.

The purpose of the 2012 Incentive Plan is to advance the interests of the Company by affording certain employees and directors of the Company and key consultants and advisors an opportunity to acquire or increase their proprietary interests in the Company. The 2012 Incentive Plan authorizes the grant of stock options (incentive and non-statutory), stock appreciation rights and restricted stock. Options are granted at the fair market value of the Company's stock on the date of grant. Options generally vest over a period of two to three years from their respective grant dates and expire 10 years from the date of grant. As of December 31, 2016 and 2015, the Company had not awarded any stock appreciation rights under the 2012 Incentive Plan.

Recipients of stock awards under our 2012 Incentive Plan become the owner of record of the stock immediately upon grant, which may be subject to certain restrictions. The balance of unvested restricted stock will be forfeited and automatically transferred back to us at no cost upon the termination of the recipient's employment. Upon vesting of restricted stock that is made to recipients who are employees, the recipient has the option to settle minimum withholding taxes by electing to have us withhold otherwise deliverable shares having a fair market value equal to the required tax obligations ("net-settlement"). The net-settlement shares are then immediately cancelled and retired and reduce the shares available for issuance under the Company's 2012 Incentive Plan.

The Company uses the Black-Scholes option pricing model to estimate the fair value of stock-based awards on the date of grant. The assumptions employed in the calculation of the fair value of share-based compensation expense were calculated as follows for all years presented:

- Expected dividend yield — based on the Company's historical dividend yield.
- Expected volatility — based on the Company's historical market price at consistent points in a period equal to the expected life of the options.
- Risk-free interest rate — based on the US Treasury yield curve in effect at the time of grant.
- Expected life of options — based on the Company's historical life of options exercised, giving consideration to the contractual terms of the grants, vesting schedules and expectations of future employee behavior.

The following table summarizes the assumptions used to estimate the fair value of stock options granted during the years ended December 31, 2016 and 2015:

	2016	2015
Expected dividend yield	0%	0%
Weighted-average expected volatility	142% - 147%	147% - 149%
Weighted-average risk-free interest rate	1.59% - 2.40%	2.14% - 2.27%
Expected life of options	10 Years	10 Years

Total compensation cost related to stock options was $472,780 and $770,704 for the years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, there was $365,744 of unrecognized compensation costs related to stock options, which is expected to be recognized over a weighted average period of 1.1 years.

The following table represents stock option activity as of and for the two years ended December 31, 2016 and 2015, respectively:

	Number of Options	Option Price Per Share	Weighted Average Exercise Price
Outstanding at December 31, 2014	820,865	$0.86 - 17.00	$ 4.03
Forfeited	(278,334)	1.50 - 17.00	5.71
Granted	928,500	0.78 - 1.32	1.31
Outstanding at December 31, 2015	1,471,031	$0.78 - 10.40	$ 2.00
Forfeited	(574,758)	0.84 - 5.40	2.40
Granted	725,250	0.55 - 0.84	0.69
Outstanding at December 31, 2016	1,621,523	$0.55 - 10.40	$ 1.28
Exercisable at December 31, 2016	648,163	$0.78 - 10.40	$ 1.75

The total grant date fair value of options vested during the years ended December 31, 2016 and 2015 was $572,786 and $325,361, respectively.

10. Licenses And Exclusive Channel Collaboration Agreements

The Company has the following material licenses and Exclusive Channel Collaboration ("ECC") agreements:

The University of Florida Research Foundation Licenses

MU1140 – The Company has exclusively licensed the intellectual property for our MU1140 lantibiotic technology from the UFRF. The original license agreement was dated June 22, 2000 and was subsequently amended on September 15, 2000, July 10, 2002, September 25, 2002, March 17, 2003 and April 19, 2013. The amended license agreement provides the Company with an exclusive worldwide license to make, use and sell products and processes covered by Patent No. 5,932,469 entitled "Antimicrobial Polypeptide, Nucleic Acid and Methods of Use" and includes U.S. patent numbers 6,964,760; 7,067,125; 6,391,285; 6,475,771 and the following foreign patents based on the technology in the '469 patent: Australian patent number 7488871, Canadian patent number 2295986, European patent number 1019084 validated in France, Germany, Ireland, Italy, Spain, Sweden and United Kingdom. The Company's license is for the period of the patents, which expire from 2017 through 2019, subject to the performance of terms and conditions contained therein. The Company has ongoing obligations and commitments with respect to the MU1140 License. The Company has agreed to indemnify and hold UFRF and other affiliated parties harmless from any damages caused as a result of the production, manufacture, sale, use, lease, consumption or advertisement of the licensed products. See Note 13 — Commitments and Contingencies. In the years ended December 31, 2016 and 2015 the Company paid $22,468 and $29,416 respectively to UFRF in connection with the MU1140 license.

Texas A&M License Agreement

The Company entered into an exclusive licensing agreement with Texas A&M University System (College Station, TX) ("Texas A&M") in December 2011 for access to new homologs of the lantibiotic MU1140 and other lantibiotics with improved pharmacological properties and structural features. The Company has ongoing obligations and commitments with respect to the MU1140 License. In the years ended December 31, 2016 and 2015 the Company paid Texas A&M $15,000 and $15,000, respectively, in connection with the Texas A&M license. These novel antibiotics may be useful to treat or prevent colonization and/or infections by one or more types of bacteria. The structural changes available to us from this license agreement may improve the bioactivity of MU1140. Under the terms of the Texas A&M license agreement, we filed two patent applications with the US Patent Office to secure the intellectual property related to these new lantibiotic homologs on February 27, 2012, entitled "Variants of the Lantibiotic MU1140 and Other Lantibiotics with Improved Pharmacological Properties and Structural Features" and "Replacement Therapy for Dental Carries." On July 11, 2012 the Texas A&M license agreement was amended to add references to replacement therapy in the defined terms "Licensed Technology" and "Patent Rights". All other terms of the Texas A&M license agreement remain unchanged.

On May 18, 2015, the Texas A&M license agreement was amended to extend the enrollment of first patient in a Phase 1 clinical trial using the licensed technology, from on or before June 1, 2015, to on or before June 1, 2016. All other terms of the Texas A&M license agreement as amended remained unchanged. In October of 2016, the Texas A&M license agreement was amended to extend the enrollment of first patient in a Phase 1 clinical trial using the licensed technology, from on or before June 1, 2016, to on or before June 1, 2019 and provides for a payment of $25,000 commencing in 2017 and each year thereafter prior to the calendar year of the first sale of products using the licensed technology, as minimum annual consideration for the continuation of the license agreement. All other terms of the Texas A&M license agreement as amended remained unchanged.

The term of the Texas A&M license agreement expires upon (i) the expiration of the applicable patent rights covered by the license agreement, (ii) the failure of any patent filed pursuant to the license agreement to issue, or (iii) the final and unappealable determination by a court that the patent rights are invalid. The Company may voluntarily terminate the license agreement upon 90 days written notice to Texas A&M. Texas A&M can terminate the license agreement if the Company materially breaches the license agreement and does not cure such breach within 60 days of receiving notice of such breach from Texas A&M. The Company has agreed to indemnify and hold the Texas A&M harmless from any damages caused as a result of alleged infringement of a third party's intellectual property rights or as a result the production, manufacture, sale, use, lease, consumption or advertisement of the product. See Note 13 — Commitments and Contingencies.

The Lantibiotic ECC

On June 5, 2012, the Company entered into the Lantibiotic ECC with Intrexon that governs a "channel collaboration" arrangement in which the Company 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 grants the Company 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, the Company may not sublicense the rights described without Intrexon's written consent. The Lantibiotic ECC establishes committees comprised of Company 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. The Company has agreed to indemnify and hold Intrexon harmless from any damages caused as a result of (i) our negligence or willful misconduct, (ii) the use, handling, storage, or transport of Intrexon Materials (as defined in the Lantibiotic ECC), (iii) our breach of a material representation, warranty or covenant in the Lantibiotic ECC, or (iv) the design, development, manufacture, regulatory approval, handling, storage, transport, distribution, sale or other disposition of any Oragenics Product.

Intrexon may terminate the Lantibiotic ECC if we fail to use diligent efforts to develop and commercialize Oragenics Products or if we elect not to pursue the development of a Lantibiotics Program identified by Intrexon that is a "Superior Therapy" as defined in the Lantibiotic ECC. We may voluntarily terminate the Lantibiotic ECC at any time upon 90 days written notice to Intrexon. Upon termination of the Lantibiotic ECC, the Company may continue to develop and commercialize any Oragenics Product that has been, at the time of termination:

- commercialized by the Company;
- approved by regulatory authorities;
- a subject of an application for regulatory approval that is pending before the applicable regulatory authority; or
- the subject of at least an ongoing Phase 1, Phase 2 or Phase 3 clinical trial in the Field (in the case of a termination by Intrexon due to an uncured material breach by the Company or a voluntary termination by the Company).

The Company's obligation to pay 25% of gross profits or revenue and milestone payments described above with respect to these "retained" products as well as to use diligent efforts to develop and commercialize these "retained" Oragenics Products will survive termination of the Lantibiotic ECC.

The Company has ongoing obligations and commitments with respect to the Lantibiotic ECC. See Note 13 — Commitments and Contingencies.

The Oral Mucositis ECC

On June 9, 2015, the Company entered into an the Oral Mucositis ECC with Intrexon and Intrexon Actobiotics NV ("Actobiotics"), a wholly-owned subsidiary of Intrexon, through which the Company intends to research, develop and commercialize products, including the continued development and commercialization of AG013, for use in the treatment of oral mucositis in humans and/or the administration to humans of a trefoil factor via genetically modified bacteria (including *L. lactis*) for the treatment of diseases and conditions of the oral cavity, throat, and esophagus, 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, the Company 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. The 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 (the "Technology") 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 the Company 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 and/or the administration to humans of a trefoil factor via genetically modified bacteria (including *L. lactis*) for the treatment of diseases and conditions of the oral cavity, throat, and esophagus, 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. Under the Oral Mucositis ECC, and subject to certain exceptions, we are responsible for, among other things, funding the further anticipated development of products toward the goal of commercialization, conducting preclinical and clinical development of candidate products, as well as for other aspects of manufacturing and the commercialization of the product(s).

The Company may voluntarily terminate the Oral Mucositis ECC upon 90 days written notice to Intrexon. Intrexon may also terminate the Oral Mucositis ECC if the Company breaches and fails to cure the breach within 60 days or the Company does not pursue development of the Superior Therapy under the probiotics identified by Intrexon that is a "Superior Therapy" as defined in the Oral Mucositis ECC. Upon termination of the Oral Mucositis ECC, the Company may continue to develop and commercialize any Company Product that, at the time of termination that satisfies at least one of the following criteria:

(i) the particular Company Product is being sold by the Company triggering profit sharing payments under the Oral Mucositis ECC to Intrexon;

(ii) the particular Company Product has received regulatory approval;

(iii) the particular Company Product is a subject of an application for regulatory approval in the Field covered by the Oral Mucositis ECC that is pending before the applicable regulatory authority;

(iv) the particular Company Product is AG013, and such Company Product has been the subject of at least one completed Phase 2 clinical trial (as such is defined by relevant FDA guidelines) during the Term; or

(v) the particular Company Product other than AG013 and such Oragenics Product is the subject of at least an ongoing Phase 1, Phase 2 or Phase 3 clinical trial in the Field.

Among other things, Intrexon is responsible for technology discovery efforts, cell-engineering development, and certain aspects of the manufacturing process. See Note 13 — Commitments and Contingencies.

11. Retirement Plan

In January 2004, the Company established a defined contribution Simple Individual Retirement Arrangement plan, replacing the previous plan that had been established in 2001. The new plan covers all employees and provides for a Company match of up to 3% of all employee compensation to the plan. Total matching contributions made by the Company for the years ended December 31, 2016 and 2015 were $33,237 and $24,634, respectively.

12. Income Taxes

The components of the provision for income taxes for the years ended December 31, 2016 and 2015 are as follows:

	2016	2015
Current	$ —	$ —
Deferred	(2,587,731)	(4,271,483)
Valuation Allowance	2,587,731	4,271,483
Total provision for income taxes	$ —	$ —

At December 31, 2016 and 2015, the Company had temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and their respective income tax bases, as measured by enacted state and federal tax rates, as follows:

	2016	2015
Deferred tax assets (liabilities):		
Net operating loss carryforward	$ 33,186,710	$ 30,701,734
Bad debt reserve	—	530
Inventory reserve	—	22,827
Sales return allowance	—	4,188
Accrued vacation	35,132	33,896
Deferrals of compensation to Directors & Officers	9,596	9,596
Uniform capitalization (UNICAP)	—	5,158
Non-qualified stock compensation	513,106	513,106
Restricted stock	42,590	42,590
Accrued Interest	—	(134,222)
Total deferred tax assets, net	33,787,134	31,199,403
Less valuation allowance	(33,787,134)	(31,199,403)
Total net deferred taxes	$ —	$ —

The following is a reconciliation of tax computed at the statutory federal rate to the income tax benefit in the statements of operations for the years ended December 31, 2016 and 2015:

	2016	2015
Income tax benefit computed at statutory federal rate of 34%	$(2,384,532)	$(3,981,853)
State income tax benefits, net of federal expense/benefit	(254,584)	(425,121)
Change in valuation allowance	2,587,731	4,271,483
Non-deductible expenses	185,607	288,055
Other	(134,222)	(152,564)
Total	$ —	$ —

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based upon the levels of historical taxable income and projections of future taxable income over which the deferred tax assets are deductible, the Company believes that it is more likely than not that it will not be able to realize the benefits of some of these deductible differences.

Accordingly, a valuation allowance of $33,787,134 and $31,199,403 has been provided in the accompanying financial statements as of December 31, 2016 and 2015, respectively. The 2016 net change in valuation allowance related to deferred tax assets was an increase of $2,587,731 primarily relating to net operating loss carryforwards. The 2015 net change in valuation allowance related to deferred tax assets was an increase of $4,271,483 primarily relating to net operating loss carryforwards.

At December 31, 2016, the Company has federal and state tax net operating loss carryforwards of approximately $87,663,000. The federal and state tax loss carryforward will expire through 2036, unless previously utilized. The Company also has federal research and development tax credit carryforwards of approximately $1,875,000. The federal tax credit carryforward will expire through 2026, unless previously utilized.

Pursuant to Internal Revenue Service Code Sections 382 and 383, use of the Company's net operating losses and credit carryforwards are limited due to a cumulative change in ownership of more than 50% that occurred in 2009 and in 2013. As a result of these 50% changes in ownership, the annual amount of pre-change net operating losses that may be used in periods subsequent to the change in ownership is approximately $417,000 for losses incurred through June 2009, and $3,540,000 for losses incurred through December 2013. The impact of this limitation is factored into management's valuation allowance placed against the Company's deferred tax assets.

For the years ended December 31, 2016 and 2015, the Company incurred $166,871 and $353,814, respectively, of additional unrecognized tax benefits that related to research and development credits. The entire amount of this unrecognized tax benefit, if recognized, would result in an increase to the deferred tax asset valuation allowance, and would not have an impact on the effective tax rate.

The Company files its income tax returns in the U.S. federal jurisdiction and in Florida. With few exceptions, the Company is no longer subject to federal or state income tax examinations by tax authorities for years before 2012.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

Balance as of December 31, 2014	$1,354,652
Additions based on tax positions related to the current year	353,814
Additions for the tax positions of prior years	—
Reductions for the tax positions of prior years	—
Balance as of December 31, 2015	$1,708,466
Additions based on tax positions related to the current year	166,871
Additions for the tax positions of prior years	—
Reductions for the tax positions of prior years	—
Balance as of December 31, 2016	$1,875,337

Included in the balance at December 31, 2016 and 2015, are $1,875,337 and $1,708,466, respectively, of tax positions for which there is uncertainty about the validity of certain credits. The disallowance of the credits would impact the amount of gross deferred tax assets reflected in the accompanying footnotes.

During the years 2016 and 2015 the Company did not recognize any interest and penalties. Due to the potential offset of the Company's operating loss carryforward for any future activity, the amount attributed to interest and penalties would be immaterial.

13. Commitments and Contingencies

Leases

The Company's Alachua facility is being leased from a real estate developer for a term of three years under a lease that expired in December 2014. The Company signed a new lease agreement for the same facility with the same real estate developer in July 2014 with an effective date of December 2014 for a five year term. Under the new agreement, the rental payments range from $9,641 per month to $10,851 per month. Total rental expense for the Alachua facility during the year ended December 31, 2016 was approximately $127,000.

In October of 2013, the Company renewed the leased office space for corporate, sales, and marketing personnel located in Tampa, FL. The lease is for approximately 4,168 square feet. The lease period for the office space is for thirty-nine months. Lease payments range from $6,426 per month to $6,818 per month inclusive of insurance, taxes and utilities. The lease expires on February 28, 2017. Rent expense under this lease was approximately $77,000 for the year ended December 31, 2016.

In November of 2016, the Company entered into an amendment for the leased office space for corporate personnel located in Tampa, FL. The amended lease is for approximately 2,207 square feet. The lease period for the office space is for thirty-six months commencing on March 1, 2017. Lease payments range from $4,138 per month to $4,392 per month inclusive of insurance, taxes and utilities. The lease expires on February 29, 2020.

Future annual minimum payments under all non-cancelable operating leases are as follows as of December 31, 2016:

Year ended December 31:	
2017	$193,957
2018	198,396
2019	183,234
2020	9,399
Total	$584,986

The University of Florida Research Foundation Licenses

UFRF-MU1140 License. In the Company's UFRF amended license agreement for MU1140, the Company is obligated to pay 5% of the selling price of any products developed from the UFRF licensed technology that the Company may sell as royalty to the UFRF. In addition, if the Company sublicenses any rights granted by the amended license agreement, the Company is obligated to pay to the UFRF 22% of all revenues received from the sublicenses, excluding monies received solely for development costs. The Company is 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.

The Company is required to make minimum annual maintenance payments to the UFRF for the term of the amended license agreement in the amount of $10,000 for the license agreement. The aggregate minimum annual payments are required to be paid in advance on a quarterly basis (i.e. $2,500 per quarter) for the license. The Company must also pay all patent costs and expenses incurred by the UFRF for the preparation, filing, prosecution, issuance and maintenance of the patents.

The terms of the UFRF amended license agreement expire upon the earlier of (i) the date that no patents covered by the amended license agreement remain enforceable or (ii) the payment of earned royalties under the amended license agreement, once begun, ceases for more than three calendar quarters. The Company may voluntarily terminate the license agreement upon 90 days written notice to UFRF. UFRF may terminate the amended license agreement if the Company breaches its obligations to timely pay any amounts due under the amended license agreement, to submit development reports as required under the amended license agreement or commit any other breach of any other covenants contained in the amended license agreement and the Company fails to remedy such breach within 90 days after written notice of such breach by UFRF.

The patent the Company had previously exclusively licensed from UFRF for its Replacement Therapy expired in June 2015 and the resulting license was terminated. The Company is currently evaluating its options with respect to the SMaRT Replacement Therapy technology.

Texas A&M License Agreement

Under the terms of the Texas A&M license agreement, the Company made an initial payment of five thousand dollars ($5,000) to Texas A&M. The Company must also pay to Texas A&M a royalty of five percent (5%) of net sales of products that include the licensed technology, subject to royalty stacking provisions with a two percent (2%) minimum royalty. Additionally, in order to maintain the exclusive license, commencing in 2014 and each year thereafter prior to the calendar year of the first sale of products using the licensed technology, the Company was to pay Texas A&M $15,000 as minimum annual consideration for the continuation of the license agreement. In October of 2016 the Texas A&M license agreement was amended to provide for a payment of $25,000 commencing in 2017 and each year thereafter prior to the calendar year of the first sale of products using the licensed technology, as minimum annual consideration for the continuation of the license agreement. Once the Company commences the sale of products that include the technology the Company licenses from Texas A&M the Company must pay a minimum annual amount of $100,000 to Texas A&M and every year thereafter through the expiration of the Agreement. However, once sales begin, any royalty payments the Company makes on net sales will be credited against the $100,000 required maintenance payment.

The Company must also pay all patent costs and expenses for the preparation, filing, prosecution, issuance and maintenance of the patent rights. Sales by sublicensees are subject to the royalty rate above, and the Company is responsible for certain payments to Texas A&M for any other consideration received that are not in the form of a royalty.

Pursuant to the amended Texas A&M license agreement, the Company is obligated to meet the following milestones and make milestone payments: (i) enrollment of first patient in a Phase 1 clinical trial using the licensed technology, to occur on or before June 1, 2019, with a milestone achievement payment of $50,000, (ii) completion of Phase 2 clinical trial using the licensed technology to occur on or before June 1, 2022, with a milestone achievement payment of $100,000, (iii) completion of Phase 3 clinical trial of the licensed technology to occur on or before June 1, 2025, with a milestone achievement payment of $150,000, and (iv) first sale of the licensed technology to occur on or before June 1, 2026 with a milestone achievement payment of $400,000. If we fail to accomplish the milestones or fail to achieve net sales of products including the licensed technology for two consecutive calendar years Texas A&M at its sole option may waive the requirement, negotiate the missed milestones or terminate the license agreement. None of the Texas A&M milestones had been achieved as of December 31, 2016.

The Lantibiotic ECC

Under the Lantibiotic ECC, and subject to certain exceptions, the Company is responsible for, among other things, funding the further anticipated development of lantibiotics toward the goal of commercialization, conducting nonclinical and clinical development of candidate lantibiotics, as well as for other aspects of manufacturing and the commercialization of the product(s). Among other things, Intrexon is responsible for technology discovery efforts, cell-engineering development, certain aspects of the manufacturing process, and costs of filing, prosecution and maintenance of Intrexon's patents.

Subject to certain expense allocations and other offsets provided in the Lantibiotic ECC, the Company will pay Intrexon on a quarterly basis 25% of gross quarterly profits derived in that quarter from the sale of products developed from the Lantibiotic ECC, calculated on an Oragenics Product-by-Oragenics Product basis. The Company has likewise agreed to pay Intrexon on a quarterly basis 50% of revenue obtained in that quarter from a sublicensor in the event of a sublicensing arrangement.

In addition, in partial consideration for each party's execution and delivery of the Lantibiotic ECC, the Company entered into a Stock Issuance Agreement with Intrexon. Pursuant to the Stock Issuance Agreement, the Company issued to Intrexon 4,392,425 shares of the Company's common stock as an initial technology access fee, in consideration for the execution and delivery of the Lantibiotic ECC and granted Intrexon certain equity participation rights and registration rights. Under the Stock Issuance Agreement and as part of the Lantibiotic ECC, the Company has also agreed to make certain payments to Intrexon upon the Company's achievement of designated milestones in the form of shares of Company common stock or, at the Company's option, make a cash payment to Intrexon (based upon the fair market value of the shares otherwise required to be issued). The milestone events and amounts payable are as follows:

(i) upon filing of the first Investigational New Drug application with the U.S. Food and Drug Administration for an Oragenics Product, that number of shares equal to the number of shares of common stock comprising 1.0% of the Base Shares (as defined below);

(ii) upon the dosing of the first patient in the first Phase 2 clinical study with an Oragenics Product, that number of shares equal to the number of shares of common stock comprising 1.5% of the Base Shares;

(iii) upon the dosing of the first patient in the first Phase 3 clinical study with an Oragenics Product, that number of shares equal to the number of shares of common stock comprising 2% of the Base Shares;

(iv) upon the filing of the first New Drug Application ("NDA") or Biologics License Application ("BLA") with the U.S. Food and Drug Administration for an Oragenics Product, or alternatively the filing of the first equivalent regulatory filing with a foreign regulatory agency, that number of shares equal to the number of shares of Common Stock comprising 2.5% of the Base Shares; and

(v) upon the granting of the first regulatory approval of an Oragenics Product, that number of shares equal to the number of shares of Common Stock comprising 3% of the Base Shares.

Base Shares is defined in the Stock Issuance Agreement to mean (i) the number of shares of Company common stock together with any securities or instruments convertible or exercisable for shares of common stock issued and outstanding at the time of the applicable milestone event, (ii) minus any shares issuable upon conversion of Capital Inducement Securities. Capital Inducement Securities is defined in the Stock Issuance Agreement to mean warrants or other convertible securities of the Company issued to investors in connection with a debt or equity investment in the Company that are issued in addition to the primary investment securities and in an amount not to exceed 10% of the overall number of shares issued in the investment (on an as-converted to common stock basis).

None of the Lantibiotic ECC milestones had been achieved as of December 31, 2016.

The Oral Mucositis ECC

Under the Oral Mucositis ECC, and subject to certain exceptions, the Company is responsible for, among other things, funding the further anticipated development of products toward the goal of commercialization, conducting preclinical and clinical development of candidate products, as well as for other aspects of manufacturing and the commercialization of the product(s). Among other things, Intrexon is responsible for technology discovery efforts, cell-engineering development, and certain aspects of the manufacturing process.

The Company will pay Intrexon on a quarterly basis 12% of the net sales derived from the sale of products developed from the exclusive channel collaboration. The Company has likewise agreed to pay Intrexon on a quarterly basis 50% of revenue obtained in that quarter from a sublicensor in the event of a sublicensing arrangement.

The Company has also agreed to make certain payments to Intrexon upon the Company's achievement of designated milestones in the form of shares of Company 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 the Company's financial statements with Intrexon's financial statements, or at the Company's option make a cash payment to Intrexon. The Commercialization Milestone Events and amounts payable are as follows:

(i) two million United States dollars ($2,000,000) within thirty (30) days of the first instance of the achievement of the Phase 2 Milestone Event meaning the first dosing of a patient by or on behalf of Oragenics, or an Affiliate or permitted sublicensee of Oragenics, in a Phase 2 clinical trial, whether such occurs in the United States of America under the jurisdiction of the FDA or elsewhere under the jurisdiction of a foreign regulatory agency, for each different Oragenics Product;

(ii) five million United States dollars ($5,000,000) within thirty (30) days of the first instance of the achievement of the Phase 2b/3 Milestone Event meaning meeting of the primary endpoint by or on behalf of Oragenics, or an Affiliate or permitted sublicensee of Oragenics, in a Phase 3 clinical trial, whether such occurs in the United States of America under the jurisdiction of the FDA or elsewhere under the jurisdiction of a foreign regulatory agency, for each different Oragenics Product;

(iii) five million United States dollars ($5,000,000) within thirty (30) days of the first instance of the achievement of the Regulatory Approval Application Milestone Event for each different Oragenics Product which Regulatory Approval Application Milestone Event meaning for a given Oragenics Product, the first to occur of (a) the filing by Oragenics, an Affiliate thereof, or a permitted sublicensee thereof, of a FDA New Drug Application or a Biologics License Application with the FDA seeking approval of such Oragenics Product, or (b) the filing of an equivalent approval or marketing application for such Oragenics Product with an equivalent regulatory authority in a foreign jurisdiction;

(iv) ten million United States dollars ($10,000,000) within thirty (30) days of the first instance of the achievement of the Approval Milestone Event for each different Oragenics Product which Approval Milestone Event meaning the first to occur of (a) the First Commercial Sale of an Oragenics Product anywhere in the Territory, or (b) 90th day after the approval of a FDA New Drug Application for an Oragenics Product by the FDA or equivalent regulatory action in a foreign jurisdiction;

(v) Oragenics shall pay Intrexon a milestone payment of five million United States dollars ($5,000,000) within thirty (30) days of the first instance of the achievement of the New Indication Milestone Event meaning the filing by or on behalf of Oragenics, an Affiliate of Oragenics, or a permitted sublicensee of Oragenics a Supplemental FDA Application with the FDA or with another equivalent regulatory agency seeking approval of an indication for use of the product AG013 other than the current regulatory-approved indication; and

(vi) Oragenics shall pay Intrexon a milestone payment of five million United States dollars ($5,000,000) within thirty (30) days of the first instance of the achievement of the New Product Milestone Event meaning the filing of a regulatory package filed with the FDA or with another equivalent regulatory agency by or on behalf of Oragenics, an Affiliate of Oragenics, or a permitted sublicensee of Oragenics, that is deemed (according to relevant FDA guideline) to be a different drug product than AG013.

None of the Oral Mucositis ECC milestones had been achieved as of December 31, 2016.

The Oral Mucositis ECC provides that in the event (i) Oragenics is required to make a milestone payment in cash as an issuance of shares would cause Intrexon to consolidate the Company's financial statements with Intrexon's financial statements, and (ii) Oragenics reasonably concludes that a cash milestone payment would have an adverse effect on its working capital needs over the next twelve (12) months, then such cash payment shall be in the form of an interest bearing promissory note with a maturity date of less than twelve (12) months and include other conventional market terms that would not be expected to unreasonably have an adverse effect on Oragenics working capital needs over such twelve (12) month period.

14. Unaudited Quarterly Financial Information

The quarterly interim financial information shown below has been prepared by the Company's management and is unaudited. It should be read in conjunction with the audited financial statements appearing herein.

	2016			
	First(1)	Second	Third	Fourth
Revenues	$ —	$ —	$ —	$ —
Total operating expenses	2,074,645	1,733,282	2,026,670	2,707,908
Profit from discontinued operations	11,113	1,420,947	42,566	9,386
Net Loss	(2,062,885)	(312,615)	(1,963,007)	(2,674,797)
Loss per share:				
Basic and diluted net loss per share from continuing operations	$ (0.05)	$ (0.04)	$ (0.04)	$ (0.05)
Basic and diluted net profit per share from discontinued operations	$ 0.00	$ 0.04	$ 0.00	$ 0.00

	2015			
	First(1)	Second	Third	Fourth
Revenues	$ —	$ —	$ —	$ —
Total operating expenses	1,374,858	6,344,223	1,865,934	2,195,851
Profit (Loss) from discontinued operations	78,573	13,928	36,419	(174)
Net Loss	(1,292,777)	(6,335,471)	(1,863,676)	(2,219,409)
Loss per share:				
Basic and diluted net loss per share from continuing operations	$ (0.04)	$ (0.17)	$ (0.05)	$ (0.06)
Basic and diluted net profit per share from discontinued operations	$ 0.00	$ 0.00	$ 0.00	$ (0.00)

(1) Certain amounts previously reported as revenue, cost of revenue, research and development, selling, general and administrative relating to the consumer probiotic business are now reported as profit (loss) from discontinued operations.

Table of Contents

EXHIBIT INDEX

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
3.1	Amended and Restated Articles of Incorporation	SB-2	333-100568	3.3	10/16/02	
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation	8-K	001-32188	10.2	10/30/09	
3.3	Articles of Amendment to Amended and Restated Articles of Incorporation	8-K	001-32188	3.1	9/27/10	
3.4	Articles of Amendment to Amended and Restated Articles of Incorporation	8-K	001-32188	3.1	09/01/11	
3.5	Articles of Amendment to Amended and Restated Articles of Incorporation	8-K	001-32188	3.1	01/13/17	
3.6	Bylaws	SB-2	333-100568	3.2	10/16/02	
3.7	First Amendment to Bylaws	8-K	001-32188	3.1	6/9/10	
3.8	Second Amendment to Bylaws	8-K	001-32188	3.1	8/24/10	
4.1	Specimen Stock Certificate	S-1/A	333-169031	4.0	10/05/10	
10.1	Standard Exclusive License Agreement with Sublicensing Terms between the Company and the University of Florida Research Foundation, Inc. effective June 22, 2000 (the "MU1140 License Agreement")	SB-2	333-100568	10.5	10/16/02	
10.2	First Amendment to the MU1140 License Agreement dated September 15, 2000	SB-2	333-100568	10.6	10/16/02	
10.3	Second Amendment to the MU1140 License Agreement dated June 10, 2002	SB-2	333-100568	10.7	10/16/02	
10.4	Third Amendment to the MU1140 License Agreement dated September 25, 2002	SB-2	333-100568	10.4	10/16/02	
10.5	Fourth Amendment to the Antimicrobial Polypeptide License Agreement dated March 2003	SB-2/A-3	333-100568	10.36	4/9/03	
10.6	Fifth Amendment to the Antimicrobial Polypeptide License Agreement dated April 19, 2013	8-K	001-32188	10.1	4/23/13	
10.7	License Agreement by and between Oragenics Inc. and Texas A&M University System dated December 20, 2011	10-K	001-32188	10.28	4/16/12	

Table of Contents

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
10.8	Exclusive Channel Collaboration Agreement by and between Oragenics, Inc. and Intrexon Corporation dated as of June 5, 2012.*	8-K	001-32188	10.1	6/11/12	
10.9	Stock Issuance Agreement by and between Oragenics, Inc. and Intrexon Corporation dated as of June 5, 2012.	8-K	001-32188	10.2	6/11/12	
10.10	Amendment No. 1 to the Exclusive Channel Collaboration Agreement between Oragenics, Inc. and Intrexon Corporation dated July 21, 2016.	10Q	001-32188	10.10	8/15/16	
10.11	Exclusive Channel Collaboration Agreement by and between Oragenics, Inc. and Intrexon Corporation dated as of June 9, 2015.*	8-K	001-32188	10.1	7/11/15	
10.12	Stock Purchase and Issuance Agreement by and between Oragenics, Inc. and Intrexon Corporation dated as of June 9, 2015.*	8-K	001-32188	10.2	7/11/15	
10.13	Lease Agreement between the Company and Hawley-Wiggins LLC dated October 28, 2011 (13700 Progress Blvd, Alachua, FL 32615).	10-K	001-32188	10.20	4/16/12	
10.14	Amendment to Lease Agreement between the Company and Hawley-Wiggins LLC dated July 13, 2014 (13700 Progress Blvd, Alachua, FL 32615).	10-Q	001-32188	10.2	8/7/14	
10.15	Stock Purchase Agreement by and between the Company and Purchasers dated July 30, 2012.	8-K	001-32188	10.1	8/2/12	
10.16	2012 Equity Incentive Plan.+	8-K	001-32188	4.1	10/25/12	
10.17	Amended and Restated Executive Employment Agreement between the Company and Michael Sullivan dated effective January 1, 2015.+	8-K	001-32188	10.1	2/25/15	
10.18	Executive Employment Agreement between the Company and Martin Handfield dated May 11, 2010.+	10-Q	001-32188	10.16	11/14/11	
10.19	Executive Employment Agreement between the Company and Alan Joslyn dated effective June 6, 2016.+	8-K	001-32188	10.1	6/6/16	
10.20	Asset Purchase Agreement	8-K	001-32188	2.1	6/23/16	
10.21	Promissory Note	8-K	001-32188	10.1	6/27/16	
10.22	Guaranty	8-K	001-32188	10.2	6/27/16	
10.23	Transition Services Agreement	8-K	001-32188	10.3	6/27/16	
10.24	Sublease	8-K	001-32188-	10.4	6/27/	
10.25	Stock Purchase Agreement dated June 30, 2016	8-K	001-32188	10.1	6/30/16	
10.26	Unsecured Promissory Note	8-K	001-32188	10.2	6/30/16	
10.27	Amendment No. 1 to Unsecured Promissory Note	8-K	001-32188	10.1	9/15/16	
10.28	Form of Placement Agent Warrant.	8-K	001-32188	10-3	8/2/12	
10.29	Form of Employee Stock Option Agreement.+	10-K	001-32188	10.26	3/26/13	
10.30	Form of Consultant Stock Option Agreement.+	10-K	001-32188	10.27	3/26/13	

Table of Contents

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
10.31	Form of Notice of Grant of Stock Options and Stock Option Award Agreement (Employee). +	8-K	001-32188	10.1	3/18/15	
10.32	Form of Notice of Grant of Stock Options and Stock Option Award Agreement (Directors). +	8-K	001-32188	10.2	3/18/15	
10.33	Form of Director Restricted Stock Award Agreement. +	8-K	001-32188	10.3	3/18/15	
23.1	Consent of Mayer Hoffman McCann P.C., an independent public accounting firm.					X
24.1	Powers of Attorney (included on signature page).					X
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).					X
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase					X
101.LAB	XBRL Taxonomy Extension Label Linkbase					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase					X

* Confidential treatment has been granted as to certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended, or Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

\+ Executive management contract or compensatory plan or arrangement.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the inclusion in this Annual Report (Form 10-K) of Oragenics, Inc. of our report dated February 27, 2017, with respect to the 2016 and 2015 financial statements of Oragenics, Inc. We consent to the incorporation of our report by reference in the following Registration Statements:

(i) Form S-8 Registration Statements (Nos. (Nos. 333-110646, 333-150716, 333-163083 and 333-184588) of Oragenics, Inc. pertaining to the Oragenics, Inc. 2012 Equity Incentive Plan; and

(ii) Registration Statements (Form S-1 No. 333-183685) and related Prospectus of Oragenics, Inc. for the registration of 9,437,834 shares of its common stock and (Form S-3 No. 333-190609 and No. 333-213321).

/s/ Mayer Hoffman McCann P.C.

Clearwater, Florida

February 27, 2017

Exhibit 31.1

CERTIFICATION

I, Alan Joslyn, certify that:

1. I have reviewed this annual report on Form 10-K of Oragenics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2017

/s/ Alan Joslyn

Alan Joslyn, President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Michael Sullivan, certify that:

1. I have reviewed this annual report on Form 10-K of Oragenics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2017

/s/ Michael Sullivan

Michael Sullivan, Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Oragenics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Alan Joslyn, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written certification has been provided to the company and will be retained by the company and furnished to the Securities and Exchange Commission or its staff upon request.

Dated this 27th day of February, 2017

/s/ Alan Joslyn
Alan Joslyn
President and Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Oragenics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Sullivan, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in this Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written certification has been provided to the company and will be retained by the company and furnished to the Securities and Exchange Commission or its staff upon request.

Dated this 27th day of February, 2017

/s/ Michael Sullivan
Michael Sullivan
Chief Financial Officer