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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, 2014

☐ **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, as of June 30, 2014 was approximately $28,421,454 based upon a last sales price of $1.95 as reported by the NYSE MKT.

As of February 26, 2015, there were 36,178,944 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the definitive proxy statement for our 2015 annual meeting of stockholders, which is to be filed within 120 days after the end of the fiscal year ended December 31, 2014, are incorporated by reference into Part III of this Form 10-K, to the extent described in Part III.

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FORWARD LOOKING STATEMENTS AND CERTAIN CONSIDERATIONS

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

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

- We have incurred significant operating losses since our inception and cannot assure you that we will increase revenues or achieve profitability.
- We will need to raise additional capital to fully implement our business strategy.
- The success, timing and expenses of our collaboration efforts with Intrexon and expected clinical trials.
- Our ability to achieve success in our identification of homologs and the nonclinical testing of our lantibiotic product candidates.
- We are subject to extensive and costly regulation by the FDA, 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.
- Our ability to consummate a transaction or agreement with respect to our seeking strategic alternatives for our consumer probiotic business under the terms pf such transaction or agreement.
- Orders we receive for our consumer and professional products may be subject to terms and conditions that could result in their cancellation or the return of products to us.
- 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 ability 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.

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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 the world leader in novel antibiotics against infectious disease. We also develop, market and sell proprietary probiotics specifically designed to enhance oral health for humans and pets, under the brand names Evora and ProBiora.

Our Antibiotics

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 since 1927 when the first lantibiotic, Nisin, was discovered. We believe lantibiotics are generally recognized by the scientific community to be potent antibiotic agents.

We have performed nonclinical testing on MU1140, which has demonstrated the molecule's novel mechanism of action. 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. 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*. 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.

The challenge presented by lantibiotics is that they 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. Standard fermentation methods are used to make a variety of currently marketed antibiotics. When traditional fermentation methods are used to make lantibiotics the result has historically been the production of only minute amounts of the lantibiotic.

In order to meet the challenge associated with producing sufficient quantities of MU1140 for our clinical trials and ultimately our commercialization efforts, in June 2012, we entered into the Lantibiotic Exclusive Channel Collaboration agreement ("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. We continue to pursue our research and development and collaboration efforts with Intrexon in accordance with the terms of the Lantibiotic ECC toward the development of the MU1140 molecule and potential derivatives of the molecule. We commenced limited nonclinical activities on MU1140 developed under the Lantibiotic ECC with Intrexon, in the second half of 2013. Through our work with Intrexon, we have been able to produce an exponential increase in the fermentation titer of the target compound MU1140 and the discovery of a new purification process for MU1140. Since then, our exclusive collaboration generated a substantial number of homologs of MU1140, and we screened these homologs and found several candidates with either enhanced therapeutic profiles or different specificities against resistant bacteria from that of the parent compound, MU1140. The decision to examine these new homologs of MU1140 meant we had to reproduce the fermentation and purification steps on at least 10-15 homologs. 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 are working with third party manufacturers to produce additional quantities of designated homologs, based upon the developments achieved from our work with Intrexon and outside contractors. The additional quantities of designated homologs that are needed for the consummation and pursuit of our nonclinical testing activities including the pre-IND meeting, technology transfer

to a GLP manufacturing facility and the drug product necessary for completing all pre-IND studies are underway. We currently expect to have a pre Investigational New Drug ("IND") meeting with the FDA in the second half of 2015 and thereafter be in a position to file the IND for a first-in-human clinical study in 2016. We will work aggressively in the course of our research and development to meet these events.

Our Probiotic Products

We are marketing a variety of probiotic products that we developed. Our probiotic products contain the active ingredient ProBiora3, a patented blend of oral care probiotics that promote fresher breath, whiter teeth and support overall oral health. We have conducted scientific studies on ProBiora3 in order to market our products under self-affirmed Generally Recognized As Safe status ("GRAS"). We have historically sold our ProBiora3 products through multiple distribution channels. We continue to seek improvement in the performance of our oral care probiotics products, to better serve our customers, and we continue to evaluate new delivery systems, which we believe will enable us to deliver ProBiora3 to new markets and end-users.

Since initial commercialization of our ProBiora3 products we have attempted to improve market awareness and sales of our oral probiotic product line with limited success to date and we have reduced our marketing expenditures accordingly to focus more on lantibiotics. The allocation of limited financial resources between research and development of lantibiotics for our other product candidates and sale and marketing efforts for our ProBiora3 products, among other factors, resulted in our December 2014 announcement that we would seek to explore strategic alternatives for the probiotic business. These alternatives could include joint ventures, strategic partnerships or alliances, a sale of the probiotic products business or other possible transactions. There can be no assurance that a transaction or agreement, will be consummated with terms favorable to us.

Live Biotherapeutic Products (LBPs)

On September 30, 2013, we entered into a second worldwide exclusive channel collaboration agreement with Intrexon that governs a "channel collaboration" arrangement in which we will use Intrexon's proprietary technology relating to the identification, design, culturing and/or production of genetically modified cells, DNA vectors and in vivo control of expression for the development and commercialization of LBPs, specifically the direct administration to humans of genetically modified bacterial LBPs for the treatment of diseases of the oral cavity, throat, sinus and esophagus, including, but not limited to, aphthous stomatitis and Behcet's disease (the "LBPs ECC"). Our efforts in connection with developing bacteria-based biotherapeutics for oral cavity, throat, sinus and esophagus diseases, is being reconsidered. Our initial planned focus was to develop a genetically engineered bacterial strain designed to deliver and release a therapeutic locally at the oral disease sites to target pain management, reduce inflammation, and improve patient outcomes in Behcets Disease (and/or Aphtous Stomatitis). In reviewing and considering the potential opportunities with Intrexon and our Key Opinion Leaders, we concluded that other therapeutic indications may be more commercially viable, and as such, we are exploring other options with respect to this collaboration.

Other Product Candidates and Technologies.

We also possess and have developed other product candidates and technologies that originated from the discoveries of our scientific team. These other product candidates and technologies include our SMaRT Replacement Therapy and our weight loss agent, LPT3-04. For our other product candidates and technologies, we do not expect to devote financial resources toward continued research and development.

Our SMaRT 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 or for consideration in our LBP program.

Our Weight Loss Agent-LPT3-04. LPT3-04 is a natural occurring dietary substance with an excellent safety and tolerance profile that is believed to support weight loss in overweight men and women. LPT3-04 is normally consumed in the human diet in small amounts, in the course of our SMaRT Replacement Therapy research; our scientific team also discovered that consumption of a significant amount of LPT3-04, resulted in dose-dependent weight loss in experimental animal models. In December 2013 we entered into an exclusive licensing agreement for our LPT3-04 weight-loss product candidate with LPThera LLC for further development of this technology.

Our Products and Product Candidates

We are currently developing our antibiotic product candidate, MU1140 as well as other homolog antibiotic product candidates, researching LBPs, commercializing our ProBiora3 probiotic products and have other product candidates, including SMaRT Replacement Therapy positioned 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 eight issued U.S. patents and five 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, and SMaRT Replacement Therapy, which are 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.

Product/Candidate	Description	Application	Status
Antibiotics	MU1140 and homologs: Member of lantibiotic class of antibiotics	Healthcare-associated infections	Nonclinical testing
Live Biotherapeutic Products	Bacteria based biotherapeutics	Oral cavity diseases	Early stage R&D
ProBiora3	ProBiora3: Blend of three beneficial oral care probiotic bacteria	Oral health, teeth whitening, breath freshening (for humans, and companion pets)	Commercial (GRAS, Food)
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

MU1140, 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 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 (API) toward the goal of commercialization for the treatment of infectious diseases in humans and companion animals. 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 produced a synthetic version of MU1140 known as MU1140-S, but we determined to cease our pursuit of its further development due to the manufacturing process involved.

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 $35.7 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 2014, 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 pathogenic bacteria resistant to known antibiotics cause between 6.3% and 89.1% of HAIs, and individual hospitals have resistance rates as high as 70% for many Gram positive infections. 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. difficile., Mycobacterium tuberculosis* or, 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 a better profile, 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 currently anticipate the eventual selection of a single lead drug candidate in 2015.

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 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 expect that we will be in a position to file an Investigational New Drug (IND) application with the FDA in 2016 with a pre-IND meeting in the second half of 2015.

Manufacturing

Through our work with Intrexon, we have been able to produce an exponential 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 that are needed for the consummation and pursuit of our nonclinical testing activities supporting the pre-IND meeting is currently underway.

Live Biotherapeutic Products (LBPs)

The strategy is to develop genetically engineered safe bacterial strains designed to produce, deliver and release therapeutics locally at oral disease sites to prevent or cure a disease. This ECC collaboration with Intrexon is based upon utilizing Intrexon's synthetic biology expertise and proprietary technologies and Oragenics' knowledge and experience in utilizing genetically modified bacteria (SMART therapy). While we previously anticipated that bacterial prototypes would start becoming available in the second half of 2014 and migrate to genetically modified probiotics that can produce cytokine therapeutics for Behcet's or Aphthous Stomatitis in mid-2015 toward the goal of proof of concept studies in animals. We are now considering the pursuit of other therapeutic indications that may be more commercially-viable in the long run.

This ECC collaboration with Intrexon is based upon utilizing Intrexon's synthetic biology expertise and proprietary technologies and Oragenics' knowledge and experience in utilizing genetically modified bacteria (SMART therapy). We still believe in the potential of specifically targeting several diseases with bacteria engineered to deliver therapeutic agents directly to the target with high specificity and safety.

Market Opportunity

We believe the market for the treatment of diseases of the oral cavity, throat, sinus and esophagus, through LBPs to be potentially significant and provide opportunities to treat currently unmet medical needs.

Our Solution

Together with Intrexon, we are exploring the use of genetically modified bacteria to treat oral indications. By inserting genes that can allow the chosen bacteria to excrete a therapeutic agent, we believe we can engineer these bacteria to produce a variety of specific agents which might be used to treat disease and symptoms.

Our Strategy

We had expected to develop a full research plan in 2014 and then begin the work in 2015 of choosing the required bacteria and therapeutic agents, however, we are reviewing and considering the potential opportunities with Intrexon and our Key Opinion Leaders, and we have concluded that therapeutic indications other than those originally considered may be more commercially viable, and as such, we are analyzing these indications with the goal of developing a research plan.

Regulatory Issues

We believe there will be substantial regulatory issues to address based on our previous experience with our genetically modified SMaRT Replacement Therapy. We fully expect that safety issues will be a priority with the regulatory bodies and we expect to address those issues through the use of genetically modified "fail-safe" mechanisms we will engineer into the bacteria as well as through testing in several safety models to insure any product developed will be able to meet regulatory standards.

Manufacturing

We believe once we have established the bacteria and the correct therapeutic agent, manufacturing the product for nonclinical development work, pre-IND work and eventually human clinical trials will follow standard methodologies and use standard processing and scale-up techniques.

ProBiora3 Oral Care Probiotics

ProBiora3 is a proprietary blend of three naturally occurring strains of beneficial bacteria, including *Streptococcus oralis* KJ3, *Streptococcus uberis* KJ2, and *Streptococcus rattus* JH145, which promotes fresher breath, whiter teeth, and supports overall oral health. We believe that ProBiora3 is the most comprehensive oral care probiotics technology currently available in the oral healthcare market. The scientific basis for the oral health benefits provided by these three strains of bacteria has been documented in numerous peer-reviewed publications over the last 30 years. We promote ProBiora3 as the active ingredient in our consumer branded products, including EvoraPlus, EvoraKids and EvoraPet, and the professional branded product, EvoraPro. EvoraPlus and EvoraKids are flavored probiotic tablets intended for daily use by adults and children, respectively, after brushing their teeth. EvoraPet is intended for companion pets such as cats and dogs, and comes in a tasteless and odorless powder form. The powder is intended to be sprinkled on a pet's food once per day. EvoraPro is a professional strength product designed for the dental office channel. In addition to our house-branded products, we also market ProBiora3 as an active ingredient for private label products, as well as in bulk for licensing applications.

Market Opportunity

Probiotics are live microorganisms that confer a health benefit to their host when administered in sufficient amounts. The beneficial bacteria in a probiotic formulation help to maintain a healthy balance of bacteria in the body. Examples of common probiotic applications are yogurt containing live cultures, *acidophilus* capsules to improve digestion, and products for improved immune system and vaginal and urinary tract health. According to a report published by MarketsandMarkets (www.marketsandmarkets.com), the overall probiotic market was valued at $24.23 billion in 2011 and is expected to grow at a CAGR of 6.8% from 2012 to 2017. In 2011, Asia-Pacific led the global market with share of 40.0% followed by Europe and North America in terms of revenue. Probiotics products are relatively more common in Asia and Europe, accounting for 42% and 30% of the global market. The probiotics market in the United States, however, is emerging, and products that address gastrointestinal problems and other uses are rapidly becoming available, especially as dietary supplements and cultured foods and beverages. According to Transparency Market research (http://www.transparencymarketresearch.com/probiotics-market.html), probiotic foods & beverages are the dominant segments in the global market and are expected to grow at a CAGR of 6.8% from 2013 to 2018. Probiotic demand for food & beverage segment is estimated to reach USD 37.9 billion in 2018. Following food and beverages, the market for dietary supplements and animal feed are also witnessing significant growth.

- **Oral Care For Humans:** According to Packaged Facts, oral care products in the U.S. retailed at $9.1 billion in 2008 and $10.9 billion is possible by 2014. In addition, over 62.3 million Americans visited the dentist in 2009.
- **Companion Pets:** In 2011 to 2012, approximately 62% of U.S. households owned a pet, with an estimated 38.3 million and 45.8 million households owning cats and dogs, respectively, according to the American Pet Products Association or APPA. The APPA also claims that total 2011 U.S. pet industry expenditures were $51 billion, representing an increase of over 5% from 2010. Within this market, approximately $11.8 billion was spent on Supplies/OTC Medicine.

Our Probiotic Products

ProBiora3 is a blend of three naturally occurring strains of bacteria for use in the promotion of oral health, including *Streptococcus oralis* strain KJ3, or *S. oralis*; *Streptococcus uberis* strain KJ2, or *S. uberis*; and *Streptococcus rattus* strain JH145, or *S. rattus*. In a healthy human oral cavity, *S. oralis* and *S. uberis* are commonly found in significant amounts, and conversely, the levels of bacteria associated with a disruption of gum health are usually quite low. The opposite situation prevails in periodontal disease sites, where the beneficial bacteria, *S. oralis* and *S. uberis*, are usually undetectable. Our scientists have demonstrated that *S. oralis* and *S. uberis* produce hydrogen peroxide, which interferes with the growth of certain potentially harmful anaerobic bacteria, and also gently and naturally whitens teeth. The third bacterial strain in our ProBiora3 blend, *S. rattus*, is able to establish and maintain a healthy balance of bacteria on the tooth surfaces by competing with certain other potentially harmful bacteria that are known to challenge tooth health.

ProBiora3 has been tested for safety and efficacy in the laboratory and in animal and human trials. In our pilot human study, a twice-daily administration of ProBiora3 was well tolerated by subjects and no safety issues were observed. ProBiora3 produced substantial decreases in the numbers of key potentially harmful bacteria, associated with disruptions from tooth and periodontal health, in young healthy adults.

We market products containing ProBiora3 under our own house brand names, and have branded ProBiora3 as an active ingredient for licensing and private labeling. Our house brand products contain different ratios, or blends, of the three natural strains contained in ProBiora3, which vary depending on the intended use of the product. Our ProBiora3 products are designed for repetitive use in order to achieve the intended benefits, which we believe provides us with the potential for recurring revenues as consumers who continue to seek the benefits of our products will continue to make repeat purchases. Our ProBiora3 products include:

- **EvoraPlus:** a product with equal weight of all three strains that is optimally designed for the general consumer market. EvoraPlus is a mint-flavored probiotic tablet packaged in a 30-unit bottle, representing a one-month supply. The intended use for EvoraPlus is for consumers to take one tablet once per day, preferably after brushing their teeth in the evening.
- **EvoraKids:** a product that has higher levels of *S. rattus,* which addresses dental health, but reduced levels of *S. oralis and S. uberis* since challenges to gum health is not a typical pediatric concern. EvoraKids is a fruit-flavored chewable probiotic tablet packaged in a 30-unit bottle, representing a one-month supply. The intended use for EvoraKids is for consumers to take one tablet once per day, preferably after brushing their teeth in the evening.
- **EvoraPet:** a product that has higher levels of *S. oralis* and *S. uberis*, which addresses tooth staining and breath problems common to dogs and cats, but has reduced levels of *S. rattus* since a challenge to tooth health is not a typical concern in companion pets. EvoraPet comes in powder form, which is odorless and tasteless. The powder is intended to be sprinkled on a pet's food once per day. It is sold in a jar containing a measuring scoop that provides the recommended dosage per application, with two sizes representing either a one or two-month supply.
- **EvoraPro:** a professional strength version of EvoraPlus that is designed for the dental office channel. EvoraPro is a mint-flavored probiotic tablet packaged in a 90-tablet bottle, representing a three-month supply. The intended use for EvoraPro is for patients, after a professional visit, for home use, with instructions to take one tablet once per day, preferably after brushing their teeth in the evening. EvoraPro can only be purchased from a professional dental office. EvoraPro was launched in early August 2010 and is currently supplied to dental professionals through major dental dealers. In 2012, we launched EvoraPro as a 90-day bottle (previously 30-day) to more closely align with the scheduling of dental patients recurring office visits and consistent with our focus on this channel.

Package and Delivery Transition

We strive to be attentive to the needs of the market and ultimate consumers regarding the use of our ProBiora3 products and as such revise and improve on our product delivery mechanisms. For example, in 2012, we instituted a change in EvoraPro to a 90-day package to correlate more closely to consumer's visit to dental offices.

Our Regulatory Strategy – United States

In the United States, we market ProBiora3 as a food ingredient under self-affirmed Generally Recognized as Safe, or GRAS, status. GRAS is available for food ingredients that are generally recognized as being safe for human use and do not claim to treat, prevent, or cure a disease. Furthermore, food products that make only cosmetic or structure-function claims are typically able to enter the market through what is known as self-affirmed GRAS status, which designates that we have performed all necessary research, including the formation of an expert panel to review safety concerns, and are prepared to use these findings to defend ProBiora3's self-affirmed GRAS status. In 2008, we convened a panel, the members of whom we believed to be qualified as experts by their scientific training and professional experience, to analyze and evaluate the safety data for ProBiora3. After review, the panel concluded that the safety data of ProBiora3 was sufficient to support our claim to self-affirmed GRAS status for human consumption.

Our marketing for ProBiora3 includes the cosmetic claims of teeth whitening and breath freshening, along with the general structure-function claim that ProBiora3 supports oral health. Regulations vary in markets outside the United States and it may be possible to assert other benefits including health and disease prevention claims associated with probiotics use, especially after independent clinical studies have been completed and appropriate regulatory filings are approved. At present, we are aware of several independent academic studies that have been initiated on a variety of potential health and cosmetic benefits associated with ProBiora3 probiotics use by humans.

Our Regulatory Strategy – International

Regulations vary by country and, as such, we rely on the expertise of local partners to which we sell to assist us in navigating through any applicable regulatory requirements. We are generally aware of the varying regulatory requirements in various geographies, and seek to address these requirements on a case-by-case basis.

Sales, Marketing and Distribution

ProBiora3 products are available through several channels:

- **Direct-to-Consumer:** Our direct-to-consumer channel is primarily directed towards web-based sales, comprised of internet sales through our own websites. We currently operate one corporate website through which we market our branded products. An "Oragenics Store" provides the consumer with access to purchase our products.
- **Professional Offices:** The professional offices channel encompasses general dentists, specialists and dental hygienists. EvoraPro is an extra-strength, probiotic designed to be taken after dental cleaning or treatment. We currently have distribution agreements with leading distributors of products to the dental professional market. In addition, we have a partnership with a private label customer in the dental space.
- **Domestic:** The domestic channel encompasses arrangements whereby we offer either our products for resale under a third-party's brand name or the rights to distribute our branded products. We typically establish private labeling arrangements in order to leverage an existing company's brand equity and distribution channels. We have private label partnerships allowing for distribution of ProBiora3 based products throughout the United States.
- **International:** Since the launch of our first product, EvoraPlus, we have entered into exclusive distribution agreements for our products internationally in various geographic locations. We believe the international market represents a significant potential opportunity, and we continually search for appropriate partners who have the marketing ability and resources to successfully introduce our ProBiora3 products to consumers internationally.

Our distribution agreements range in terms between one and three years. They typically provide for exclusivity tied to a geographic territory or our market. Such agreements also typically provide for termination by the parties upon thirty (30) days written notice. Following an initial required stocking order, subsequent distributor orders are placed according to the quantity and name of each product ordered. The distributor is generally required to make guaranteed minimum purchases during a specified time period to maintain exclusivity. In the event such guaranteed minimums are not met, we may terminate the distribution agreement. Distributors are required to pay an advance equal to part of the price of the product. We require the distributor to maintain liability insurance. All rights terminate upon expiration or termination of the agreement. For international distribution agreements, payment is to be made to us in U.S. currency and we pay no taxes or other fees assessed by any governmental entity in connection with the international sale of ProBiora3 products.

ProBiora3 is now formulated as a cosmetic mouthwash tablet for use in the European Union. All Oragenics' independent distributors can now distribute the ProBiora3 tablets in the EU under a Cosmetic designation.

Manufacturing

We have contracted with multiple suppliers to either manufacture, blend, tablet, and/or package our products. We currently have one supplier that is able to produce the three strains of bacteria needed to produce ProBiora3. We currently have a contract with this manufacturer for the production and supply of only one strain and we are currently in the process of negotiating a contract for the supply and production of the other two strains. We currently have enough ProBiora3 to meet our currently expected needs for all of 2015. This supplier uses proprietary methodologies to produce these three strains of bacteria. We have one supplier who is able to blend and tablet EvoraPlus, EvoraKids, and EvoraPro. We have one additional supplier that is able to tablet EvoraPlus, EvoraKids, and EvoraPro. We have several suppliers that are currently able to package our products. We have one supplier that is able to blend and package EvoraPet.

With each supplier, we place orders for components or finished product to be produced for a fixed fee. We pay either a portion of the fixed fee upon submission of our orders with the balance of the fixed fee paid upon completion of the manufacturing process or the entire fixed fee is paid at the time the manufacturing, blending, tableting, or packaging is completed. Packaged probiotics products are shipped to us or to a destination specified by us, or to a private label distributor. We currently maintain an inventory of our products for internet sales and other sales to distributors. We believe our arrangements with our contract suppliers are satisfactory to meet our current and expected future needs.

Other Product Candidates and Technologies

LPT3-04 Weight Loss Product

In the course of our SMaRT Replacement Therapy research, 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 is a newly formed entity that will need 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. 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 LPT3-4 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 LPT3-4 license agreement)	Q3 2021
6.	First Commercial Sale (as defined in the LPT3-4 license agreement)	Q3 2021

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.

Market Opportunity

According to the World Health Organization, more than 1.4 billion adults, ages 20 and over, were overweight in 2008. Further, according to a healthcare market research report published by MarketsandMarkets, the total global weight loss and diet management product and services market is estimated to reach $671.8 billion by 2015; growing at a CAGR of 11.5% from 2010 to 2015.

SMaRT 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.

Market Opportunity

Dental diseases are the most prevalent chronic infectious diseases in the world, affecting up to 90% of schoolchildren and the vast majority of adults. Annual expenditures on the treatment of dental caries in the U.S. are estimated to be $40 billion a year according to the Dental, Oral and Craniofacial Data Resource Center. Tooth decay is characterized by the demineralization of enamel and dentin, eventually resulting in the destruction of the teeth. Dietary sugar is often misperceived as the cause of tooth decay; however, the immediate cause of tooth decay is lactic acid produced by microorganisms that metabolize sugar on the surface of the teeth. Studies suggest that of the approximately 700 oral microorganisms, *S. mutans*, a bacterium found in virtually all humans, is the principal causative agent in the development of tooth decay. Residing within dental plaque on the surface of teeth, *S. mutans* derives energy from carbohydrate metabolism as it converts dietary sugar to lactic acid which, in turn, promotes demineralization in enamel and dentin, eventually resulting in a cavity. The rate at which mineral is lost depends on several factors, most importantly the frequency and amount of sugar that is consumed.

Fluoride is used to reduce the effect of lactic acid-based demineralization of enamel and dentin. Despite the widespread use of fluoride in public water systems, toothpastes, dental treatments and sealants, and the use of antiseptic mouth rinses, over 50% of 5-to-9-year-olds and almost 80% of 17-year-olds in the United States have at least one cavity or filling, according to the U.S. Surgeon General. In addition to non-compliance with the behavioral guidelines of the American Dental Association such as routine brushing and flossing, there are several factors that are likely to increase the incidence and frequency of tooth decay, including increasing consumption of both dietary sugar and bottled water. Bottled water generally does not contain fluoride, and thus does not impart any of the protective effects of fluoridated water from public systems.

Our Solution

Our SMaRT Replacement Therapy technology is based on the creation of a genetically altered strain of *S. mutans,* called SMaRT, which does not produce lactic acid. Our SMaRT strain is engineered to have a selective colonization advantage over native *S. mutans* strains in that SMaRT produces minute amounts of a lantibiotic that kills off the native strains but leaves the SMaRT strain unharmed. Thus SMaRT Replacement Therapy can permanently replace native lactic acid-producing strains of *S. mutans* in the oral cavity, thereby potentially providing lifelong protection against the primary cause of tooth decay. The SMaRT strain has been extensively and successfully tested for safety and efficacy in laboratory and animal models. SMaRT Replacement Therapy is designed to be applied topically to the teeth by a dentist, pediatrician or primary care physician during a routine office visit. A suspension of the SMaRT strain is administered using a cotton-tipped swab during a single five-minute, pain-free treatment. Following treatment, the SMaRT strain should displace the native, decay-causing *S. mutans* strains over a six to twelve month period and permanently occupy the niche on the tooth surfaces normally occupied by native *S. mutans*.

Tooth decay is a largely preventable disease through implementation of an appropriate oral care hygiene program including brushing, flossing, irrigation, sealants and antiseptic mouth rinses. Nevertheless, tooth decay remains the most common chronic infectious disease in the world, which indicates that the lack of patient compliance with an overall oral care regimen remains a critical issue in tooth decay prevention. We believe that SMaRT Replacement Therapy addresses the issue of patient compliance by requiring only a one-time, five-minute treatment for the potential lifelong prevention of tooth decay.

Regulatory Status

We initiated our first Phase 1 clinical trial in April 2005, but we found it difficult to find subjects who fit the trial's highly cautious inclusion and exclusion criteria, particularly with respect to the subjects' lack of dentition. We concluded this trial early after enrolling only two of the 15 planned subjects. The FDA then recommended that we revise the protocol for the evaluation of ten healthy male subjects, ranging from 18 to 30 years old and with normal dentition, in an institutionalized setting. After we submitted additional information, the FDA issued a clinical hold letter in June 2007 for the proposed trial with the attenuated strain, citing the need for a plan with respect to serious adverse effects; a plan for the eradication of the attenuated strain in trial subjects' offspring; and a required pregnancy test for female partners of subjects. We submitted additional protocols in response to the FDA's concerns. In August 2007, the FDA issued a clinical hold letter with required revisions to the protocol for offspring of subjects. We submitted a response to the clinical hold letter in September 2007, and the FDA removed the clinical hold for our Phase 1 trial in the attenuated strain in October 2007.

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. Due to the enrollment difficulty we encountered with our initial our Phase 1a clinical trial and then with our phase 1b clinical trial, we determined to discontinue pursuit of our Phase 1b clinical trial. Our current efforts are primarily focused on possible partnering opportunities that may exist for our SMaRT Replacement Therapy. There can, however, be no assurances that we will be able to negotiate acceptable terms with a licensee or partner.

Manufacturing

The SMaRT strain grows readily in a variety of cultivation media and under a variety of common growth conditions including both aerobic and anaerobic incubations. The SMaRT strain can also utilize various carbon and nitrogen sources and is highly acid tolerant. There is no significant limitation to the manufacturing scale of our SMaRT strain other than the size of the containment vessel. In connection with our clinical trial, we engaged a contract manufacturer to produce an attenuated version our SMaRT strain, using a standard operating procedure provided by us that we believe is readily transferable to outside contract manufacturers with large scale GMP fermentation capabilities.

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 SMaRT Replacement Therapy and 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.

SMaRT Replacement Therapy – We have exclusively licensed the intellectual property for our replacement therapy technology from the UFRF. The original license agreement was dated August 4, 1998 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. 5,607,672, entitled "Replacement Therapy for Dental Caries", which was filed in the U.S. PTO on June 7, 1995 and made effective on March 4, 1997. The patent will expire on June 7, 2015. Our license is for the period of the patent, subject to the performance of terms and conditions contained therein. We have in licensed technology from Texas A&M University (discussed below) which may enable us to design a second generation of SMaRT Replacement Therapy which could result in the potential for a new exclusivity period from that provided by the SMaRT Replacement Therapy patent.

Additional Terms of UFRF License Agreements - In the amended license agreements for SMaRT Replacement Therapy and 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) May 1, 2013(for the SMaRT Replacement Therapy license agreement) and 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 agreements in the amount of $10,000 for each license agreement and $20,000 in aggregate. The aggregate minimum annual payments are required to be paid in advance on a quarterly basis which amounts to $5,000 per quarter for both licenses. We must also pay all patent costs and expenses incurred by the UFRF for the preparation, filing, prosecution, issuance and maintenance of the patents. 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 products.

The terms of the UFRF amended license agreements expire upon the earlier of (i) the date that no patents covered by the license agreements remain enforceable or (ii) the payment of earned royalties under the amended license agreements, 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 agreements if we breach our obligations to timely pay any amounts due under the amended license agreements, to submit development reports as required under the license agreements or commit any other breach of any other covenants contained in the license agreements and we fail to remedy such breach within 90 days after written notice of such breach by UFRF.

After the effective date of termination of the SMaRT Replacement Therapy amended license agreement, we may sell all licensed products and complete licensed products in the process of manufacture at the time of such termination and sell the same, provided we make the royalty payments described above and submit the reports required under the SMaRT Replacement Therapy amended license agreement.

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." 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 I 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 II 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 III 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.

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.

Our 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.

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).

None of the Lantibiotic ECC milestones had been achieved as of December 31, 2014.

Our Live Biotherapeutic Products/ ECC

On September 30, 2013, we entered into the LBPs ECC with Intrexon that governs a "channel collaboration" arrangement in which we will use Intrexon's proprietary technology relating to the identification, design, culturing and/or 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 "LBPs Program"). The LBPs ECC establishes committees comprised of our representatives and Intrexon representatives that will govern activities related to the LBPs 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 LBPs Program and established the priorities, as well as approved the budgets for such projects.

The LBPs ECC grants us 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, we may not sublicense the rights described without Intrexon's written consent. Under the LBPs ECC, and subject to certain exceptions, we are responsible for, among other things, funding the further anticipated development of probiotics toward the goal of commercialization, conducting nonclinical 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, certain aspects of the manufacturing process, and costs of filing, prosecution and maintenance of Intrexon's patents.

We will pay Intrexon 10% of the net sales derived from the sale of products developed from the exclusive channel collaboration relating to the LBPs Program. We have 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.

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 LBPs ECC), (iii) our breach of a material representation, warranty or covenant in the LBPs ECC, or (iv) the design, development, manufacture, regulatory approval, handling, storage, transport, distribution, sale or other disposition of any Company Product.

We may voluntarily terminate the LBPs ECC upon 90 days written notice to Intrexon. Intrexon may also terminate the LBPs ECC if we breach the LBPs ECC 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 LBPs ECC.

Upon termination of the LBPs ECC, we 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 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 of the LBPs Program.

Our obligation to pay 10% of net sales 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" Company Products will survive termination of the LBPs ECC.

In addition, in partial consideration for each party's execution and delivery of the LBPs ECC, on September 30, 2013 we 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, we paid Intrexon an up-front technology access fee of $6,000,000 (the "Technology Access Fee") in consideration for the execution of the LBPs ECC. The Technology Access Fee was paid to Intrexon by us through the (i) issuance of 1,348,000 (at $3.00 per share) shares of our common stock (the "Technology Access Shares"), and (ii) a convertible promissory note in the amount of $1,956,000 which was payable, at our option, in cash or shares of our common stock (the "Convertible Note"). The Convertible Note matured on December 31, 2013 and required us to obtain shareholder approval prior to conversion of the Convertible Note. The conversion price was equal to the closing price per share of our common stock on the last trading day immediately prior to the date of conversion. On December 18, 2013, we issued 698,241 shares of our common stock to Intrexon in satisfaction of principal and interest due on the Convertible Note at a conversion price of $2.82 per share.

On September 30, 2013 we also sold to Intrexon 1,300,000 shares of our common stock at a price per share of $3.00 for gross proceeds of $3,900,000. The proceeds from this sale are expected to be used for development of our key initiatives relating to the LBPs Program, and general corporate purposes.

Under the SPIA and as part of the LBPs ECC, we have also agreed to make certain payments to Intrexon upon our achievement of designated milestones. The milestone payments are each payable to Intrexon, at our election (subject to an election right of Intrexon if the milestone is achieved by a sublicensee), either in cash or in shares of our 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 us or on behalf of us, or an Affiliate (as that term is defined in the LBPs ECC) or our permitted sublicensee, in a phase II 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;
- $5,000,000 within thirty (30) days of the first meeting of the primary endpoint by us or on our behalf, or an Affiliate or our permitted sublicensee, 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 LBPs ECC) of a Company Product, or (b) the approval of a New Drug Application (as that term is defined in the LBPs ECC) for a Company Product by the FDA or equivalent regulatory action in a foreign jurisdiction.

None of the LBPs ECC milestones had been achieved as of December 31, 2014.

Government Regulations

The formulation, manufacturing, processing, packaging, labeling, advertising, distribution and sale of our products are subject to regulation by federal agencies, including, but not limited to the Food and Drug Administration, or FDA, and the Federal Trade Commission, or FTC. These activities also are regulated by various agencies of the states, localities and foreign countries in which our products are sold. In particular, the FDA, under the Federal Food, Drug, and Cosmetic Act, or FDCA, regulates the safety, manufacturing, labeling and distribution of drugs, medical devices, food, and dietary supplements. In addition, the FTC has primary jurisdiction to regulate the advertising of drugs, medical devices, food and dietary supplements. In foreign countries these same activities may be regulated by Ministries of Health, or other local regulatory agencies. The manner in which products sold in foreign countries are registered, how they are formulated, or what claims may be permitted may differ from similar products and practices in the United States.

FDA Regulation—Food

Under the FDCA, the FDA is responsible for ensuring that foods are safe, wholesome, and correctly labeled. The FDA enforces statutory prohibitions against misbranded and adulterated foods, and establishes safety standards for food processing and ingredients, manufacturing procedures for processed foods, and labeling standards for food products.

All facilities engaged in manufacturing, processing, packing or holding food for consumption in the United States must be registered with FDA before such activities begin. Those who manufacture, package, or hold food must comply with the Good Manufacturing Practices, or GMPs, for foods. The GMPs describe the methods, equipment, facilities, and controls for producing processed food, including requirements for personnel such as education, training and cleanliness requirements; proper maintenance and sanitization of buildings, facilities, and equipment; and processes and controls.

Acceptable claims for foods fall into three categories: health claims, structure/function claims and nutrient content claims. Health claims describe a relationship between a food, food component, or dietary ingredient and reducing the risk of a disease or health-related condition. The FDA authorizes these types of health claims based on an extensive review of the scientific literature, generally as a result of the submission of a health claim petition.

Manufacturers also may make certain health claims based on "authoritative statements" from a scientific body of the U.S. Government or the National Academy of Sciences. Structure/function claims describe the role of a nutrient or dietary ingredient intended to affect or maintain normal structure or function of the body, and may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function. Nutrient content claims expressly or by implication characterize the level of a nutrient in a food, by using terms such as "free," "high" or "low." The FDA's regulations define the nutrient content claims that may be used and the requirements for making such claims.

Labels for food must not be false or misleading. Required information for labels includes the name of the food, the net quantity, the name and address of the manufacturer, packer or distributor, the ingredient list, and a Nutrition Facts label. In addition to the information required to be in a Nutrition Facts label, other nutrients must be included in the Nutrition Facts label if the nutrients are added as a nutrient supplement to the food, if the label makes a nutrition claim about them, or if advertising or product literature connects the nutrients to the food. The FDA considers information that is required or permitted in the Nutrition Facts label, on the front label or elsewhere on the package to be a nutrition content claim. In such cases, the package label must comply with the regulations for nutrient content claims.

Under the FDCA, any substance that is intentionally added to food is a food ingredient, which is subject to premarket review and approval by the FDA, unless the substance is Generally Recognized As Safe, or GRAS, which means that the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food ingredient. Under FDA's regulations, the use of a food substance may be GRAS either through scientific procedures that may be voluntarily submitted to the FDA, or, for a substance used in food before 1958, through experience based on common use in food. General recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as required to obtain approval of the substance as a food ingredient and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information. General recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers. To be considered "safe" for its intended use, there must be a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use. The specific data and information that demonstrate safety depend on the characteristics of the substance, the estimated dietary intake, and the population that will consume the substance.

Registered food facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States are required to submit a report to the FDA's Reportable Food Registry, or RFR, when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death. The RFR covers all foods regulated by FDA except infant formula and dietary supplements. Registered facilities must report as soon as practicable, but in no case later than 24 hours after it is determined that an article of food is a reportable food.

FDA Regulation—Dietary Supplements

The Dietary Supplement Health and Education Act of 1994, or DSHEA, amended the FDCA by establishing regulatory standards with respect to dietary supplements, and defining dietary supplements as a new category of food. Dietary supplements include vitamins, minerals, amino acids, nutritional supplements, herbs and botanicals intended for ingestion that are labeled as dietary supplements and are not represented for use as a conventional food or as a sole item of a meal or the diet. Under DSHEA, a firm that manufactures or distributes dietary supplements must determine that such products are safe and that any representations or claims made about the products are substantiated by adequate evidence to show that the claims are not false or misleading.

DSHEA does not require manufacturers or distributors to seek approval from the FDA before producing or selling a dietary supplement unless the supplement contains one or more ingredients that are considered to be a "new dietary ingredient." A "new dietary ingredient" is one that was not marketed in the United States before October 15, 1994. The manufacturer or distributor of a dietary supplement that contains a "new dietary ingredient" must provide the FDA with information, including any citations to published articles, demonstrating why the ingredient is reasonably expected to be safe for use in a dietary supplement at least 75 days before the dietary supplement is introduced or delivered for introduction into interstate commerce. This requirement does not apply if the ingredient has been recognized as a food substance and is present in the food supply.

Because dietary supplements are foods, manufacturers of dietary supplements must register the facilities where the supplements are manufactured, processed, packed or held with the FDA before such activities begin. Those who manufacture, package or hold dietary supplements also must comply with GMPs for dietary supplements. According to the GMPs, dietary supplements must be prepared, packaged, labeled and held in compliance with specific requirements, including detailed quality control requirements, such as those for maintaining and cleaning facilities and instruments, hiring and training personnel and ensuring the appropriate manufacturing environment, testing requirements, recordkeeping requirements and handling of customer complaints. Anyone who manufactures, packages, labels or holds dietary supplements must evaluate and ensure the identity, purity, strength and composition of the products. FDA regulations also require that certain information appear on dietary supplement labels, including the name of the dietary supplement, the amount of the dietary supplement, nutrition labeling, a complete list of ingredients and the name and place of business of the manufacturer, packer or distributor.

Manufacturers must ensure, and have substantiation showing, that claims made about dietary supplements are truthful and not misleading. Acceptable claims for dietary supplements are the same as those for conventional foods: health claims, structure/function claims and nutrient content claims. However, additional requirements apply to manufacturers of dietary supplements who make structure/function claims. Manufacturers of dietary supplements must notify the FDA of any structure/function claims made for a dietary supplement within 30 days of first marketing the product with the identified claims. A dietary supplement that includes a structure/function claim on its labeling is also required to bear a prescribed disclaimer: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.” The manufacturer, packer, or distributor of a dietary supplement must submit to the FDA any report it receives of a serious adverse event associated with the dietary supplement when used in the United States, accompanied by a copy of the label of the dietary supplement, no later than 15 business days after the report is received. A “serious adverse event” is an adverse event that results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, a congenital anomaly or birth defect, or requires, based on a reasonable medical judgment, medical or surgical intervention to prevent such outcomes.

The FDA may take action to restrict use of a dietary supplement or to remove it from the marketplace if the agency believes the supplement presents a significant or unreasonable risk of illness or injury under conditions of use suggested in the labeling or under ordinary conditions of use. Under DSHEA, the FDA bears the burden of proof to show that a dietary supplement presents a significant or unreasonable risk of illness or injury. The FDA also may take enforcement action against a dietary supplement manufacturer or distributor for unlawful promotion of a dietary supplement, such as making claims that a supplement treats, prevents or cures a specific disease or condition. These claims would subject the dietary supplement to regulation as a drug product. If dietary supplements do not meet applicable requirements, the manufacturer may need to undertake a voluntary recall.

FDA Regulation—Biological Products and New Drug Products

Under the FDCA all new drugs and biological products are subject to pre-market approval by the FDA. In contrast to chemically synthesized small molecular weight drugs, which have a well-defined structure and can be thoroughly characterized, biological products are generally derived from living material—human, animal, or microorganism—are complex in structure, and thus are usually not fully characterized. Biological products include blood-derived products, vaccines, in vivo diagnostic allergenic products, immunoglobulin products, products containing cells or microorganisms, and most protein products. Biological products subject to the Public Health Service, or PHS, Act also meet the definition of *drugs* under the FDCA, therefore both biological products and drugs are regulated under provisions of the FDCA. However, only biological products are licensed under the PHS Act. The overall development process for biological products is similar to that for drugs. The steps ordinarily required before a biological product or new drug may be marketed in the United States include:

- completion of nonclinical studies according to Good Laboratory Practice, or GLP, regulations;
- the submission of an IND application to the FDA, which must become effective before human clinical trials may commence;

- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices to establish the safety and efficacy of the proposed biological product or new drug for its intended use;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product is manufactured, processed, packaged or held to assess compliance with GMPs; and
- the submission to, and review and approval by, the FDA of a biologics license application, or BLA, or new drug application, or NDA, that includes satisfactory results of nonclinical testing and clinical trials.

Nonclinical tests include laboratory evaluation of the product candidate, its formulation and stability, as well as animal studies. The FDA requires that nonclinical tests be conducted in compliance with GLP regulations. The results of nonclinical testing are submitted as part of an IND application to the FDA together with manufacturing information for the clinical supply, analytical data, the protocol for the initial clinical trials and any available clinical data or literature. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. FDA may also impose clinical holds at any time before or during studies due to safety concerns or non-compliance.

Clinical trials to support BLAs and NDAs involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated. Clinical trials are typically conducted in three sequential phases, but the phases may overlap.

In Phase 1 clinical trials, the biological or new drug product candidate is initially introduced into human subjects or patients and assessed for safety, dosage tolerance, absorption, metabolism, distribution and excretion, including any side effects associated with increasing doses.

Phase 2 clinical trials usually involve studies in a limited patient population to identify possible adverse effects and safety risks; preliminarily assess the efficacy of the product candidate in specific, targeted indications; and assess dosage tolerance and optimal dosage.

If a product candidate is found to be potentially effective and to have an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken within an expanded patient population at multiple study sites to further demonstrate clinical efficacy and safety, further evaluate dosage and establish the risk-benefit ratio of the product and an adequate basis for product labeling.

Phase 4, or post-marketing, trials may be mandated by the FDA or may be conducted voluntarily. Phase 4 trials are typically initiated to monitor the safety and efficacy of a biological product or new drug in its approved population and indication over a longer period of time, so that rare or long-term adverse effects can be detected over a much larger patient population and time than was possible during prior clinical trials. Alternatively, Phase 4 trials may be used to test a new method of product administration, or to investigate a product's use in other indications. Adverse effects detected by Phase 4 trials may result in the withdrawal or restriction of a product.

If the required Phase 1, 2 and 3 clinical testing is completed successfully, the results of product development, nonclinical studies and clinical trials, descriptions of the manufacturing process and other relevant information concerning the safety and effectiveness of the biological product or new drug candidate are submitted to the FDA in the form of a BLA or NDA. In most cases, the BLA or NDA must be accompanied by a substantial user fee. The FDA may deny a BLA or NDA if all applicable regulatory criteria are not satisfied or may require additional data, including clinical, toxicology, safety or manufacturing data. It can take several years for the FDA to approve a BLA or NDA once it is submitted, if at all, and the actual time required for any product candidate may vary substantially, depending upon the nature, complexity and novelty of the product candidate. Before approving an application, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve a BLA or NDA unless it determines that the manufacturing processes and facilities are in compliance with GMP requirements.

If the FDA evaluations of the BLA or NDA and the manufacturing facilities are favorable, the FDA will issue an approval letter. If the FDA determines that it will not approve an NDA or BLA in its present form for one or more reasons, the FDA will issue a complete response letter. The complete response letter usually contains a number of conditions that must be met before FDA will approve the BLA or NDA. If the BLA or NDA does not meet the criteria for approval, the FDA may deny the application.

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.

FDA Regulation—Medical Devices

Medical devices also are subject to extensive regulation by the FDA. To be commercially distributed in the United States, devices that are not exempt from FDA's premarket notification, or 510(k) procedures, or are pre-amendment devices, meaning they were on the market prior to May 28, 1976, must receive either 510(k) clearance or pre-market approval, or PMA, from the FDA prior to marketing. Devices are assigned to one of three classes depending on the controls the FDA deems necessary to ensure the safety and effectiveness of the devices. Devices deemed to pose the least risk are placed in Class I. A Class I device is 510(k) exempt unless the device is intended for a use which is of substantial importance in preventing impairment of human health, or the device presents a potential unreasonable risk of illness or injury. Class II devices require the manufacturer to submit a pre-market notification to FDA unless they are 510(k) exempt. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, devices deemed not substantially equivalent to a previously 510(k) cleared device and certain other devices are placed in Class III. Most Class III devices require approved PMAs before marketing, although some Class III devices can get to market through the 510(k) process.

To obtain 510(k) clearance, a manufacturer must submit a pre-market notification demonstrating that the proposed device is "substantially equivalent" to a "predicate device," which is a previously 510(k) cleared Class I or Class II device, a pre-amendment Class III device for which the FDA has not yet called for PMA applications or a device that was in commercial distribution before May 28, 1976. To demonstrate substantial equivalence, the applicant must show that the device has the same intended use and the same technological characteristics as the predicate, or if the device has different technological characteristics than the predicate, the device does not raise new questions of safety and effectiveness, and is at least as safe and effective as the predicate. The FDA's 510(k) clearance pathway usually takes from four to twelve months, but it can last longer. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA approval.

A product not eligible for 510(k) clearance must follow the PMA pathway, which requires proof that there is a reasonable assurance of a device's safety and efficacy to the FDA's satisfaction. The PMA pathway is much more costly and lengthy than the 510(k) pathway. A PMA application typically must provide extensive nonclinical and clinical trial data and also information about the device and its components including, among other things, device design, manufacturing and labeling. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with quality system regulation requirements, which impose elaborate testing, control, documentation and other quality assurance procedures. Upon acceptance by the FDA of what it considers a completed filing, the FDA commences an in-depth review of the PMA application, which typically takes from one to two years, but may last longer. Even after approval of a PMA, a new PMA or PMA supplement is required in the event of a modification affecting the safety or effectiveness of the device.

FDA Regulation—Post-Market Requirements

Even if regulatory clearances or approvals for our product candidates are obtained, our products and the facilities manufacturing our products, including foods, will be subject to continued review and periodic inspections by the FDA. The FDA may perform these inspections at any time without advanced notice. For example, as a condition of approval of an NDA, the FDA may require us to engage in post-marketing testing and surveillance and to monitor the safety and efficacy of our products. Holders of an approved NDA, BLA, or PMA, or 510(k) clearance are subject to several post-market requirements, including the reporting of certain adverse events involving their products to the FDA, provision of updated safety and efficacy information, and compliance with requirements concerning the advertising and promotion of their products.

The FDA will inspect manufacturing facilities to confirm that the facilities comply with GMP requirements. To comply with GMP requirements, manufacturers must expend money, time and effort in the area of production and quality control to ensure full compliance. For example, manufacturers of biologic products must establish validated systems to ensure that products meet high standards of sterility, safety, purity, potency and identity, and must report to the FDA any deviations from GMP or any unexpected or unforeseeable event that may affect a product's safety, purity, or potency. The regulations also impose documentation requirements and require manufacturers of drugs, biologics or devices to investigate and correct any unexplained discrepancy or the failure of a lot or unit to meet any of its specifications.

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.

FTC Regulation

The advertising of our products is subject to regulation by the FTC under the Federal Trade Commission Act, in addition to state and local regulation. The Federal Trade Commission Act prohibits unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce. The Federal Trade Commission Act also provides that the dissemination or the causing to be disseminated of any false advertisement pertaining to drugs or foods, which would include dietary supplements, is an unfair or deceptive act or practice. Under the FTC's Substantiation Doctrine, an advertiser is required to have a "reasonable basis" for all objective product claims before the claims are made. Failure to adequately substantiate claims may be considered either deceptive or unfair practices. Pursuant to this FTC requirement we are required to have adequate substantiation for all advertising claims made for our products.

In recent years the FTC has initiated numerous investigations of dietary supplement and weight loss products and companies. We may be the subject of investigation in the future, and the FTC may impose limitations on our advertising of products. The FTC has a variety of processes and remedies available to it for enforcement, both administratively and judicially, including compulsory processes, cease and desist orders, and injunctions. FTC enforcement can result in orders requiring, among other things, limits on advertising, corrective advertising, consumer redress, divestiture of assets, rescission of contracts and such other relief as may be deemed necessary.

International Regulation

Our product candidates are subject to regulation in every country where they will be tested or used. Whether or not we obtain FDA approval for a product candidate, we must obtain the necessary approvals from the comparable regulatory authorities of foreign countries before we can commence testing or marketing of a product candidate in those countries. The requirements governing the conduct of clinical trials and the approval processes vary from country to country and the time required may be longer or shorter than that associated with FDA approval. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution, would apply to any product that is approved outside the United States.

Future Legislation and Regulations

In the future we may be subject to additional laws or regulations by the FDA or other federal, state or foreign regulatory authorities, the repeal of laws or regulations, or more stringent interpretations of current laws or regulations. We are unable to predict the nature of such future laws, regulations, or interpretations, nor can we predict what effect additional governmental regulations or

administrative orders, when and if promulgated, would have on our business in the future. For example, for dietary supplements, the FDA or other governmental regulatory bodies could require the reformulation of certain products to meet new standards, the recall or discontinuance of certain products not able to be reformulated, imposition of additional record keeping requirements, expanded documentation of the properties of certain products, expanded or different labeling and scientific substantiation. Any or all of such requirements could have a materially adverse effect on our business, financial condition, results of operations and cash flows.

Competition

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

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

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

MU1140 Homologs and Other Lantibiotics

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

Live Biotherapeutic Products

There are several companies pursuing the area of genetically modified bacteria for use in treating symptoms and disease. Several large pharmaceutical companies are also thought to be looking at this area and they have significantly more resources than we do.

ProBiora3 Oral Care Probiotics

Many companies sell probiotics that are principally designed for digestive health, vaginal and urinary tract health, and immune system support. Our product will not compete directly with the products of these companies. Researchers at the University of Hiroshima in Japan have published studies indicating that *Lactobacillus reuteri*, or *L. reuteri*, a bacterial species isolated from the gastrointestinal tract, can reduce the levels of *S. mutans* in the mouth and may aid in the prevention of tooth decay. *L. reuteri* is widely used as a probiotic for other indications and recently has been promoted for dental health. We are aware of a probiotic product from BioGaia AB/Sunstar, containing a strain of *L. reuteri*, which is on the market today as GUM ® PerioBalance ® and is targeted to maintain oral health. Another probiotic bacteria for oral care, known as BLIS K12 probiotic, is commercially available from BLIS Technologies, Ltd., a New Zealand company. BLIS K12 is promoted as a probiotic for bad breath and contains the bacterium, *Streptococcus salivarius* K12. This bacterium principally colonizes the tongue and throat surfaces in the oral cavity, and as such is promoted only for its oral care activity as an aid for halitosis. We believe ProBiora3, with its unique blend of three proprietary probiotic strains, potentially has greater beneficial actions for maintaining oral health than these other products.

LPT3-04 Weight Loss Agent

The weight loss/management product category contains a host of companies selling solutions for boosting metabolism and thus increasing the body's rate of burning fat, for affecting satiety, or for blocking the absorption of fats or carbohydrates from the digestive tract. Many of these competitors are large companies with considerable resources and significant experience in this market area.

SMaRT Replacement Therapy

We are not aware of any direct competitors with respect to our licensed, patented replacement therapy technology. However, there may be several ways to disable or eradicate *S. mutans*. We know that certain companies and several academic and research institutions, such as the Forsyth Institute, the University of Alabama, and Guy's Hospital of London, are developing and testing caries vaccines aimed at eradicating *S. mutans*. An alternative approach involves topical application of adhesion- blocking synthetic peptides that prevent *S. mutans* from attaching to the tooth surface. Products that result in the elimination of *S. mutans* from the natural ecosystem would, however, require major studies to determine whether such eradication of naturally occurring bacteria might not create serious, unintended consequences. The problem with eradicating *S. mutans* is that it disrupts the natural ecosystem leaving a void for another pathogen potentially more harmful than *S. mutans* to dominate. We are not aware that any other company has filed an IND with the FDA to test their technology to address the matter. Any product based on our replacement therapy technology will compete against traditional oral care products used to combat tooth decay. These products include fluoride-based toothpastes as well as fluoride treatments and tooth sealants administered by dentists. These competitors could include, among others, Colgate, Procter & Gamble, Unilever, GlaxoSmithKline, and Dentsply.

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, 2014, we held approximately: two U.S. issued patents, five U.S. patent applications pending, two Patent Cooperation Treaty pending applications, twenty eight

foreign issued patents, and eleven twenty-two foreign patent applications pending. In addition, as of December 31, 2014, we have licenses for approximately six U.S. issued patents, zero U.S. patent applications pending, eleven foreign issued patents and zero foreign patent application pending. 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 as of December 31, 2014 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	2017	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

ProBiora3

Patent No.	Patent Expiration	Title/Product	Ownership	Jurisdiction Where Granted
7,931,892	2027	Compositions and Methods for the Maintenance of Oral Health	Owned	USA
8,865,156	2025	Compositions and Methods for the Maintenance of Oral Health	Owned	USA

SMaRT

Patent No.	Patent Expiration	Title/Product	Ownership	Jurisdiction Where Granted
5,607,672	2015	Replacement Therapies for Dental Caries of Oral Health	Exclusive License	USA

We have exclusively licensed the intellectual property for our MU1140 antibiotic product candidate, and SMaRT Replacement Therapy from the UFRF. Our exclusive license agreements extend 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.

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 interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, or in opposition proceedings in a foreign patent office, either 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. All of our brand products are sold under trademarks. 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 of material importance to our business. We have developed many brand names and trademarks for our products. Accordingly, our future success may depend in part upon the goodwill associated with our brand names. 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 hold U.S. trademark registrations for EVORAKIDS ®, EVORAPRO ®, EVORAPLUS ®, TEDDY’S PRIDE ®, STREPTOCOCCUS ORALIS KJ3®, STREPTOCOCCUS RATTUS JH145®, STREPTOCOCCUS UBERIS KJ2®, PROBIORA3® and ORAGENICS® (oral care probiotic preparations). We hold a European Community trademark registration for PROBIORA3®. Finally, we have applications pending and/or registered for key oral care probiotics brand marks in an additional 13 14 countries.

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 in marketing our products.

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 $3,065,053 and $9,358,957 on research and development of our technologies during the years ended December 31, 2014 and 2013, respectively. Approximately $6,000,000 of the 2013 research and development costs for 2013 consisted of a one-time up front Technology Access Fee we paid to Intrexon.

Employees

We have twelve 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 $5.8 million and $16.1 million for the years ended December 31, 2014, and 2013, respectively. As of December 31, 2014 our accumulated deficit was approximately $75.9 million. We have devoted a significant amount of our financial resources to research and development, including our nonclinical development activities and clinical trials, and currently we only have our ProBiora3 products available for commercial sale which to date has not generated significant revenue. We expect that the costs associated with our exclusive channel partnerships with Intrexon Corporation in the areas of lantibiotics ("Lantibiotics Program") and LBPs ("LBPs Program") and the development and commercialization of our product candidates under the Lantibiotics Program (which includes MU1140 homologs) and LBPs Program 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 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. As a result of the approximately $14.0 million in net proceeds from our private placement of common stock in September 2013 and our underwritten public offering in November 2013, we anticipate that our cash resources as of December 31, 2014 will be sufficient to fund our operations through March 2016. 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. Because we currently expect to devote a significant portion of our resources to develop and commercialize product candidates under our Lantibiotics Program and our LBPs Program with Intrexon and for ProBiora3 sales and marketing efforts further progress with the development of our other product candidates may be significantly delayed and may depend on the success of our development efforts involving our antibiotic candidates. Our actual costs, as well as the actual revenues from sales of our ProBiora3 products, 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 beyond twelve months, 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 planned nonclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. 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. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

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 utilize fermentation 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.

Our ProBiora3 products are currently our only source of product revenue and have not generated substantial revenues to date.

Currently our sole source of product revenues is from sales of our ProBiora3 products, which began in late 2008 and have generated only modest revenues to date. Sales of our ProBiora3 products were $939,926, $949,593 and $1,194,878 for the years ended December 31, 2014, 2013 and 2012, respectively. There can be no assurance our ProBiora3 product sales will ever generate significant revenue.

We are currently exploring strategic alternatives for our probiotic business and there can be no assurance that such strategic alternatives will result in any successful agreements or transactions.

In December of 2014, we announced that we would explore strategic alternatives for the probiotic business. These alternatives could include joint ventures, strategic partnerships or alliances, a sale of the probiotic products business or other possible transactions. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

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

Our product candidates under our Lantibiotics Program and LBPs 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. 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, we would expect to file an Investigational New Drug application with the FDA by the second half of 2016. 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 partnering arrangements with Intrexon are based on an early stage technology in the fields of lantibiotic and probiotics.

Our exclusive channel collaboration arrangement with Intrexon contemplates the use of Intrexon's advanced transgene and cell engineering platforms for the development and production of lantibiotics and LBPs**.** 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 LBPs 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 LBPs Program with Intrexon.

Because our collaborations with Intrexon are in the early stage and we have not yet identified a specific product candidate from the Intrexon collaborations, 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.

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

Under our ECCs with Intrexon we are responsible for, among other things, funding the further anticipated development of lantibiotics and LBPs 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). During the first 18 months, neither we nor Intrexon may terminate the ECC's, except under limited circumstances. 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 ECC's and if the ECC's are 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 other product candidates are in early stage development and will 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. We recently determined to cease pursuit of our second Phase 1 clinical trial for SMaRT Replacement Therapy. There can be no assurance we will be able to establish a partner relationship or sublicense our Replacement Therapy technology for future development. 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 the remainder of 2015. 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 LBPs 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 revenues and 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 are to a large extent fixed. As a result, we may not be able to reduce our costs sufficiently to compensate for an unexpected shortfall in revenues, and even a modest shortfall in revenues could disproportionately and adversely affect financial results for that quarter. Individual products represent meaningful portions of our revenues in any quarter. 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;
- fluctuations in the size and rate of growth of overall consumer and retailer demand for our ProBiora3 products;
- our success in entering new geographic markets;
- decisions by us to incur additional expenses, such as increases in marketing or research and development;
- the level of expenses associated with our clinical trials;
- accounting rules governing recognition of revenues;
- the amount we reserve against returns and allowances; 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 announced guidance or the expectations of research analysts or investors, in which case the price of our common stock could decrease significantly.

Current and future economic and market conditions could materially adversely affect our revenues, expense levels and profitability.

The U.S. economy and the global economy are recovering from a severe recession. Factors such as uncertainties in consumer spending, a sustained regional and/or global economic downturn or slow recovery may reduce the demand for our ProBiora3 products. Furthermore, challenging economic conditions also may impair the ability of our customers to pay for our commercial products. Because consumer spending for our ProBiora3 products can generally be considered a discretionary purchase, we may experience a more negative impact on our business due to these conditions than other companies that do not depend on discretionary spending. If demand for our ProBiora3 products declines or our customers are otherwise unable to pay for our products, we may be required to offer extensive discounts or spend more on marketing than budgeted and our revenues, expense levels, and liquidity position will be materially adversely affected.

We are subject to government regulation of the processing, formulation, packaging, labeling and advertising of our consumer products.

Under the Federal Food, Drug, and Cosmetic Act, or FDCA, companies that manufacture and distribute foods, such as our ProBiora3 products, are limited in the claims that they are permitted to make about nutritional support on the product label without FDA approval. Any failure by us to adhere to the labeling requirements could lead to the FDA's requiring that our products be repackaged and relabeled, which would have a material adverse effect on our business. In addition, companies are responsible for the accuracy and truthfulness of, and must have substantiation for, any such statements. These claims must be truthful and not misleading. Statements must not claim to diagnose, mitigate, treat, cure or prevent a specific disease or class of disease. We are able to market our ProBiora3 products in reliance on the self-affirmed Generally Recognized As Safe, or self-affirmed GRAS, status of our active ingredient, ProBiora3. No governmental agency or other third party has made a determination as to whether or not ProBiora3 has achieved GRAS status. We make this determination based on independent scientific opinions that ProBiora3 is not harmful under its intended conditions of use. If the FDA, another regulatory authority or other third party denied our self-affirmed GRAS status for ProBiora3, we could face significant penalties or be required to undergo the regulatory approval process in order to market our probiotic products, and our business, financial condition and results of operations will be adversely affected. We cannot guarantee that in such a situation ProBiora3 would be approved.

The FDA's Good Manufacturing Practices, or GMPs, describe the methods, equipment, facilities, and controls for producing processed food and set the minimum sanitary and processing requirements for producing safe and wholesome food. Those who manufacture, package, or hold human food must comply with the GMPs. If we or our suppliers fail to comply with the GMPs, the FDA may take enforcement action against us or our suppliers.

The processing, formulation, packaging, labeling and advertising of our probiotic products are subject to regulation by one or more federal agencies including the FDA, the Federal Trade Commission and the Environmental Protection Agency. Our activities are also subject to regulation by various agencies of the states and localities in which our probiotic products are sold. Any changes in the current regulatory environment could impose requirements that would limit our ability to market our probiotic products and make bringing new products to market more expensive. In addition, the adoption of new regulations or changes in the interpretation of existing regulations may result in significant compliance costs or discontinuation of product sales and may adversely affect our business, financial condition and results of operations. While our ProBiora3 products are categorized as foods, it is possible that the FDA or a state regulatory agency could classify these products as a cosmetic or a drug. If the products are classified as cosmetics rather than a food, we would be limited to making claims that the products cleanse and beautify, but we could not make structure or function claims. If our probiotic products are classified as drugs, we would not be able to market the ProBiora3 products without going through the drug approval process. Either of these events would limit our ability to effectively market our products and would adversely affect our financial condition and results of operations. If the FDA or a state regulatory agency viewed the products as cosmetics or drugs, they could claim that the products are misbranded and require that we repackage and relabel the products and impose civil and/or criminal penalties. Either or both of these situations could adversely affect our business and operations.

If we undertake product recalls or incur liability claims with respect to our ProBiora3 products, such recalls or claims could increase our costs and adversely affect our reputation, revenues and operating income.

Our ProBiora3 products are designed for human and animal consumption and we may face product recalls or liability claims if the use of our products is alleged to have resulted in injury or death. ProBiora3 is classified as a food ingredient and is not subject to pre-market regulatory approval in the United States. Our ProBiora3 products contain ingredients that do not have long histories of human or animal consumption. Previously unknown adverse reactions resulting from consumption of these ingredients could occur. We may have to undertake various product recalls or be subject to liability claims, including, among others, that our ProBiora3 products include inadequate instructions for use or inadequate warnings concerning possible side effects and interactions with other substances. A product recall or liability claim against us could result in increased costs and could adversely affect our reputation with our customers, which, in turn, could have a material adverse effect on our business, financial condition and results of operations.

Product liability insurance is expensive, is subject to deductibles and coverage limitations, and may not be available in the future. While we currently maintain product liability insurance coverage, we cannot be sure that such coverage will be adequate to cover any incident or all incidents. In addition, we cannot be sure that we will be able to obtain or maintain insurance coverage at acceptable costs or in a sufficient amount, that our insurer will not disclaim coverage as to a future claim or that a product liability claim would not otherwise adversely affect our business, financial condition and results of operations. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. Uncertainties resulting from the initiation and continuation of product liability litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Product liability litigation and other related proceedings may also require significant management attention.

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 and to SMaRT Replacement Therapy, our license to these product candidates may be terminated and we will be unable to commercialize these product candidates.

We hold our MU1140 and SMaRT Replacement Therapy product candidates under licenses 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 agreements in the amount of $10,000 for each license agreement and $20,000 in aggregate. The aggregate minimum annual payments are required to be paid in advance on a quarterly basis (i.e. $5,000 per quarter) for both licenses. 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 and to SMaRT Replacement Therapy if we breach our obligations to timely pay these amounts, to submit development reports as required under the license agreements or commit any other breach of any other covenants contained in the license agreements 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 agreements are terminated, we will be unable to commercialize these product candidates.

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) May 1, 2013 (for the SMaRT Replacement Therapy license agreement) and 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 achieve sufficient sales of our ProBiora3 products or 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.

We depend on third-party manufacturers for our ProBiora3 products and we recently received notice from a supplier that it would discontinue producing two of the three strains of bacteria needed to produce ProBiora3. The loss of any manufacturer or any interruptions in the supply of our ProBiora3 products would have a negative impact on our revenues and profitability.

We currently have no manufacturing facilities and are dependent upon establishing relationships with independent manufacturers to supply our product needs. Although we have qualified and used at least two contract manufacturers for each step in our manufacturing process, we do not have a long-term supply agreement or commitment with any of our manufacturers. One supplier had produced two of the three strains of bacteria needed to produce ProBiora3 and one supplier is able to produce one of the strains of bacteria needed to produce ProBiora3. These suppliers use proprietary methodologies to produce these three strains of bacteria. During the second quarter of 2014. we received notice from the supplier producing two of the three bacteria strains needed to produce our ProBiora3 products, that it will discontinue manufacturing such strains effective December 20, 2014. While we are actively seeking another supplier, there can be no assurances that we will be able to secure an alternate supplier or that the terms of such arrangements would be economically viable. If our manufacturers are unable or unwilling to produce our ProBiora products in sufficient quantities, or at all, at acceptable pricing in accordance with specifications we establish from time to time we would need to find alternative manufacturers that are qualified. If, in such instances, we are unsuccessful in obtaining alternative manufacturers, it could impair our ability to sell our ProBiora3 products and would have a negative impact on our revenues and profitability. In addition, competitors who own their manufacturing facilities may have an advantage over us with respect to pricing, availability of product and in other areas through their control of the manufacturing process.

The risks associated with the numerous factors that could cause interruptions in the supply of our products, including manufacturing capacity limitations, regulatory inspections, changes in our sources for manufacturing, disputes with a manufacturer, our failure to timely locate and obtain replacement manufacturers as needed and conditions affecting the cost and availability of raw materials, are magnified when the suppliers are limited in number. Any interruption in the supply of finished products could hinder our ability to timely distribute our products and satisfy customer demand. If we are unable to obtain adequate product supplies to satisfy our customers' orders, we may lose those orders, our customers may cancel other orders, and they may choose instead to stock and purchase competing products. This could result in a loss of our market share and negatively affect our revenues and operations.

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 our ProBiora3 products, SMaRT Replacement Therapy, MU1140, 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, and continue to commercialize our ProBiora3 products, 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 our ProBiora3 products. Furthermore, manufacturing MU1140 or our other potential product candidates on a commercial scale have not yet been undertaken, so 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 ProBiora3 products 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.

If we are required to find an additional or alternative source of supply, there may be additional costs and delays in the development 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.

Our ProBiora3 products and our product candidates face various forms of competition from other products in the marketplace.

The pharmaceutical and biotechnology industries are characterized by intense competition, rapid product development and technological change. Most of the competition that our ProBiora3 products and our product candidates face comes from companies that are large, well established and have greater financial, marketing, sales and technological resources than we have. Our ProBiora3 products compete with a range of consumer and nutraceutical products. Our commercial success with product candidates will depend on our ability and the ability of any sub-licensees to compete effectively in marketing and product development areas including, but not limited to, sales and branding, drug safety, efficacy, ease of use, patient or customer compliance, price, marketing and distribution. There can be no assurance that competitors will not succeed in developing and marketing products that are more desirable or effective than our ProBiora3 products or the products developed from our product candidates or that would render our products obsolete and non-competitive. We anticipate that our SMaRT Replacement Therapy technology would compete with other companies attempting to develop technologies in the oral health care market, including vaccines.

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 (Dr. Martin Handfield and Mr. Albert Fosmoe). In October 2014, Dr. John Bonfiglio our Chief Executive Officer resigned and our Board of Directors is working to identify a successor. Mr. Michael Sullivan, Certified Public Accountant who was hired in February 2012 as our Chief Financial Officer, is currently acting as our Interim Principal Executive Officer while a replacement for Dr. Bonfiglio is being sought. 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. It is possible that when these studies are conducted, 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. 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 or that we will be generating significant revenues from any of our products, such as ProBiora3, sufficient to cover the associated costs. If we do not generate sufficient revenues to cover the associated costs or we cannot obtain financing on acceptable terms or at all, our business, financial condition and results of operations will be materially adversely affected.

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

We are subject to risks of doing business internationally as we attempt to expand our sales through international distributor relationships.

We have entered into a number of international distributor agreements for our ProBiora3 products. As a result, we expect to increase our revenues from international sales. A number of factors can slow or prevent international sales, or substantially increase the cost of international sales, and we may encounter certain risks of doing business internationally including the following:

- reduced protection and enforcement for our intellectual property rights;
- unexpected changes in, or impositions of, legislative or regulatory requirements that may limit our ability to sell our products and repatriate funds to the United States;
- political and economic instability;
- fluctuations in foreign currency exchange rates;
- difficulties in developing and maintaining distributor relationships in foreign countries;
- difficulties in negotiating acceptable contractual terms and enforcing contractual obligations;
- exposure to liabilities under the U.S. Foreign Corrupt Practices Act;
- potential trade restrictions and exchange controls;
- creditworthiness of foreign distributors, customer uncertainty and difficulty in foreign accounts receivable collection;
- the burden of complying with foreign laws; and
- potential for fines for claimed violations of foreign laws and regulations.

As we attempt to expand our sales internationally, our exposure to these risks could result in our inability to attain the anticipated benefits and our business could be adversely impacted. Our success will depend, in large part, on our ability to anticipate and effectively manage these and other risks associated with our international operations. However, any of these factors could adversely affect our international operations and, consequently, our operating results.

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 SMaRT Replacement Therapy and 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. 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.

The FDA instituted numerous clinical holds with respect to our Phase 1 clinical trial program for our SMaRT Replacement Therapy product candidate. Although the clinical holds were lifted with respect to the attenuated version of the SMaRT strain, a clinical hold remains in effect for our IND for the non-attenuated SMaRT strain. If the FDA does not lift the clinical hold on this IND, we will be unable to conduct the clinical trials necessary to obtain marketing approval of our product candidate. The FDA's concerns that resulted in these clinical holds may lead to the imposition of a new clinical hold or holds or the failure of our product candidates to obtain marketing approval.

In December 1998, the FDA imposed a clinical hold on the IND for our SMaRT strain. The FDA expressed concerns about the potential for DNA transfer into or from the SMaRT strain; the possible creation of an organism with increased ability to colonize and produce dental caries; and the potential for the transfer of the strain between humans. We met with the FDA to discuss proposed trials of an attenuated SMaRT strain to address the FDA's concerns, and the FDA informed us that such trials required a separate IND. We submitted an IND for the attenuated strain in March 2003.

The FDA then imposed multiple clinical holds with respect to the Phase 1 clinical trials of the attenuated strain. Specifically, we received clinical hold letters in May 2003, February 2004, June 2007 and August 2007. In connection with the clinical hold letter in May 2003, the FDA requested that we provide nonclinical data on eradication of the attenuated version of the SMaRT strain once it had been implanted and a plan for the eradication of the attenuated strain in the trial subjects and their spouse or partners. In an April 2004 meeting, the FDA suggested that we conduct two eradication trials: one in subjects without teeth, and, if successful, another trial in subjects with teeth. We submitted revised protocols in accordance with FDA's suggestions, and in November 2004 the FDA lifted the clinical hold for the attenuated strain.

We initiated our first Phase 1 clinical trial in April 2005, but we found it difficult to find subjects who fit the FDA's highly cautious inclusion and exclusion criteria, particularly with respect to the subjects' lack of dentition. We concluded this trial early after enrolling only two of the 15 planned subjects. The FDA then recommended that we revise the protocol for the evaluation of ten healthy male subjects, ranging from 18 to 30 years old and with normal dentition, in an institutionalized setting. After we submitted additional information, the FDA issued another clinical hold letter in June 2007 for the proposed trial with the attenuated strain, citing the need for a plan with respect to serious adverse effects; a plan for the eradication of the attenuated strain in trial subjects' offspring; and a required pregnancy test for female partners of subjects. We submitted additional protocols in response to the FDA's concerns. In August 2007, the FDA issued another clinical hold letter with required revisions to the protocol for offspring of subjects. We submitted a response to the clinical hold letter in September 2007, and the FDA removed the clinical hold for our Phase 1 trial in the attenuated strain in October 2007.

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. Due to the enrollment difficulty we encountered with our initial our Phase 1a clinical trial and now with our phase 1b clinical trial, we determined to discontinue pursuit of our Phase 1b clinical trial and instead focus our efforts on possible partnering opportunities that may exist for our SMaRT Replacement Therapy.

There can be no assurance that future clinical trials for the attenuated strain will be successful, or that the FDA will ever lift the clinical hold on the non-attenuated SMaRT strain. In addition, there can be no assurances that we will be able to locate a partner willing to pursue further development of our SMaRT Replacement Therapy technology. If the FDA does not lift the clinical hold on the non-attenuated SMaRT strain, we or a partner would not be able to conduct the clinical trials necessary to pursue marketing approval of the SMaRT strain.

The FDA may impose additional requirements that may significantly increase the time and expense of obtaining FDA approval. Although the FDA has removed the clinical holds with respect to our Phase 1 trials for the attenuated strain, if the FDA has further concerns regarding the safety or risks associated with our trials, the FDA could implement another clinical hold on our ongoing trial or future trials or raise concerns as a part of a future NDA review process for our SMaRT Replacement Therapy product candidate, which could delay or prevent marketing.

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, our SMaRT Replacement Therapy product candidate or any other product candidates from our Lantibiotics Program and LBPs 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, or if the FDA fails to lift the clinical hold on our IND for non-attenuated version of SMaRT, 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:

- our belief that SMaRT Replacement Therapy is one of the first genetically modified bacterial strains for use in humans, which may cause the FDA to proceed with additional caution;
- 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;
- 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 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 ProBiora3 products, 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

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 February 26, 2015, the KFLP, together with members of the Koski family, beneficially owns approximately 34.7% of our outstanding shares of common stock and Intrexon, together with its CEO, beneficially owns approximately 27.2% of our outstanding shares of common stock. After March 23, 2015 the KFLP's aggregate beneficial ownership will be 30.8% due to the expiration of outstanding warrants that are not in-the-money currently. Additionally, Christine L. Koski and Robert C. Koski, serve 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 5, 2012, contains a standstill provision pursuant to which, among other things, Intrexon has agreed that until June 5, 2015, 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.

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 new 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'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:

- 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;
- our level of, and expected future use of, working capital;
- 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.

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 your percentage ownership interest, which would have the effect of reducing your 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 36,178,944 shares as of December 30, 2014.

In connection with the Lantibiotic ECC that we entered into on June 20, 2012, we will a be required to issue additional shares of our common stock of up to 4.5% of our then outstanding common stock to Intrexon upon meeting certain commercialization milestones.

In connection with the new LBPs ECC we entered into on September 30, 2013, we will be required, at our option, to pay up to $17.0 million cash to Intrexon or issue up to $17.0 million of additional shares of our common stock to Intrexon upon meeting certain commercialization milestones. We also issued the Convertible Note in the amount of $1,956,000 which is payable, at our option, in cash or shares of our common stock. On December 18, 2013, we issued to Intrexon 698,241 shares of our common stock in connection with the conversion of the Convertible Note.

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 which expired on December 31, 2014. During the year ended December 31, 2014, as part of our non-employee director compensation program we issued an aggregate of 50,000 shares of our common stock to our non-employee directors under the Company's 2012 Equity Incentive Plan.

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 36,178,944 as of December 31, 2014.

As of December 31, 2014, there were 36,178,944 shares of our common stock outstanding, with another 2,532,094 shares of common stock issuable upon exercise of warrants to investors, 820,865 shares issuable upon exercise of options outstanding and an additional 1,501,673 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 September 30, 2013 we issued 1,348,000 restricted shares of our common stock to Intrexon as part of the technology access fee for the LBPs ECC and on the same date we also sold 1,300,000 restricted shares of our common stock to Intrexon 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 continue to 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.

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 which replaced our existing lease space located at the 3000 Bayport Drive location in Tampa. The new lease location has become our principal executive office and is also being used for sales and marketing and product distribution. The office space is 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, 2014 were $76,124 which includes insurance, taxes and utilities. Lease payments are capped during the term.

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, 2014 were $119,357 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 2014 and 2013. 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 beginning April 10, 2013 under the ticker symbol "OGEN" (we had been quoted on the over-the counter (OTC) Bulletin Board under the ticker symbol "OGEN" between September 21, 2012 and April 9, 2013 and under the ticker symbol "ORNI" between December 22, 2008 and September 20, 2012). The following table sets forth the high and low bid quotations of our common stock reflected on the OTC Bulletin Board for the first quarter and the applicable portion of the second quarter in 2013, thereafter the information is based on NYSE MKT high and low sales prices. 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 13, 2015 was $0.91 per share. As of February 13, 2015, there were approximately 56 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.

Period	2014		2013	
	High	Low	High	Low
First quarter	$4.65	$2.80	$4.12	$2.30
Second quarter	$3.11	$1.56	$3.99	$2.50
Third quarter	$2.05	$1.20	$3.49	$2.71
Fourth quarter	$1.29	$0.74	$3.32	$2.40

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, 2014. 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 the world leader in novel antibiotics against infectious disease. We also develop, market and sell proprietary oral cavity probiotics specifically designed to enhance oral health for humans and pets, under the brand names Evora and ProBiora.

Our Antibiotics

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 since 1927 when the first lantibiotic, Nisin, was discovered. We believe lantibiotics are generally recognized by the scientific community to be potent antibiotic agents.

We have performed nonclinical testing on MU1140, which has demonstrated the molecule's novel mechanism of action. 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. 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*. 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.

The challenge presented by lantibiotics is that they 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. Standard fermentation methods are used to make a variety of currently marketed antibiotics. When traditional fermentation methods are used to make lantibiotics the result has historically been the production of only minute amounts of the lantibiotic.

In order to meet the challenge associated with producing sufficient quantities of MU1140 for our clinical trials and ultimately our commercialization efforts, in June 2012, we entered into an exclusive channel collaboration agreement (the "Lantibiotic ECC") with Intrexon corporation ("Intrexon") for the development and commercialization of the native strain of MU1140 and related homologs using Intrexon's advanced transgene and cell engineering platforms. We continue to pursue our research and development and collaboration efforts with Intrexon in accordance with the terms of the Lantibiotic ECC toward the development of the MU1140 molecule and potential derivatives of the molecule. We commenced limited nonclinical activities on MU1140 developed under the Lantibiotic ECC with Intrexon in the second half of 2013. Through our work with Intrexon, we have been able to produce an exponential increase in the fermentation titer of the target compound MU1140 and the discovery of a new purification process for MU1140. Since then, our exclusive collaboration generated a substantial number of homologs of MU1140, and we screened these homologs and found several candidates with either enhanced therapeutic profiles or different specificities against resistant bacteria from that of the parent compound, MU1140. The decision to examine these new homologs of MU1140 meant we had to reproduce the fermentation and purification steps on at least 10-15 homologs. 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 are working with third party manufacturers 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 that are needed for the consummation and pursuit of our nonclinical testing activities supporting the pre-IND meeting is currently underway. We currently expect to have a pre Investigational New Drug ("IND") meeting with the FDA in the second half of 2015 and thereafter be in a position to file the IND for a first-in-human clinical study in 2016. We continue to work aggressively in the course of our research and development to meet these events.

Our Probiotic Products

We are marketing a variety of probiotic products that we developed. Our probiotic products contain the active ingredient ProBiora3, a patented blend of oral care probiotics that promote fresher breath, whiter teeth and support overall oral health. We have conducted scientific studies on ProBiora3 in order to market our products under self-affirmed Generally Recognized As Safe status ("GRAS"). We have historically sold our ProBiora3 products through multiple distribution channels. We continue to seek improvement in the performance of our oral care probiotics products, to better serve our customers, and we continue to evaluate new delivery systems, which we believe will enable us to deliver ProBiora3 to new markets and end-users.

Since initial commercialization of our ProBiora3 products we have attempted to improve market awareness and sales of our oral probiotic product line with limited success to date and we have reduced our marketing expenditures accordingly to focus more on lantibiotics. The allocation of limited financial resources between research and development of lantibiotics for our other product candidates and sale and marketing efforts for our ProBiora3 products, among other factors, resulted in our December 2014 announcement that we would seek to explore strategic alternatives for the probiotic business. These alternatives could include joint ventures, strategic partnerships or alliances, a sale of the probiotic products business or other possible transactions. There can be no assurance that a transaction or agreement, will be consummated with terms favorable to us.

Live Biotherapeutic Products (LBP)

On September 30, 2013, we entered into a second worldwide exclusive channel collaboration agreement with Intrexon that governs a "channel collaboration" arrangement in which we will use Intrexon's proprietary technology relating to the identification, design, culturing and/or production of genetically modified cells, DNA vectors and in vivo control of expression for the development and commercialization of LBPs, specifically the direct administration to humans of genetically modified bacterial LBPs for the treatment of diseases of the oral cavity, throat, sinus and esophagus, including, but not limited to, aphthous stomatitis and Behcet's disease (the "LBPs ECC"). Our efforts in connection with developing bacteria-based biotherapeutics for oral cavity, throat, sinus and esophagus diseases, is being reconsidered. Our initial planned focus was to develop a genetically engineered bacterial strain designed to deliver and release a therapeutic locally at the oral disease sites to target pain management, reduce inflammation, and improve patient outcomes in Behcets Disease (and/or Aphtous Stomatitis). After consulting several Key Opinion Leaders, we concluded that other therapeutic indications may be more commercially-viable in the long run. This approach is currently under consideration by management.

Other Product Candidates and Technologies.

We also possess and have developed other product candidates and technologies that originated from the discoveries of our scientific team. These other product candidates and technologies include our SMaRT Replacement Therapy and our weight loss agent, LPT3-04. For our other product candidates and technologies, we do not expect to devote financial resources toward continued research and development.

Our SMaRT 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. Due to the enrollment difficulty we encountered with our initial Phase 1a clinical trial and now with our Phase 1b clinical trial, we determined to discontinue pursuit of our Phase 1b clinical trial. Our current focus is on possible partnering opportunities that may exist for our SMaRT Replacement Therapy.

Our Weight Loss Agent-LPT3-04. LPT3-04 is a natural occurring dietary substance with an excellent safety and tolerance profile that is believed to support weight loss in overweight men and women. LPT3-04 is normally consumed in the human diet in small amounts, in the course of our SMaRT Replacement Therapy research; our scientific team also discovered that consumption of a significant amount of LPT3-04, resulted in dose-dependent weight loss in experimental animal models. In December 2013 we entered into an exclusive licensing agreement for our LPT3-04 weight-loss product candidate with LPThera LLC for further development of this technology.

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 the commercialization of our ProBiora3 products as well as our discovery efforts comprising research and development, clinical trials for our product candidates, protection of our intellectual property and the general and administrative support of these operations. We have generated limited revenues from grants and ProBiora3 product sales through December 31, 2014, 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 of our ProBiora3 products, which we initiated in late 2008. For the years ended December 31, 2014 and 2013, our net revenues were $939,926 and $1,032,233, respectively.

As of December 31, 2014 we had an accumulated deficit of $75,944,635 and we have yet to achieve profitability. We incurred net losses of $5,789,519 and $16,068,754 for the years ended December 31, 2014 and 2013, respectively. We expect to incur significant and increasing operating losses for the foreseeable future as we seek to advance our product candidates through nonclinical testing and clinical trials to ultimately obtain regulatory approval and eventual commercialization. We will need to raise additional capital. 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. There can be no assurance that additional capital will be available to us on acceptable terms, if at all.

Financial Overview

Net Revenues

Our revenues prior to 2008 consisted exclusively of grant funding from government agencies under the National Science Foundation's, or NSF, and National Institutes of Health's, or NIH, Small Business Innovation Research, or SBIR, grants. Since the initial launch of our ProBiora3 products in late 2008, our net revenues for the year ended December 31, 2008 and thereafter, also included sales of our ProBiora3 products. Sales of our ProBiora3 products were $939,926 and $949,593 for the years ended December 31, 2014 and 2013, respectively. Future increases in net revenue for our ProBiora3 products will depend on a number of factors, including our ability to successfully engage in marketing efforts related to our ProBiora3 products, which we have substantially scaled back. Our marketing efforts for our ProBiora3 products have had limited success to date as revenues have not significantly increased from period to period. We continue to consider options for marketing our ProBiora3 Products that can be cost-effective as we seek to manage the use of our cash resources relative to the research and development we are conducting for our other product candidates.

We expect that our future revenues will fluctuate from quarter to quarter as a result of the volume of sales of our products and the amount of license fees, research and development reimbursements, milestone and other payments from any license or strategic partnerships we may enter into in the future.

Cost of Goods Sold

Our cost of goods sold includes the production and manufacture of our ProBiora3 products, as well as shipping and processing expenses and scrap expense. Scrap expense represents product rework charges, inventory adjustments, inventory replacement reserves, and damaged inventory. Because our ProBiora3 products contain live organisms they have a limited shelf life. As such, we attempt to manage the amount of production we request of our manufacturers and the amount of inventory we maintain. We expect our costs of goods sold to increase as we are able to expand our distribution and sales efforts for our ProBiora3 products.

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 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 $3,065,053 and $9,358,957 for the years ended December 31, 2014 and 2013, respectively. Included in research and development expense for 2013 is the non-cash expense of $6,000,000 associated with an up-front payment of a technology access fee, consisting of the issuance of 1,348,000 shares of our common stock to Intrexon and the issuance of a convertible note to Intrexon for $1,956,000 in connection with the establishment of the LBPs ECC with Intrexon.

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 LBPs projects. 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. Certain of our current product development candidates are not expected to be commercially available until we are able to obtain regulatory approval from the FDA, which is not expected before 2017.

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 LBPs 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.

Selling, General and Administrative Expenses

Selling, 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:

- the exploring of strategic alternatives for, and sales and marketing of, our ProBiora3 products;
- 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.

Our Probiora3 marketing plans to date have attempted to strike a balance between the expenses of marketing and the achievement of improved sales. Striking this balance toward the goal of improving sales has been a challenge as we endeavor to achieve improved sales with an amount of marketing expenditures that are acceptable to us given our limited available cash resources and our need for the use of such resources on the development of our other product candidates. We expect to continue to consider our efforts to market ProBiora3 and evaluate such efforts and the amount of expense to be incurred relative to the expected improvement in sales and the goal of achieving improved sales while we explore strategic alternatives for the consumer probiotic business.

Other Income (Expense)

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

Income Taxes

As of December 31, 2014 and 2013, we have net operating loss carryforwards of approximately $69,735,000 and $64,151,000, respectively, to offset future federal and state income taxes. We also have research and development tax credit carryforwards of approximately $1,355,000 and $1,242,000 as of December 31, 2014 and 2013, 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 2034 and 2024, 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 ("GAAP"). The preparation of financial statements in accordance with 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, income tax valuation allowance, inventory obsolescence reserve, sales returns and allowances and allowance for doubtful accounts.

Revenue Recognition

We recognize revenues from the sales of product when title and risk of loss pass to the customer, which is generally when the product is shipped.

We record allowances for discounts and product returns at the time of sales as a reduction of revenues as such allowances can be reliably estimated based on historical experience or known trends. We maintain a return policy that allows our customers to return product within a specified period of time. Our estimate of the provision for returns is analyzed quarterly and is 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 our product returns changes, the reserve will be adjusted. While we believe that the reserves we have established are reasonable and appropriate based upon current facts and circumstances, applying different judgments to the same facts and circumstances would result in the estimated amounts for sales returns and chargebacks to vary. We could experience different circumstances in the future with respect to our ProBiora3 products and these differences could be material.

We granted guaranteed rights of return at various times to certain customers. At this time there are two dental distributors with guaranteed rights of return. The dental distributors have a six month period in which to return purchases of our product. While orders are processed and shipped on these accounts we defer recognition of revenue until the customer provides notification to us that the product has sold through to the end consumer. Once notification has been received and verified, we will record revenue in that accounting period.

Accounts Receivable

Accounts receivable are recorded at their net realizable value and consist of trade receivables from the sale of product to customers. We analyze accounts receivable on a monthly basis and determine the collectability based on the facts and circumstances relating to each customer. The company estimates their allowance for doubtful accounts based on sales trends and specific review of the creditworthiness of each customer.

Inventory

Inventories are stated at the lower of cost or market. Cost, which includes material, labor and overhead, is determined on a first-in, first-out basis. On a quarterly basis, we analyze our inventory levels and we reserve for the following: inventory that is expected to expire prior to being sold, inventory that has a cost basis in excess of its expected net realizable value, inventory in excess of expected sales requirements, or inventory that fails to meet commercial sale specifications. Expired inventory is disposed of and the related costs are written off to the reserve for inventory obsolescence. The inventory reserve at December 31, 2014 and 2013 was $50,184 and $31,462, 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 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

U.S. Generally Accepted Accounting Principles ("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 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 August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40) Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." ASU 2014-15 provides guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and about related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company's ability to continue as a going concern within one year from the date the financial statements are issued. Management will also be required to evaluate and disclose whether its plans alleviate that doubt. ASU 2014 – 15 is effective for the annual period ending after December 15, 2016, and for interim periods within annual periods ending after December 15, 2016. Earlier application is permitted. The Company is currently evaluating the requirements of ASU 2014-15 and has not yet determined its impact on the Company's financial statements.

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, "Revenue from Contracts with Customers (Topic 606)." ASU 2014-09 completes the joint effort by the FASB and International Accounting Standards Board (IASB) to improve financial reporting by creating common revenue recognition guidance for U.S. GAAP and International Financial Reporting Standards (IFRS). ASU 2014-09 applies to all companies that enter into contracts with customers to transfer goods or services. ASU 2014-09 is effective for public entities for interim and annual reporting periods beginning after December 15, 2016. Early application is not permitted and entities have the choice to apply ASU 2014-09 either retrospectively to each reporting period presented or by recognizing the cumulative effect of applying ASU 2014-09 at the date of initial application and not adjusting comparative information. The Company is currently evaluating the requirements of ASU 2014-09 and has not yet determined its impact on the Company's financial statements.

In July 2013, the FASB issued new accounting guidance on the presentation of unrecognized tax benefits, Accounting Standards Update No. 2013-11, "Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists," for fiscal years, and interim periods within those years, beginning after December 15, 2013. The new guidance requires an entity to present an unrecognized tax benefit, or a portion of an unrecognized tax benefit, as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward, except as follows: to the extent a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the applicable jurisdiction to settle any additional income taxes that would result

from the disallowance of a tax position or the tax law of the applicable jurisdiction does not require the entity to use, and the entity does not intend to use the deferred tax asset for such purpose, then the unrecognized tax benefit should be presented in the financial statements as a liability and should not be combined with deferred tax assets. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2013, with early adoption permitted. Accordingly, we adopted these presentation requirements during the first quarter of 2014. The adoption of this new guidance did not have a material impact on our financial statements or related disclosures.

There are no other new accounting pronouncements issued or effective during 2014 that have had or are expected to have an impact on the Company's financial statements.

Results of Operations:

	Years Ended December 31,		Three Months Ended December 31,	
	2014	2013	2014	2013
Revenue, net	$ 939,926	$ 1,032,233	$ 220,504	$ 434,784
Cost of sales	369,597	343,354	90,521	79,364
Operating expenses:				
Research and development	3,065,053	9,358,957	548,227	1,069,343
Selling, general and administrative	3,321,771	7,540,152	811,928	2,359,450
Total operating expenses	6,386,824	16,899,109	1,360,155	3,428,793
Loss from operations	(5,816,495)	(16,210,230)	(1,230,172)	(3,073,373)
Other income (expense):				
Interest income	36,998	23,546	7,823	8,448
Interest expense	(4,030)	(17,538)	(1,174)	(14,199)
Local business tax	(5,789)	(9,035)	(49)	(211)
Other income (expense)	(203)	144,503	—	—
Total other income (expense), net	26,976	141,476	6,600	(5,962)
Loss before income taxes	(5,789,519)	(16,068,754)	(1,223,572)	(3,079,335)
Income tax benefit	—	—	—	—
Net Loss	$(5,789,519)	$(16,068,754)	$(1,223,572)	$(3,079,335)

For the Three Months Ended December 31, 2014 and 2013

Net Revenues. We generated net revenues of $220,504 for the three months ended December 31, 2014 compared to $434,784 in the same period in 2013; a decrease of $214,280. This decrease was attributable to a decrease in grant revenues of $59,463 reflecting the completion of the work related to the grant and a net decrease in ProBiora3 revenues of $154,818 relating primarily to the reversal in 2013 of accruals for estimated sales returns and allowances. There was no such accrual reversal in 2014.

Cost of Sales. Cost of sales were $90,521 for the three months ended December 31, 2014 compared to $79,364 in the same period in 2013; an increase of $11,157. The increase was primarily attributable to a net increase in scrap expense. Gross margin for the three months ended December 31, 2014 was 68.1% versus 69.0% for the same period in 2013.

Research and Development. Research and development expenses were $548,227 for the three months ended December 31, 2014 compared to $1,069,343 in the same period in 2013; a decrease of $521,116, or 48.7%. This decrease was primarily attributed to a net decrease in stock based compensation costs of $239,880 which was primarily related to awards under the 2012 Equity Incentive Plan allocated to research and development, and a net decrease in costs associated with our lantibiotic development of $328,310**.**

Selling, General and Administrative. Selling, general and administrative expenses were $811,928 for the three months ended December 31, 2014 compared to $2,359,450 in the same period in 2013; a decrease of $1,547,522, or 65.6%. This decrease was due to decreases in stock based compensation costs of $1,589,403 which was primarily related to the achievement of performance goals and the resulting awards under our 2012 Equity Incentive Plan that were made in 2013. No such awards were made in 2014.

Other Income (Expense). Other income (expense) was $6,600 for the three months ended December 31, 2014 compared to $(5,962)) in the same period in 2013; a change of $12,562. The change was primarily attributable to a decrease in interest expense of $13,025 in 2014 as compared to 2013 related primarily to the financing of a portion of the LBPs ECC Technology Access Fee in 2013 in the form of a convertible note. No such financing occurred in 2014.

For the Years Ended December 31, 2014 and 2013

Net Revenues. We generated net revenues of $939,926 for the year ended December 31, 2014 compared to $1,032,233 for the year ended December 31, 2013; a decrease of $92,307. The decrease in net revenues was primarily attributable to an increase in revenues relating to the sales of ProBiora3 products of $87,819 which was offset by a decrease in grant revenues of $82,640 reflecting the completion of the work related to the grant and an increase in sales returns and allowances of $103,831 due to the reversal in 2013 of accruals for estimated sales returns and allowances. There was no such accrual reversal in 2014.

Cost of Sales. Cost of sales were $369,597 for the year ended December 31, 2014 compared to $343,354 for the year ended December 31, 2013; an increase of $26,243. This increase was primarily attributable to an increase in sales of our ProBiora3 products. Gross margin for the year ended December 31, 2014 was 69.9% versus 71.0% for the year ended December 31, 2013.

Research and Development. Research and development expenses were $3,065,053 for the year ended December 31, 2014 compared to $9,358,957 for the year ended December 31, 2013; a decrease of $6,293,904, or 67.2%. This decrease was primarily attributable to the payment of a $6.0 million technology access fee through the issuance of common stock and a Convertible Note payable to Intrexon pursuant to the terms of the new LBPs ECC during 2013. There was no such payment of a technology access fee to Intrexon Corporation during 2014. In addition, there was a decrease in stock based compensation costs of $242,471 allocated to research and development which is primarily related to awards under our 2012 Equity Incentive Plan.

Selling, General and Administrative. Selling, general and administrative expenses were $3,321,771 for the year ended December 31, 2014 compared to $7,540,152 for the year ended December 31, 2013; a decrease of $4,218,381, or 55.6%. This decrease was primarily attributed to decreases in: stock based compensation costs of $2,920,148 which is primarily related to awards under the 2012 Equity Incentive Plan made in 2013 and not in 2014, advertising costs decline of $871,360 related to our probiotic products, salary costs of $171,605, travel of $124,574, and filing fees of $131,303.

Other Income (Expense). Other income (expense) was $26,976 for the year ended December 31, 2014 compared to $141,476 for the year ended December 31, 2013; a change of $114,500. The change was primarily attributable to a decrease in interest expense of $13,508 and a decrease in other income of $144,706 due to the receipt of cash relating to the purchase of our membership interest in our mutual insurer by an unrelated third party in 2013 with no similar transaction occurring in 2014. These decreases were offset by an increase in interest income of $13,452.

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,	
	2014	2013
Net cash used in operating activities	$(5,559,130)	$ (6,764,533)
Net cash used in investing activities	(110,249)	(18,809)
Net cash (used) provided by financing activities	(158,210)	13,133,885
Net (decrease) increase in cash and cash equivalents	$(5,827,589)	$ 6,350,543

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 $10,226,856 and $15,811,722 as of December 31, 2014 and 2013, respectively.

The cash used by financing activities in the year December 31, 2014 was primarily due to the purchase of equipment to support our research and development activities. The cash provided by financing activities in the year December 31, 2013 was primarily due to the sale of 1,300,000 shares of our common stock to Intrexon and the sale of 4,400,000 shares of the our common stock in an underwritten public offering.

The September 2013 Private Placement and Convertible Note Payable to Shareholder

On September 30, 2013, we 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, we sold to Intrexon 1,300,000 shares of our common stock at a price per share of $3.00 for gross proceeds of $3,900,000. The proceeds from this sale of common stock are expected to be used for general corporate purposes, including the development of our key initiatives relating to the LBPs ECC.

Pursuant to the SPIA, we also paid Intrexon an up-front technology access fee of $6,000,000 (the "Technology Access Fee") in consideration for the execution of the LBPs ECC. The Technology Access Fee was paid to Intrexon by us through the (i) issuance of 1,348,000 (at $3.00 per share) shares of our common stock (the "Technology Access Shares"), and (ii) a convertible promissory note in the amount of $1,956,000 which was payable, at our option, in cash or shares of our common stock (the "Convertible Note"). The Convertible Note matured on December 31, 2013 and required us to obtain shareholder approval prior to conversion of the Convertible Note. The conversion price was equal to the closing price per share of our common stock on the last trading day immediately prior to the date of conversion. On December 18, 2013, we issued 698,241 shares of our common stock to Intrexon in satisfaction of the principal and interest due on the Convertible Note at a conversion price of $2.82 per share.

The November 2013 Underwritten Public Offering

On November 20, 2013, we completed an underwritten public offering of 4,400,000 shares of our common stock at a public offering price of $2.50 per share. The net proceeds to us, after underwriting discounts and commissions and offering expenses, were $9,904,996.

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 8, 2013, we entered into a short-term note payable for $50,037 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 due on January 10, 2014.

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 due on January 10, 2015.

On June 20, 2013, we entered into a short-term note payable for $106,994 bearing interest at 4.64% 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, 2013 and are made evenly based on a straight line amortization over an 11-month period with the final payment due on June 24, 2014.

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.

Future Capital Requirements

Our capital requirements for 2015 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 generate revenues and cash flow from our ProBiora3 products and 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 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 sufficient to satisfy our liquidity requirements. We believe our existing cash and cash equivalents will allow us to fund our operating plan through March 2016. We expect to continue to seek additional funding for our operations. 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 and in our new LBPs ECC. 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.

Because of the numerous risks and uncertainties associated with sales of our ProBiora3 products as well as 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 cash flow, if any, generated from our ProBiora3 product sales;
- 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 Corporation;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;

- the cost of commercialization activities for our ProBiora3 products and, if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- 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, 2014 and 2013, we have net operating loss carryforwards of approximately $69,735,000 and $64,151,000, respectively, to offset future federal and state income taxes. We also have research and development tax credit carryforwards of approximately $1,355,000 and $1,242,000 as of December 31, 2014 and 2013, 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 2034 and 2024, 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, 2014 and 2013, we recorded a 100% valuation allowance against our deferred tax assets of approximately $26,928,000 and $24,875,000, 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.

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 Exchange Act was performed under the supervision and participation of our senior management, including our Chief Executive Officer (through October 30, 2014) and our Interim Principal 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 (through October 30, 2014) and our Interim Principal Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures. Based upon that evaluation, our Interim Principal 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, 2014 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.

During 2011, we disclosed and identified several material weaknesses in our internal controls over financial reporting. Since that time we remediated all but one of the identified material weaknesses. The remaining material weakness relates to a lack of adequate segregation of duties due to our small number of employees. Nevertheless, based on a number of factors, including the performance of additional procedures by management designed to ensure the reliability of our financial reporting, management believes that the financial statements in our Annual Report on December 31, 2014 Form 10-K fairly present, in all material respects, our financial position, results of operations, and cash flows for the periods presented in conformity with GAAP.

While segregation of duties remains a challenge for us, management has taken steps to reduce this risk by continuing to limit access to the accounting systems wherever possible. This control weakness is expected to remain until such time as we expand and hire more accounting and finance staff. With the exception of segregation of duties management believes that, existing controls were effective and operating properly as designed. During 2014, management believes that the Company maintained a consistent and verifiable financial reporting organization and internal control procedures.

Changes in Internal Controls over Financial Reporting

Except as indicated in the preceding paragraphs about management's evaluation of disclosure controls and procedures and internal controls, our management, with the participation of our Chief Executive Officer (through October 2014) 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.

Interim Principal Executive Officer and Chief Financial Officer Certification

Appearing after the Signatures section of this report there is a Certification of the Interim Principal 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 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 Interim Principal Executive Officer and the Chief Financial Officer, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2014. 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)* and SEC guidance on conducting such assessments. Based on our assessment, we believe that, as of December 31, 2014, the Company's internal control over financial reporting was not effective due to the material weaknesses in the system of internal control described below. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Management identified that the Company has not properly segregated duties as a material weakness in that one or two individuals, initiate, authorize and complete transactions. There is limited segregation of duties which could result in a material misstatement in our financial statements. Given our staff levels, certain duties within the accounting and finance department cannot be properly segregated. However, we believe that none of these segregation of duty deficiencies resulted in material misstatement to the financial statements as we rely on certain compensating controls, including periodic substantive review of the financial statements by the Chief Executive Officer (through October 30, 2014), Chief Financial Officer, Audit Committee and Board of Directors.

Accordingly, while the Company has identified a material weakness in its system of internal control over financial reporting, it believes that it has taken reasonable cost-effective steps to ascertain that the financial information contained in this report is in accordance with generally accepted accounting principles. Management has determined that current resources would be appropriately applied elsewhere and when resources permit, they will alleviate the material weakness through various steps.

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.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Information in response to this Item is incorporated herein by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this annual report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION.

Information in response to this Item is incorporated herein by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this annual report on Form 10-K.

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

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, 2014 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	820,865	$ 4.03	1,501,673
Equity compensation plans not approved by stockholders: (1)			
None	—	$ —	—
Total:	820,865	$ 4.03	1,501,673

(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 2,532,094 shares of common stock outstanding at a weighted average exercise price of $1.93 per share.

Additional information in response to this Item is incorporated herein by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year-covered by this annual report on Form 10-K.

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

Information in response to this Item is incorporated herein by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year-covered by this annual report on Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

Information in response to this Item is incorporated herein by reference to our definitive proxy statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this annual report on Form 10-K.

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-29.

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.

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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, 2015

ORAGENICS, INC.

By: /s/ Michael O. Sullivan
Michael O. Sullivan,
Interim Principal Executive Officer, and Chief Financial Officer
(Principal 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/ Michael O. Sullivan Michael O. Sullivan	Interim Principal Executive Officer and Chief Financial Officer (Principal Accounting and Financial Officer)	February 27, 2015
/s/ Christine L. Koski Christine L. Koski	Director	February 27, 2015
/s/ Robert C. Koski Robert C. Koski	Director	February 27, 2015
/s/ Frederick W. Telling Frederick W. Telling	Chairman and Director	February 27, 2015
/s/ Charles L. Pope Charles L. Pope	Director	February 27, 2015
/s/ Alan W. Dunton Alan W. Dunton	Director	February 27, 2015

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Financial Statements

Oragenics, Inc.

Financial Statements

Years Ended December 31, 2014 and 2013

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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, 2014 and 2013 and the related statements of operations, changes in shareholders' equity, and cash flows for the years then ended. 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, 2014 and 2013, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

February 26, 2015

/s/ Mayer Hoffman McCann P.C.

Clearwater, Florida

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Oragenics, Inc.
Balance Sheets
December 31, 2014 and 2013

	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	$ 10,448,921	$ 16,276,510
Accounts receivables, net	15,608	64,434
Inventory, net	439,189	288,383
Prepaid expenses and other current assets	119,410	175,242
Total current assets	11,023,128	16,804,569
Property and equipment, net	109,292	26,913
Total assets	$ 11,132,420	$ 16,831,482
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 710,210	$ 909,957
Short-term notes payable	64,840	64,051
Deferred revenue	21,222	18,839
Total current liabilities	796,272	992,847
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 and 50,000,000 shares authorized as of December 31, 2014 and 2013 respectively; 36,178,944 and 35,993,944 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively	36,179	35,994
Additional paid-in capital	86,244,604	85,957,757
Accumulated deficit	(75,944,635)	(70,155,116)
Total shareholders' equity	10,336,148	15,838,635
Total liabilities and shareholders' equity	$ 11,132,420	$ 16,831,482

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, 2014 and 2013

	Year Ended December 31,	
	2014	2013
Revenue, net	$ 939,926	$ 1,032,233
Cost of sales	369,597	343,354
Gross profit	570,329	688,879
Operating expenses:		
Research and development	3,065,053	9,358,957
Selling, general and administrative	3,321,771	7,540,152
Total operating expenses	6,386,824	16,899,109
Loss from operations	(5,816,495)	(16,210,230)
Other income (expense):		
Interest income	36,998	23,546
Interest expense	(4,030)	(17,538)
Local business tax	(5,789)	(9,035)
Other income (expense)	(203)	144,503
Total other income (expense), net	26,976	141,476
Loss before income taxes	(5,789,519)	(16,068,754)
Income tax benefit	—	—
Net loss	$ (5,789,519)	$(16,068,754)
Basic and diluted net loss per share	$ (0.16)	$ (0.56)
Shares used to compute basic and diluted net loss per share	36,153,588	28,779,229

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

Oragenics, Inc.
Statements of Changes in Shareholders' Equity
For the Years Ended December 31, 2014 and 2013

	Common Stock		Additional Paid In Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount			
Balances at December 31, 2012	27,382,830	$27,383	$63,290,625	$(54,086,362)	$ 9,231,646
Issuance of common stock and warrants, net of expenses	7,884,024	7,884	19,849,952	—	19,857,836
Compensation expense relating to option issuances	—	—	191,202	—	191,202
Compensation expense relating to restricted stock	727,090	727	2,625,978	—	2,626,705
Net loss	—	—	—	(16,068,754)	(16,068,754)
Balances at December 31, 2013	35,993,944	$35,994	$85,957,757	$(70,155,116)	$ 15,838,635
Issuance of common stock and exercise of warrants	185,000	185	102,315	—	102,500
Compensation expense relating to option issuances	—	—	184,532	—	184,532
Net loss	—	—	—	(5,789,519)	(5,789,519)
Balances at December 31, 2014	36,178,944	$36,179	$86,244,604	$(75,944,635)	$ 10,336,148

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, 2014 and 2013

	Year Ended December 31,	
	2014	**2013**
Cash flows from operating activities:		
Net loss	$ (5,789,519)	$(16,068,754)
Adjustments to reconcile net loss to net cash used in operating activities:		
Technology access fee paid in common stock and convertible note payable to shareholder	—	6,000,000
Depreciation and amortization	27,667	76,487
Loss on sale of property and equipment	203	—
Stock issued as compensation to non-employee directors	102,500	—
Stock-based compensation expense	184,532	3,449,650
Changes in operating assets and liabilities:		
Accounts receivable, net	48,826	5,361
Inventory, net	(150,806)	(164,205)
Prepaid expenses and other current assets	214,831	203,601
Accounts payable and accrued expenses	(199,747)	(234,523)
Deferred revenue	2,383	(32,150)
Net cash used in operating activities	(5,559,130)	(6,764,533)
Cash flows from investing activities:		
Proceeds from sale of property and equipment	424	—
Purchase of property and equipment	(110,673)	(18,809)
Net cash used in investing activities	(110,249)	(18,809)
Cash flows from financing activities:		
Exercise of common stock options	—	39,800
Payments on short-term notes payable	(158,210)	(140,931)
Payment of income taxes associated with stock based compensation	—	(631,743)
Net proceeds from issuance of common stock	—	13,804,996
Restricted cash released	—	61,763
Net cash (used in) or provided by financing activities	(158,210)	13,133,885
Net (decrease) increase in cash and cash equivalents	(5,827,589)	6,350,543
Cash and cash equivalents at beginning of period	16,276,510	9,925,967
Cash and cash equivalents at end of period	$10,448,921	$ 16,276,510
Supplemental disclosure of cash flow information:		
Interest paid	$ 4,058	$ 3,108
Non-cash investing and financing activities:		
Conversion of convertible note payable and accrued interest to common shares	$ —	$ 1,969,040
Borrowings under short term notes payable for prepaid expense	$ 158,999	$ 157,005
Par value of common stock issued for cashless exercise of warrants	$ 135	$ 106

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

Oragenics, Inc.
Notes to Financial Statements
December 31, 2014 and 2013

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 the world leader in novel antibiotics against infectious disease. We also develop, market and sell proprietary probiotics specifically designed to enhance oral health for humans and pets.

Basis of Presentation

The accompanying financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States ("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 $939,926, incurred a net loss of $5,789,519 and used cash of $5,559,130 in its operating activities during the year ended December 31, 2014. As of December 31, 2014, the Company had an accumulated deficit of $(75,944,635) and cash flows from operations were negative throughout 2014.

During 2012, a significant source of debt and equity funding was provided by the Company's largest shareholder, the Koski Family Limited Partnership (the "KFLP"). In addition, in 2013 and 2012 the Company raised $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, 2014 will be sufficient to meet the business objectives as presently structured through March 2016.

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

Recently Adopted Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40) Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." ASU 2014-15 provides guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and about related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company's ability to continue as a going concern within one year from the date the financial statements are issued. Management will also be required to evaluate and disclose whether its plans alleviate that doubt. ASU 2014 – 15 is effective for the annual period ending after December 15, 2016, and for interim periods within annual periods ending after December 15, 2016. Earlier application is permitted. The Company is currently evaluating the requirements of ASU 2014-15 and has not yet determined its impact on the Company's financial statements.

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, "Revenue from Contracts with Customers (Topic 606)." ASU 2014-09 completes the joint effort by the FASB and International Accounting Standards Board (IASB) to improve financial reporting by creating common revenue recognition guidance for U.S. GAAP and International Financial Reporting Standards (IFRS). ASU 2014-09 applies to all companies that enter into contracts with customers to transfer goods or services. ASU 2014-09 is effective for public entities for interim and annual reporting periods beginning after December 15, 2016. Early application is not permitted and entities have the choice to apply ASU 2014-09 either retrospectively to each reporting period presented or by recognizing the cumulative effect of applying ASU 2014-09 at the date of initial application and not adjusting comparative information. The Company is currently evaluating the requirements of ASU 2014-09 and has not yet determined its impact on the Company's financial statements.

In July 2013, the FASB issued new accounting guidance on the presentation of unrecognized tax benefits, Accounting Standards Update No. 2013-11, "Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists," for fiscal years, and interim periods within those years, beginning after December 15, 2013. The new guidance requires an entity to present an unrecognized tax benefit, or a portion of an unrecognized tax benefit, as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward, except as follows: to the extent a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the applicable jurisdiction to settle any additional income taxes that would result from the disallowance of a tax position or the tax law of the applicable jurisdiction does not require the entity to use, and the entity does not intend to use the deferred tax asset for such purpose, then the unrecognized tax benefit should be presented in the financial statements as a liability and should not be combined with deferred tax assets. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2013, with early adoption permitted. Accordingly, we adopted these presentation requirements during the first quarter of 2014. The adoption of this new guidance did not have a material impact on our financial statements or related disclosures.

There are no other new accounting pronouncements issued or effective during 2014 that have had or are expected to have an impact on the Company's financial statements.

Use of Estimates

The preparation of financial statements in conformity with U.S. Generally Accepted Accounting Principles ("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, income tax valuation allowance, inventory obsolescence reserve, sales returns and allowances and allowance for doubtful accounts.

Guaranteed Rights of Return

The Company has granted guaranteed rights of return to two dental distributor customer accounts. The Company defers recognition of revenue on these accounts until the customer provides notification to the Company that the product has been sold to the end consumer or the guaranteed right of return period expires. Once notification has been received and verified, the Company records revenue in that accounting period. The Company had $21,222 and $18,839 of revenue deferred under guaranteed rights of return arrangements included in deferred revenue in the balance sheets as of December 31, 2014 and 2013, 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

Accounts receivable are recorded at their net realizable value and consist of trade receivables from the sale of product to customers. We analyze accounts receivable on a monthly basis and determine the collectability based on the facts and circumstances relating to each customer. The Company estimates their allowance for doubtful accounts based on sales trend and specific review of the creditworthiness of each customer. As of December 31, 2014 and 2013, the Company had recorded an allowance for doubtful accounts of approximately $1,000 and $128,000, respectively.

Inventory

Inventories are stated at the lower of cost or market. Cost, which includes material, labor and overhead, is determined on a first-in, first-out basis. On a quarterly basis, we analyze our inventory levels and reserve for inventory that is expected to expire prior to being sold, inventory that has a cost basis in excess of its expected net realizable value, inventory in excess of expected sales requirements, or inventory that fails to meet commercial sale specifications. Expired inventory is disposed of and the related costs are written off to the reserve for inventory obsolescence. The inventory reserve at December 31, 2014 and 2013 was approximately $50,100 and $31,500, respectively.

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 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

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.

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, shares associated with the stock options and warrants are not included because they are antidilutive. 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

We recognize revenues from the sales of product when title and risk of loss pass to the customer, which is generally when the product is shipped.

We record allowances for discounts and product returns at the time of sales as a reduction of revenues as such allowances can be reliably estimated based on historical experience or known trends. We maintain a return policy that allows our customers to return product within a

specified period of time. Our estimate of the provision for returns is analyzed quarterly and is 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 our product returns changes, the reserve will be adjusted. While we believe that the reserves we have established are reasonable and appropriate based upon current facts and circumstances, applying different judgments to the same facts and circumstances would result in the estimated amounts for sales returns and chargebacks to vary. Because our ProBiora3 products have only recently been introduced, we could experience different circumstances in the future and these differences could be material.

The Company has granted guaranteed rights of return at various times to certain customers. At this time there are two dental distributors with guaranteed rights of return. Orders are processed and shipped on these accounts however the Company defers recognition of revenue until the customer provides notification to the Company that the product has sold to the end consumer. Once notification has been received and verified, the Company will record 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, 2014 and 2013.

Advertising Expenses

The Company's policy is to expense advertising and marketing costs as incurred. For the years ended December 31, 2014 and 2013, advertising and marketing expense was $61,085 and $895,078, respectively.

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 the following: employee-related expenses, which include salaries and benefits and attending science conferences; costs incurred in connection with our 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 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.

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 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.

Concentrations

The Company is dependent on four key suppliers to provide probiotics, blending, warehousing and packaging of its EvoraPlus, EvoraPro, and Teddy's Pride products during the years ended December 31, 2014 and 2013, respectively. The majority of the Company's cost of sales are from these key suppliers. As of December 31, 2014 and 2013, our accounts payable and accrued expenses for these vendors totaled $189,120 and $146,284, respectively.

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, 2014, the uninsured portion of this balance was $10,198,921. As of December 31, 2013, the uninsured portion of this balance was $16,026,510.

3. Inventory, net

Inventory, net consists of the following as of December 31, 2014 and 2013:

	2014	2013
Finished goods	$113,553	$191,509
Rights of Return Agreements	6,910	7,790
Raw Materials	368,910	120,547
Total inventory	489,373	319,846
Less: inventory reserve	(50,184)	(31,463)
Inventory, net	$439,189	$288,383

4. Property and Equipment, net

Property and equipment, net consists of the following as of December 31, 2014 and 2013:

	2014	2013
Furniture and fixtures	$ 20,742	$ 20,742
Laboratory equipment	872,380	769,157
Leasehold improvements	487,871	487,871
Office and computer equipment	285,326	278,779
	1,666,319	1,556,549
Accumulated depreciation and amortization	(1,557,027)	(1,529,636)
Property and equipment, net	$ 109,292	$ 26,913

Depreciation and amortization expense for the years ending December 31, 2014 and 2013 was $27,667 and $76,487, respectively.

5. Related Party Transactions

At December 31, 2014 and 2013 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.

As of December 31, 2014, Intrexon Corporation owned approximately 24.4% of our outstanding common stock. During the year ended December 31, 2014 and 2013, we paid $866,030 and $1,463,019, respectively to Intrexon Corporation (“Intrexon”) under the Exclusive Channel Collaboration Agreement to develop and commercialize lantibiotics (the “Lantibiotic ECC”) and we paid $46,892 and $0, respectively to Intrexon under the Exclusive Channel Collaboration Agreement to develop and commercialize genetically modified probiotics (the “LBPs ECC”).

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following as of December 31, 2014 and 2013:

	2014	2013
Accounts payable trade	$483,641	$249,234
Intrexon Collaboration Agreement	780	323,538
Legal fees	102,258	154,205
Vacation	77,776	85,299
Deferred compensation	25,500	25,500
Consulting fees	5,000	18,000
Sales return allowance	12,637	33,342
Other	2,618	20,839
Total accounts payable and accrued expenses	$710,210	$909,957

7. Short Term Notes Payable

The Company had the following short-term notes payable as of December 31, 2014 and 2013:

	2014	2013
Product liability insurance financing of $50,694 and $50,037, due in monthly installments of $5,223 and $5,155 including principal and interest at 6.57% and 6.57% through January 10, 2015 and January 10, 2014, respectively	$ 5,195	$ 5,127
Directors' and officers' liability insurance financing of $108,306 and $106,994, due in monthly installments of $10,076 and $9,954 including principal and interest at 4.64% and 4.64% through June 24, 2015 and June 24, 2014	59,645	58,924
Total short-term notes payable	$64,840	$64,051

8. Shareholders' Equity

Common Stock

Exclusive Channel Collaboration Agreement with Intrexon-LBPs–Share Issuance

On September 30, 2013, in conjunction with the Company's execution and delivery of the LBPs ECC with Intrexon, the Company also 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 (i) 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, and (ii) paid Intrexon an up-front technology access fee of $6,000,000 (the "Technology Access Fee") in consideration for the execution of the LBPs 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 any exercise by the Company of its right to convert the Convertible Note into common stock. The conversion price was 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. The payment of this Technology Access Fee resulted in the Company recording a non-cash expense of $6,000,000 during the quarter ended September 30, 2013. The Company obtained the requisite shareholder approval to have the additional shares of its common stock listed and, 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 based upon a conversion price of $2.82 per share. The Company intends to use the proceeds from the private placement sale of common stock to Intrexon towards development of the Company's key initiatives relating to the LBPs ECC, and general corporate purposes. Under the terms of the SPIA and LBPs ECC, the Company agreed to issue to Intrexon additional shares of its common stock based upon the achievement of certain milestones. See Note 13 — Commitments and Contingencies.

2012 Incentive Plan Issuances

On October 18, 2013, both the Board of Directors and the Compensation Committee of the Board of Directors of the Company met and determined that one of the performance goals established in the Company's Long-Term Incentive Program ("LTIP"), as amended, (See Note 9) had been achieved. The performance goal met was the goal related to the broadening of the Intrexon relationship to include a new area outside of lantibiotics. The aggregate shares awarded under the LTIPs of 422,359, consisted of a total of 165,925 shares to non-employee directors and 256,434 shares to executive officers. Of the aggregate 422,359 shares awarded under the LTIPs, 84,287 shares were retained by the Company for applicable tax withholding obligations.

On November 27, 2013, both the Board of Directors and the Compensation Committee of the Board of Directors of the Company met and determined that one of the performance goals established in the Company's LTIPs had been achieved. The performance goal met was the goal related to the Capital raise by the Company of $12,000,000 or more in a single year. The aggregate shares awarded under the LTIPs of 502,654, consisted of a total of 191,985 shares to non-employee directors and 310,669 shares to executive officers. Of the aggregate 502,654 shares awarded under the LTIPs, 113,636 shares were retained by the Company for applicable tax withholding obligations.

The November 2013 Underwritten Public Offering

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. The net proceeds from this public offering after deducting underwriting discounts and direct offering expenses were $9,904,996 and are expected to be used for our ongoing clinical development of lantibiotics, probiotics sales and marketing and for general corporate purposes, including research and development activities for our other product candidates and any future product candidates that we may develop or acquire, as well as for general and administrative costs. In addition, we may use a portion of the net proceeds for licensing or acquiring intellectual property to incorporate into our products and product candidates or our research and development programs. We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or products; however, we have no current commitments or obligations to do so.

Award Of Shares to Non-employee Directors

On May 30, 2014, each continuing non-employee Director, Frederick Telling, Charles Pope, Alan Dunton, Christine Koski and Robert Koski were granted an award of 10,000 fully vested shares of the Company's common stock under the Company's 2012 Equity Incentive Plan as part of the Company's non-employee Director compensation program. The Company recognized $102,500 in expense relating to this award.

Warrants

The Company's outstanding and exercisable warrants as of December 31, 2014 are presented below:

Exercise Price	Warrants Outstanding	Expiration Dates
$ 1.50	361,169	7/31/17
$ 2.00	2,170,925	3/23/15
	2,532,094	

On January 31, 2013 Griffin Securities Inc. exercised 200,000 of their previously issued warrants resulting in the net issuance of 106,250 shares of our common stock.

On May 30, 2013, warrants to acquire 127,888 and 161,000 shares of the Company's common stock at prices of $26.00 and $15.00 per share, respectively expired.

On January 13, 2014, 210,000 previously issued warrants were exercised resulting in the net issuance of 135,000 shares of our common stock.

As of December 31, 2014 there are 2,532,094 warrants and 820,865 stock options outstanding. If all warrants and stock options were exercised, the total number of outstanding common shares would be 39,531,903 as of December 31, 2014.

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, 1,677,462 shares have been issued under the 2012 Incentive Plan. As a result of such issuances as of December 31, 2014 there is currently an aggregate of 2,322,538 shares available for issuance under the 2012 Incentive Plan, of which 820,865 shares are covered by outstanding option awards and 1,501,673 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, 2014 and 2013, 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 or in connection with our LTIP awards which vest immediately that are 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. There were no stock awards to employees in 2014 and as such, no shares were withheld. The number of shares withheld to cover tax payments was 197,923 in fiscal 2013; tax payments made were $631,743.

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, 2014 and 2013:

	2014	2013
Expected dividend yield	0%	0%
Weighted-average expected volatility	150% - 155%	159% - 166%
Weighted-average risk-free interest rate	2.26% - 2.77%	1.86% - 2.80%
Expected life of options	10 years	10 years

Total compensation cost related to stock options was $184,532 and $191,202 for the years ended December 31, 2014 and 2013, respectively. As of December 31, 2014, there was $150,388 of unrecognized compensation costs related to stock options, which is expected to be recognized over a weighted average period of 1.3 years.

The following table represents stock option activity as of and for the two years ended December 31, 2014 and 2013, respectively:

	Number of Options	Option Price Per Share	Weighted Average Exercise Price
Outstanding at December 31, 2012	660,423	$1.20 - 17.00	$ 4.70
Forfeited	(56,050)	1.20 - 5.40	2.19
Granted	61,000	2.75 - 3.55	3.13
Exercised	(31,533)	1.20 - 1.50	1.26
Outstanding at December 31, 2013	633,840	$1.20 - 17.00	$ 4.88
Forfeited	(70,475)	1.50 - 4.00	2.93
Granted	257,500	0.86 - 2.84	1.65
Outstanding at December 31, 2014	820,865	$0.86 - 17.00	$ 4.03
Exercisable at December 31, 2014	583,882	$1.20 - 17.00	$ 5.02

The total grant date fair value of options vested during the years ended December 31, 2014 and 2013 was $257,007 and $166,512, respectively.

Long-Term Performance-Based Incentive Programs

During 2011 the Compensation Committee and Board of Directors established long-term performance-based incentive programs for certain executive participants as well as non-employee directors as part of director compensation, each as part of, and under the Company's 2012 Incentive Plan. These programs resulted in 567,103 and 0 shares of common stock being issued in aggregate to our executive officers and 357,910 and 0 shares of common stock being issued in aggregate to our non-employee directors during the years ended December31, 2013 and December 31, 2014, respectively. During 2013 the original program award performance goals were amended and the original termination date of the program extended for a year. These programs expired on December 31, 2014. The Board and Compensation Committee may determine to reinstate such performance –based incentives programs or establish new programs in the future**.**

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, Inc. ("UFRF") 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, 2014 and 2013 the Company paid $32,467 and $41,953 respectively to UFRF in connection with the MU1140 license.

SMaRT Replacement Therapy—The Company has exclusively licensed the intellectual property for its replacement therapy technology from the UFRF. The original license agreement was dated August 4, 1998 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. 5,607,672, entitled "Replacement Therapy for Dental Caries", which was filed in the U.S. PTO on June 7, 1995 and made effective on March 4, 1997. The patent will expire on June 7, 2015. The Company's license is for the period of the patent, subject to the performance of terms and conditions contained therein. The Company issued 29,997 shares of common stock to UFRF as partial consideration in 1998 for the SMaRT Replacement Therapy License. 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. The Company has ongoing obligations and commitments with respect to the SMaRT Replacement Therapy License. See Note 13 — Commitments and Contingencies. In the years ended December 31, 2014 and 2013 the Company paid $10,000 and $49,575 respectively to UFRF in connection with the SMaRT Replacement Therapy license.

The Texas A&M License.

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, 2014 and 2013 the Company paid Texas A&M $-0- and $-0- 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." 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 LBPs ECC

On September 30, 2013, the Company entered into the LBPs ECC with Intrexon that governs a "channel collaboration" arrangement in which the Company will use Intrexon's proprietary technology relating to the identification, design, culturing and/or 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 "LBPs Program"). The LBPs ECC grants the Company an exclusive worldwide license to utilize Intrexon's Technology for the LBPs Program, to develop and commercialize genetically modified probiotic products 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. The LBPs ECC establishes committees comprised of Company and Intrexon representatives that will govern activities related to the LBPs 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) the Company's negligence or willful misconduct, (ii) the use, handling, storage, or transport of Intrexon Materials (as defined in the LBPs ECC), (iii) the Company's breach of a material representation, warranty or covenant in the LBPs ECC, or (iv) the design, development, manufacture, regulatory approval, handling, storage, transport, distribution, sale or other disposition of any Company Product. The Company has ongoing obligations and commitments with respect to the LBPs ECC. 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. The Company has ongoing obligations and commitments with respect to the Lantibiotic ECC. See Note 13 — Commitments and Contingencies.

11. Retirement Plan

In January 2004, the Company established a defined contribution Simple Individual Retirement Arrangement (IRA) 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, 2014 and 2013 were $34,488 and $27,747, respectively.

12. Income Taxes

The components of the provision for income taxes for the years ended December 31, 2014 and 2013 are as follows:

	2014	2013
Current	$ —	$ —
Deferred	(2,052,871)	(5,679,857)
Valuation Allowance	2,052,871	5,679,857
Total provision for income taxes	$ —	$ —

At December 31, 2014 and 2013, 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:

	2014	2013
Deferred tax assets (liabilities):		
Net operating loss carryforward	$ 26,440,553	$ 24,339,362
Bad debt reserve	432	48,263
Inventory reserve	18,885	11,840
Sales return allowance	4,755	12,546
Accrued vacation	29,267	32,098
Deferrals of compensation to Directors & Officers	9,596	9,596
Uniform capitalization (UNICAP)	2,958	(130)
Non-qualified stock compensation	513,106	513,106
Restricted stock	42,590	42,590
Accrued Interest	(134,222)	(134,222)
Total deferred tax assets, net	26,927,920	24,875,049
Less valuation allowance	(26,927,920)	(24,875,049)
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, 2014 and 2013:

	2014	2013
Income tax benefit computed at statutory federal rate of 34%	$(1,968,437)	$(5,463,376)
State income tax benefits, net of federal expense/benefit	(210,160)	(583,296)
Change in valuation allowance	2,052,871	5,679,857
Non-deductible expenses	110,518	248,178
Other	15,208	118,637
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 $26,927,920 and $24,875,049 has been provided in the accompanying financial statements as of December 31, 2014 and 2013, respectively. The 2014 net change in valuation allowance related to deferred tax assets was an increase of $2,052,871 primarily relating to net operating loss carryforwards. The 2013 net change in valuation allowance related to deferred tax assets was an increase of $5,679,857 primarily relating to net operating loss carryforwards.

At December 31, 2014, the Company has federal and state tax net operating loss carryforwards of approximately $69,735,000. The federal and state tax loss carryforward will expire through 2034, unless previously utilized. The Company also has federal research and development tax credit carryforwards of approximately $1,355,000. The federal tax credit carryforward will expire through 2024, 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, 2014 and 2013, the Company incurred $112,871 and $361,143, respectively, of additional unrecognized tax benefits that resulted in a decrease to the deferred tax asset valuation allowance, 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 2010.

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

Balance as of December 31, 2012	$ 880,638
Additions based on tax positions related to the current year	361,143
Additions for the tax positions of prior years	—
Reductions for the tax positions of prior years	—
Balance as of December 31, 2013	$1,241,781
Additions based on tax positions related to the current year	112,871
Additions for the tax positions of prior years	—
Reductions for the tax positions of prior years	—
Balance as of December 31, 2014	$1,354,652

Included in the balance at December 31, 2014 and 2013, are $1,354,652 and $1,241,781, 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 2014 and 2013 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, 2014 was approximately $119,000.

In October 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 in the amounts ranging from $6,426 per month to $6,818 per month inclusive of insurance, taxes and utilities. The lease expires on February 29, 2017. Rent expense under this lease was approximately $76,000 for the year ended December 31, 2014.

Future annual minimum payments under all non-cancelable operating leases are as follows as of December 31, 2014:

Year ended December 31:	
2015	$218,370
2016	216,638
2017	138,932
2018	134,337
2019	126,520
Total	$834,797

The University of Florida Research Foundation Licenses

UFRF-MU1140 and Replacement Therapy Licenses. In the Company's UFRF amended license agreements for SMaRT Replacement Therapy and MU1140, the Company is obligated to pay 5% of the selling price of any products developed from the UFRF licensed technologies that the Company may sell as royalty to the UFRF. In addition, if the Company sublicenses any rights granted by the amended license agreements, 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) May 1, 2013 (for the SMaRT Replacement Therapy license agreement) and 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 agreements in the amount of $10,000 for each license agreement and $20,000 in aggregate. The aggregate minimum annual payments are required to be paid in advance on a quarterly basis (i.e. $5,000 per quarter) for both licenses. 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 agreements expire upon the earlier of (i) the date that no patents covered by the amended license agreements remain enforceable or (ii) the payment of earned royalties under the amended license agreements, 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 agreements if the Company breaches its obligations to timely pay any amounts due under the amended license agreements, to submit development reports as required under the amended license agreements or commit any other breach of any other covenants contained in the amended license agreements and the Company fails to remedy such breach within 90 days after written notice of such breach by UFRF.

After the effective date of termination of the SMaRT Replacement Therapy amended license agreement, the Company may sell all licensed products and complete licensed products in the process of manufacture at the time of such termination and sell the same, provided the Company makes the royalty payments described above and submit the reports required under the SMaRT Replacement Therapy amended license agreement.

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 must pay Texas A&M $15,000 as minimum 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 is not in the form of a royalty.

Pursuant to the 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 I 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 II clinical trial using the licensed technology to occur on or before June 1, 2019, with a milestone achievement payment of $100,000, (iii) completion of Phase III clinical trial of the licensed technology to occur on or before June 1, 2022, with a milestone achievement payment of $150,000, and (iv) first sale of 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 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, 2013. The Company plans to seek an extension of the first enrollment of a patient milestone referred to above prior to the due date.

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 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, 2014.

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 LBPs ECC

Under the LBPs 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 nonclinical 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, certain aspects of the manufacturing process, and costs of filing, prosecution and maintenance of Intrexon’s patents.

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 LBPs 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.

Under the SPIA and as part of the LBPs 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 LBPs 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 LBPs ECC) of a Company Product, or (b) the approval of a New Drug Application (as that term is defined in the LBPs ECC) for a Company Product by the FDA or equivalent regulatory action in a foreign jurisdiction.

None of the LBPs ECC milestones had been achieved as of December 31, 2014.

The Company may voluntarily terminate the LBPs ECC upon 90 days written notice to Intrexon. Intrexon may also terminate the LBPs ECC if the Company breaches the LBPs 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 LBPs ECC. Upon termination of the LBPs 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 LBPs Program.

The Company's obligation to pay 10% of net sales 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" Company Products will survive termination of the LBPs ECC.

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.

	2014			
	First	Second	Third	Fourth
Revenue	$ 214,660	$ 303,752	$ 201,010	$ 220,504
Total operating expenses	1,783,858	2,080,663	1,162,148	1,360,155
Net loss	(1,640,884)	(1,895,519)	(1,029,544)	(1,223,572)
Loss per share:				
Basic and Diluted	$ (0.05)	$ (0.05)	$ (0.03)	$ (0.03)

	2013			
	First	Second	Third	Fourth
Revenue	$ 176,407	$ 167,668	$ 253,374	$ 434,784
Total operating expenses	1,848,582	2,156,279	9,465,455	3,428,793
Net loss	(1,589,960)	(2,074,035)	(9,325,424)	(3,079,335)
Loss per share:				
Basic and Diluted	$ (0.06)	$ (0.08)	$ (0.34)	$ (0.09)

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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	Bylaws	SB-2	333-100568	3.2	10/16/02	
3.6	First Amendment to Bylaws	8-K	001-32188	3.1	6/9/10	
3.7	Second Amendment to Bylaws	8-K	001-32188	3.1	8/24/10	
4.1	Specimen Stock Certificate	S-1/A	333-169031	4.0	10/05/10	
10.1	Exclusive License Agreement between the Company and the University of Florida Research Foundation, Inc. effective August 4, 1998 for Replacement Therapy for Dental Caries (the "Replacement Therapy License Agreement")	SB-2	333-100568	10.1	10/16/02	
10.2	First Amendment to Replacement Therapy License Agreement dated September 15, 2000	SB-2	333-100568	10.2	10/16/02	
10.3	Second Amendment to Replacement Therapy License Agreement dated June 2002	SB-2	333-100568	10.3	10/16/02	
10.4	Third Amendment to Replacement Therapy License Agreement dated September 25, 2002	SB-2	333-100568	10.4	10/16/02	
10.5	Fourth Amendment to Replacement Therapy License Agreement dated March 2003	SB-2/A-3	333-100568	10.36	4/9/03	
10.6	Fifth Amendment to Replacement Therapy License Agreement dated April 19, 2013	8-K	001-32188	10.2	4/23/13	
10.7	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	
10.8	First Amendment to the MU1140 License Agreement dated September 15, 2000	SB-2	333-100568	10.6	10/16/02	
10.9	Second Amendment to the MU1140 License Agreement dated June 10, 2002	SB-2	333-100568	10.7	10/16/02	
10.10	Third Amendment to the MU1140 License Agreement dated September 25, 2002	SB-2	333-100568	10.4	10/16/02	
10.11	Fourth Amendment to the Antimicrobial Polypeptide License Agreement dated March 2003	SB-2/A-3	333-100568	10.36	4/9/03	
10.12	Fifth Amendment to the Antimicrobial Polypeptide License Agreement dated April 19, 2013	8-K	001-32188	10.1	4/23/13	
10.13	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	

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Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
10.14	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	
10.15	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	
10.16	Exclusive Channel Collaboration Agreement by and between Oragenics, Inc. and Intrexon Corporation dated as of September 30, 2013.*	8-K	001-32188	10.1	10/01/13	
10.17	Stock Purchase and Issuance Agreement by and between Oragenics, Inc. and Intrexon Corporation dated as of September 30, 2013.	8-K	001-32188	10.2	10/01/13	
10.18	First Amendment to the Stock Purchase and Issuance Agreement dated September 30, 2013.	8-K	001-32188	10.3	10/01/13	
10.19	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	
10.20	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	
10.21	Stock Purchase Agreement by and between the Company and Purchasers dated July 30, 2012.	8-K	001-32188	10.1	8/2/12	
10.22	2012 Equity Incentive Plan.+	8-K	001-32188	4.1	10/25/12	
10.23	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	
10.24	Executive Employment Agreement between the Company and Martin Handfield dated May 11, 2010.+	10-Q	001-32188	10.16	11/14/11	
10.25	Executive Employment Agreement between the Company and Albert Fosmoe dated effective January 1, 2015.+	8-K	001-32188	10.2	2/25/15	
10.26	Form of Placement Agent Warrant.	8-K	001-32188	10-3	8/2/12	
10.27	Form of Employee Stock Option Agreement.+	10-K	001-32188	10.26	3/26/13	
10.28	Form of Consultant Stock Option Agreement.+	10-K	001-32188	10.27	3/26/13	
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

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Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
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					
101.SCH	XBRL Taxonomy Extension Schema					
101.CAL	XBRL Taxonomy Extension Calculation Linkbase					
101.DEF	XBRL Taxonomy Extension Definition Linkbase					
101.LAB	XBRL Taxonomy Extension Label Linkbase					
101.PRE	XBRL Taxonomy Extension Presentation Linkbase					

* 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 26, 2015, with respect to the 2014 and 2013 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 Statement (Form S-3 Nos. 333-183685) and related Prospectus of Oragenics, Inc. for the registration of 9,437,834 shares of its common stock.

/s/ Mayer Hoffman McCann P.C.

Clearwater, Florida

February 27, 2015

Exhibit 31.1

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, 2015

/s/ Michael Sullivan
Principal 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, 2015

/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, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Sullivan, Principal 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, 2015.

/s/ Michael Sullivan
Michael Sullivan
Principal 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, 2014 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, 2015.

/s/ Michael Sullivan
Michael Sullivan
Chief Financial Officer