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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, 2011

☐ **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.)**
3000 Bayport Drive, Suite 685 Tampa, FL	**33607**
(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
None	

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

Common stock, par value $.001 per share

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, 2011 was approximately $7,392,103 based upon a last sales price of $3.30 as reported by the OTCBB.

As of March 31, 2012, there were 12,170,795 shares of the registrant's Common Stock outstanding.

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NOTE REGARDING REVERSE STOCK SPLIT

On September 24, 2010, we filed Articles of Amendment to our Amended and Restated Articles of Incorporation with the Secretary of State of the State of Florida to effect a reverse split of our common stock at a ratio of one for twenty. All historical share and per share amounts have been adjusted to reflect the resulting reverse stock split.

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 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:

- Our inability to raise additional capital.
- We have incurred significant operating losses since our inception and cannot assure you that we will increase revenues or achieve profitability.
- As a result of our lack of financial liquidity, our auditors have indicated there is substantial doubt about our ability to continue as a going concern.
- If we fail to achieve positive cash flows from our operations and we fail to raise additional capital to meet our capital needs, we may need to significantly curtail or cease operations.
- If we raise additional capital it may be on terms that result in substantial dilution to our existing shareholders,
- 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 ProBiora3 products and proposed product candidates or increase sales of our ProBiora3 products.
- 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 a continuing or worsening worldwide 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.
- Success, timing and expenses of our expected clinical trials.
- If we are unable to raise sufficient capital our license for our SMaRT™ Replacement Therapy and MU-1140 with the University of Florida Research Foundation could be terminated.

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

PART I

ITEM 1. BUSINESS.

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

Overview

Over the last year we have repositioned the Company as a probiotic nutraceutical company focused on becoming the world leader in oral care probiotics for humans and companion pets. We are focusing the majority of our efforts and resources on growing our oral probiotic business both with our branded Evora products and through licensing and private label sales (with ProBiora3). In so doing, we seek to increase our share of a growing probiotic market that according to 'Probiotics Market (2009-2014),' published by MarketsandMarkets is expected to reach $36 billion worldwide by 2014.

The Company is the 2011 recipient of a competitive award from Frost and Sullivan for excellence in oral care probiotics. We expect this prestigious award to help us to gain awareness both in the marketplace and with new potential customers. To further support recognition of our products, the Company has initiated clinical studies at the University of Washington and Loma Linda University with the intent of submitting the results from the trials to Food & Drug Administration for approval to make certain health claims about ProBiora3. We are also expanding our product line to include new delivery vehicles for our products such a gum, fast dissolving mints and melting strips. We are also increasing our efforts to gain regulatory approval in certain regions of the world and are engaging Key Opinion Leaders (KOL's) in the dental profession to help gain awareness about the benefits of oral care probiotics.

The business plan assumes we can grow revenues both within the United States and throughout the rest of the world. To do so, we have revised our focus to those opportunities that best support our mission to become the world leader in oral care probiotics for humans and companion pets. We have also discontinued selling our Evora products through mass retail channels and instead are focused on the dental professional channel with an emphasis on building awareness in this channel through education and new clinical data. We are also continuing to sell our Evora human and pet products through the internet.

Stemming from over thirty years of leadership in oral care research, Oragenics has developed through its research and development ("R&D") a suite of patented technologies outside of its probiotics business. Our activities with these technologies will be limited. These R&D projects will be taken to an appropriate point where they can be licensed, sold, partnered, or spun-out. Future R&D will focus primarily on getting claims, new delivery vehicles, and new data to support our probiotics business.

In early 2012, we announced the successful completion of a weight loss clinical trial utilizing its LPT3-04 compound. In a double blinded placebo controlled study, LPT3-04 caused a statistically significant weight loss in the active group as compared to the placebo group. We are actively looking for a partner(s) for this product at this time. LPT3-04 is a completely natural ingredient which all of us ingest and actually produce in small amounts every day. We believe it to be safe and potentially useable alongside other weight loss regimens.

Our SMaRT Replacement Therapy is designed to be a painless, one-time, topical treatment applied to the teeth that has the potential to offer lifelong protection against dental caries, or tooth decay. Dental diseases are the most prevalent chronic infectious diseases in the world, affecting up to 90% of schoolchildren and the vast majority of adults. In the United States alone, the annual cost to treat tooth decay is estimated to be $40 billion. SMaRT is based on the creation of a genetically modified strain of bacteria that colonizes in the oral cavity and replaces native decay-causing bacteria. The plan for the SMaRT replacement therapy is to attempt to complete the ongoing Phase 1b study in 2012 and find a development partner to continue its journey toward commercialization.

While developing SMaRT Replacement Therapy, members of our scientific team discovered that the SMaRT bacterial strain produces MU1140, a molecule belonging to the novel class of antibiotics known as lantibiotics. MU1140 has proven active in preclinical studies against Gram positive bacteria responsible for a number of healthcare-associated infections, HAIs. The direct cost to the U.S. healthcare system from HAIs is estimated to be up to $45 billion annually. After several technical setbacks, the synthesis of MU-1140 is nearing completion. We have engaged Bachem, a well-regarded peptide synthesis company, to help us increase our yield and efficiency and produce enough material to complete preclinical proof-of-concept. As with SMaRT therapy we will look for a development partner once we have suitable preclinical data.

Oragenics was founded in 1996 to commercialize the results of more than 30 years of research in oral biology by our principal founder and retired Chief Scientific Officer, Dr. Jeffrey Hillman. Dr. Hillman earned a DMD from Harvard School of Dental Medicine and a PhD in Molecular Genetics from Harvard University. He began his research career at the Harvard-affiliated Forsyth Institute in Boston, Massachusetts, where he introduced the concept of replacement therapy to prevent tooth decay by using a genetically modified strain of *Streptococcus mutans*, or *S. mutans*, to replace the decay-causing strains of *S. mutans* that are present on human teeth. He subsequently continued this research, now called SMaRT Replacement Therapy, at the University of Florida College of Dentistry. Under Dr. Hillman's leadership, our scientific team has also developed other technologies such as ProBiora3, LPT3-04 Weight Loss Agent, MU1140 and our DPOLT platform. Additionally, we are developing non-core technologies that originated from the discoveries of our scientific team, including CMAT, which is a biomarker discovery platform, which we believe could provide significant potential opportunities for us. Dr. Hillman retired from the Company and resigned from our Board of Directors in late 2011. He is currently acting as and remains a consultant to the Company. Dr. Martin Handfield has assumed the role of Vice President of R&D. Dr. Handfield has worked with Dr. Hillman for over 13 years and is now responsible for moving our efforts forward.

Our Product Portfolio

We are currently developing and seeking partners or commercializing four primary products or product candidates, including ProBiora3, LPT3-04, SMaRT Replacement Therapy, and MU1140-S. Our product portfolio is protected by ten issued U.S. patents and twelve filed U.S. patent applications, including patents exclusively licensed from the University of Florida Research Foundation, Inc., or UFRF. We are the exclusive worldwide licensee to the patents for SMaRT Replacement Therapy and MU1140, which are owned by the UFRF. We have retained worldwide commercialization rights to each of these products. Additionally, we believe that our SMaRT Replacement Therapy will qualify for a 12-year data exclusivity period within the United States FDA under the recently passed Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act.

Product/Candidate	Description	Application	Status
ProBiora3	Blend of three beneficial oral care probiotic bacteria	Oral health, teeth whitening, breath freshening (for humans, and companion pets)	Commercial (GRAS, Food) - additional Clinical Trials underway to expand and enhance claims
LPT3-04	Naturally occurring chemical agent	Weight loss	Commercial Development (Dietary Sup)
SMaRT Replacement Therapy	Genetically modified strain of *S. mutans* that does not produce lactic acid	Tooth decay	2nd Phase 1 clinical trial
MU1140-S	Member of lantibiotic class of antibiotics	Healthcare-associated infections	Preclinical testing

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 mints 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 MarketsandMarkets, the global probiotics market is expected to reach $36 billion by 2014, representing a CAGR of 12.6% from 2009 to 2014. Probiotics products are relatively more common in Asia and Europe, with Europe accounting for nearly 42% and Asia accounting for 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. The Probiotic Foods & Beverages category currently represents over 75% of the overall probiotics market in the United States.

- **Oral Care:** The consumer oral care market in the United States was $9.6 billion in 2010 and is expected to reach $10.9 billion by 2014, according to Packaged Facts. Packaged Facts segments this market into three comprehensive product categories: (i) Dental Preparations, which include toothpastes, tooth cleaners/whiteners, and denture products; (ii) Implements/Appliances, including toothbrushes, dental floss and irrigators; and (iii) Gum/Mouthwash/Breath Fresheners, which represented $2.5 billion of the oral care market in 2010.
- **Companion Pets:** In 2010, approximately 63% 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 estimates that total 2011 U.S. pet industry expenditures were $49 billion, representing an increase of 4.2% from 2010. Within this market, approximately $10.5 billion was spent on Supplies/OTC Medicine, representing about a 4.0% increase over 2010.

Our Solution

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 extensively 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 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 was initially launched in December 2008, but distribution was limited to sales through our own website. In March 2010, we obtained national distribution for EvoraPlus in the domestic mass retail channel and continued to expand our distribution in the domestic mass retail channel until early 2011 when we positioned back to distribution through direct-to-consumer channels. 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. We launched EvoraKids into commercial distribution in January 2010.
- **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. We launched Teddy's Pride in October 2009. We have completed the rebranding of Teddy's Pride in 2011 for the domestic market as EvoraPet and have launched a targeted rebranding effort in certain international markets of Teddy's Pride to EvoraPet.
- **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 30-unit bottle, representing a one-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.

Package and Delivery Transition

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

Our Regulatory Strategy

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. The same data dossier could be applied to support the safety for companion pet consumption of ProBiora3.

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 fillings 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.

Sales, Marketing and Distribution

All of our house-branded ProBiora3 products have been launched and are currently available through direct-to-consumer channels. Because our available capital resources limited our ability to engage in significant advertising and marketing campaigns, we made a strategic decision to leave the mass retail channel during the first quarter of 2011. Instead, we refocused our strategy on selling our house-branded consumer ProBiora3 products through multiple direct-to-consumer channels.

- **Direct-to-Consumer:** Our direct-to-consumer channels encompasses three sub-channels, including (i) Internet sales through our own websites; (ii) direct-response television, or DRTV, which is usually initiated through an infomercial; and (iii) electronic-response television, or ERTV, which entails marketing through television shopping networks such as Home Shopping Network and QVC.
    i. Internet sales: We currently operate one corporate website through which we market our branded products direct to the consumer. An “Oragenics Store” provides the consumer with access to purchase our products. We initiated in the third quarter of 2011 an affiliate marketing program whereby we pay external website operators click-through revenues when a customer visits our websites via an affiliate site and subsequently makes a purchase.
    ii. DRTV: We have developed a two-minute spot infomercial for EvoraPet, our pet oral care product, that we have tested on select networks and in select markets. The infomercial has been designed to promote a direct response from viewers. Our tests proved sufficiently successful, and we were able to forecast a positive return on our marketing spend. We would anticipate expanding the geographic area and broadcasting frequency of the infomercial in 2012, if funding is available.
    iii. ERTV: We have been in discussions with both of the major domestic ERTV operators as well as companies that have established brands on their respective channels. We anticipate consummating one or more ERTV marketing opportunities by the second half of 2012.
- **Professional Offices:** The professional offices channel encompasses two principal sub-channels: (i) the dental professional channel, which includes general dentists, specialists and dental hygienists; and (ii) the veterinarian professional channel. In August 2010, we launched EvoraPro, which is a product exclusively for the dental professional sub-channel. EvoraPro is an extra-strength, probiotic designed to be taken after dental cleaning or treatment. In 2011 we entered into distribution agreements with leading distributors of products to the dental professional market. If successful, we intend on following a similar distribution plan to penetrate the veterinarian professional channel. We would look to initiate a campaign in the veterinarian channel by the end of the third quarter 2012.
- **Private Label:** The private label channel encompasses arrangements whereby we or third-party manufacturers market our products for resale under a third-party’s brand name. We typically establish private labeling arrangements in order to leverage an existing company’s brand equity and distribution channels. The first major private labeling agreement we consummated was with Garden of Life, which is a leading U.S. nutritional supplement products brand. Garden of Life has contracted to sell our EvoraPlus product under the brand name Probiotic Smile. Garden of Life sells exclusively in the health food channel, which includes many stores geographically disbursed around the United States. Oragenics has entered into a number of additional agreements, including Nutrahealth (US) and Pharmaforce (Denmark) for the distribution of product incorporating ProBiora3. Another notable private labeling sub-channel is the multi-level marketing, or MLM, channel. We have been in discussions with a number of large MLM companies regarding private labeling opportunities for our products.

- **International:** Since the launch of our first product, EvoraPlus, we have entered into exclusive distribution agreements for our products internationally in various geographic locations. For example, we have executed distributorship agreements, with Australian Pharmaceuticals Industries (Australia, New Zealand), Benelux Cosmetics (Belgium, Netherlands, Luxembourg), and Vetcom (Korea). The international distributorship agreements we have entered into to date typically provide for territorial exclusivity and require that the distributors provide upfront payment to us either by irrevocable letters of credit or wire transfers prior to our initiating production and as a result, we believe that we do not bear any credit risk with such agreements. We also require distributors to take possession of product at our manufacturing facility, which substantially reduces our inventory risk. We continually evaluate the effectiveness of these arrangements and may seek to terminate distributorship agreements in which limited purchase activity occurs.

Manufacturing

When produced, ProBiora3 comes in powder form. ProBiora3 is manufactured by separate fermentation of each of the three strains. The cells are recovered by centrifugation or filtration and freeze dried. Experimentally determined amounts of the resulting powders are blended with natural bulking agents to deliver the proper number of viable cells of each strain per unit weight. ProBiora3 for human use may be incorporated into various delivery vehicles; for example, in the case of EvoraPlus and EvoraKids, flavoring agents are added and the powder is pressed into tablets, which are sealed in plastic bottles. In the case of EvoraPet, the powder is not flavored and is simply added in bulk to a plastic container. Freeze-dried cells in ProBiora3-containing products are stable for up to 18 months after manufacture when kept in cool, dry conditions. The cells are revitalized when they come in contact with moisture, for example the saliva present in the oral cavity.

We have contracted with multiple manufacturers to: (i) produce our active ingredient, ProBiora3, (ii) blend and tablet EvoraPlus, EvoraKids, EvoraPet and EvoraPro, and (iii) package our products. Each of our contract manufacturers has the ability to scale production as needed. With each manufacturer, we place orders for components or finished product to be produced for a fixed fee which we are expected to pay upon completion of the manufacturing process. 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 manufacturers are satisfactory to meet our current and expected future needs. We have qualified and used at least two contract manufacturers for each step in our manufacturing process, although we do not have a long-term supply agreement or commitment with any of our manufacturers.

LPT3-04 Weight Loss Product

LPT3-04 is a naturally occurring compound, which is normally consumed in the human diet in small amounts. In the course of our SMaRT Replacement Therapy research, we discovered that consumption of significantly larger amounts of LPT3-04 resulted in dose-dependent weight loss in experimental animal models. The mechanism of action appears to be induction of apoptosis, or programmed cell death, specifically in white fat cells. LPT3-04 consumption in the required amounts has been shown to be safe in humans. Anecdotally, weight loss has been observed in human volunteers. Due to the natural sweetness of LPT3-04 and the relatively large amounts of it that need to be consumed on a daily basis to achieve the desired weight loss effect, product development efforts focused on incorporating the compound into bars, milkshakes, and other food products. We have used these food products in a blinded placebo-controlled human safety and efficacy study that began in the third quarter of 2011. We conducted a human clinical trial on LPT3-04. Adult volunteers in the trial experienced a statistically significant reduction in body weight following 12 weeks of daily supplementation with LPT3-04. Further, there were no safety concerns as the volunteers experienced no serious adverse events during the trial, including depression. We have submitted a patent application for the use of LPT3-04 for weight regulation with the United States Patent and Trademark Office, or U.S. PTO.

Market Opportunity

The World Health Organization estimated that by 2015, there will be more than 1.5 billion overweight consumers. Further, according to a 2012 healthcare market research report published by MarketsandMarkets, the total global weight loss market is expected to be $586.3 billion by 2014, with a compound growth rate of 10.9% from 2009 to 2014.

Our Solution

With the successful completion of the pivotal proof-of-concept human clinical trial, and the additional supporting laboratory and animal safety and effectiveness studies, we are currently seeking licensing partners that will further develop this technology and commercialize food and beverage products, on a global basis, that encourage the weight management of both humans and companion pets.

SMaRT Replacement Therapy

SMaRT Replacement Therapy 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 tooth decay caused by *S. mutans* , the principal cause of this disease. We have extensively and successfully tested the SMaRT strain for safety and efficacy in laboratory and animal models and, in the first quarter of 2011 we initiated a second Phase 1 clinical trial in the United States with an attenuated version of our SMaRT Replacement Therapy, at the Phase 1 facilities of our Clinical Research Group (CRO) partner, PRA International.

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. In 2008, U.S. consumers drank more bottled water than any other alcoholic or non-alcoholic beverage, with the exception of carbonated soft drinks, according to the Beverage Marketing Corporation.

Our Solution

Our 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.

We have commenced a second Phase 1 clinical trial of an attenuated version of our SMaRT Replacement Therapy, which will examine the safety and genetic stability of the SMaRT strain during administration to ten healthy adult male subjects over a two-week institutionalized period, with a 4-week post-clinic follow-up period of both the treated subjects and their partners. As a precautionary measure, this trial uses an attenuated version of the SMaRT strain that is dependent on D-alanine, which is a specific amino acid not normally found in the human diet. D-Alanine is being administered though a mouthwash provided to the patient group, and must be administered daily or the attenuated strain will perish in the oral cavity. We expect the second Phase 1 clinical trial of the attenuated strain, including a six-month follow-up examination of subjects after the active phase of the trial, to be concluded in the second half of 2012. If the second Phase 1 trial of the attenuated strain is successful and if the FDA lifts the clinical hold on the IND for the non-attenuated version of the SMaRT strain, we anticipate that we would conduct a third Phase 1 trial using the non-attenuated SMaRT strain instead of the attenuated version.

Our Strategy

Our strategy is to develop our SMaRT Replacement Therapy through Phase 1 clinical safety trials, while actively seeking to license our SMaRT Replacement Therapy to, or partner with, a major pharmaceutical company. While we believe that the completion of Phase 1 trials would definitively represent a significant milestone in the development of SMaRT Replacement Therapy, and would result in a substantial increase in the value of this technology, partnering at the earliest possible time would provide the necessary resources to actively continue clinical testing. It is possible that we will be unable to negotiate acceptable terms with a licensee or partner until Phase 1 trials have been completed. However, we anticipate that we would need to partner with a major pharmaceutical company prior to undertaking Phase 2/3 trials and the subsequent marketing of the product if our SMaRT Replacement Therapy ultimately achieves FDA approval. For our on-going second Phase 1 clinical trial we have retained PRA International as the clinical research organization, CRO, for clinical trials management services.

Manufacturing

The manufacturing methods for producing the SMaRT strain of *S. mutans* are standard Good Manufacturing Practice, or GMP, fermentation techniques. These techniques involve culturing bacteria in large vessels and harvesting them at saturation by centrifugation or filtration. The cells are then freeze dried or suspended in a pharmaceutical medium appropriate for application in the human oral cavity. These manufacturing methods are commonplace and readily available within the pharmaceutical industry. A single dose of our SMaRT Replacement Therapy contains approximately 100 billion *S. mutans* cells, in approximately 5 milliliters of formulated product. 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. For our first Phase 1 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.

MU1140 and Other Lantibiotics

Our retired founder and Chief Scientific Officer, Dr. Jeffrey Hillman discovered our lantibiotic, MU1140, in the course of developing SMaRT Replacement Therapy. MU1140 is a potent antibiotic that is naturally produced by the parent of the SMaRT strain, and we have produced a synthetic version of MU1140 known as MU1140-S. MU1140 is active against all Gram positive

bacteria against which it has been tested, including those responsible for a variety of healthcare-associated infections, or HAIs. The key technology that enables our production of MU1140-S is our Differentially Protected Orthogonal Lanthionine Technology, or DPOLT, which is a patented, novel organic chemistry synthesis platform developed by our scientific team. We reported the successful, analytical scale synthesis of MU1140-S using DPOLT in October 2008, and thus achieved what we believe will lead to the first-ever synthetic route to commercial-scale production of lantibiotics.

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, based on the 35 million patients admitted to 7,000 acute-care institutions in the United States, with an annual incidence of approximately 1.7 million cases, which result in 99,000 deaths. 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. HAIs are estimated to more than double the mortality and morbidity risks of any admitted patient in a U.S. hospital, which is the equivalent of 350,000 years of life lost annually. The critical care market for antibiotics is approximately $7 billion in the United States alone. Cubicin, a Gram positive lipopeptide antibiotic which was launched in the US market in November 2003 by the biotechnology company Cubist, had 2011 global sales of $735.5 million.

The need for novel antibiotics is increasing as a result of the growing resistance of target 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. Vancomycin, which was introduced in 1956, has served as the last line of defense against certain life-threatening infections, and, more recently, Cubicin has also served in this capacity, but bacterial resistance to these drugs has been growing at an increasing rate. Novel antibiotics have become increasingly scarce as major pharmaceutical companies have focused 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, from 2003 to 2007, only five new antibiotics were approved, of which only two possessed a novel mechanism of action.

Lantibiotics such as MU1140 are highly modified peptide antibiotics made by a small group of Gram positive bacterial species. Approximately 50 lantibiotics have been discovered since 1927 when the first lantibiotic, nisin, was discovered. Lantibiotics are known to be potent antibiotic agents; however, all attempts to investigate their clinical usefulness have met with uniform 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, typically result in production of only minute amounts of the lantibiotic. In cases where large amounts of a lantibiotic are made, such as with nisin, the unique chemical structure of lantibiotics has prevented the necessary purification needed for clinical testing.

Our Solution

MU1140 has demonstrated activity against a wide variety of disease-causing Gram positive bacteria, including MRSA, VRE, *C. diff., Mycobacterium tuberculosis,* or *M. tuberculosis,* and anthrax. We have performed extensive preclinical testing on MU1140, which has demonstrated the molecule’s novel mechanism of action. In order to produce sufficient quantities for our clinical trials and commercialization efforts, we intend to use a synthetic version of MU1140, known as MU1140-S.

We created MU1140-S using our patented, novel organic chemistry synthesis platform known as DPOLT. We believe that DPOLT will enable large-scale, cost-effective production of clinical grade MU1140-S. We reported the successful, analytical scale synthesis of MU1140-S using DPOLT in October 2008, which we believe will lead to the first-ever synthetic route to commercial-scale production of a lantibiotic. In addition, we believe that DPOLT will allow us to synthetically produce any of the 50 known lantibiotics due to the shared chemical structure features of this class of molecule. We intend to use DPOLT to create a pipeline of lantibiotics for therapeutic use.

Regulatory Status

We have performed extensive preclinical testing using native MU1140, which demonstrated the following features:

- Bactericidal activity against Gram positive species and against both replicating and non-replicating *M. tuberculosis*;
- Unusual chemical structure, which makes it extremely stable;
- No immune response in a variety of animal models, even with the use of strong adjuvants and carriers;
- Negligible toxicity when supra-therapeutic doses were tested in yeast, and fibroblast and kidney cell lines;
- *In vivo* efficacy in mouse and rat models, in which animals were infected interperitoneally with MRSA (60xLD50) and MU1140 was administered intravenously at doses well below its maximum tolerated dose;
- Novel mechanism of action that involves binding to and abducting Lipid II, which is required for cell wall biosynthesis;
- No spontaneous, genetically stable resistant mutants to MU1140;
- Synergy with an aminoglycoside; and
- Good pharmaceutical properties.

It will be necessary to conclude the preclinical testing of MU1140-S, including toxicity testing in rodent and non-rodent animal models before filing an Investigational New Drug, or IND, application with the FDA. We estimate that, once commenced, the regulatory process will require at least four years of clinical testing and the application and FDA approval of a New Drug Application, or NDA, before MU1140-S would be commercially available.

Our Strategy

We intend to complete the commercially viable synthetic route for MU1140-S and then continue preclinical testing of MU1140-S while we seek to license MU1140-S to, or partner with, a major pharmaceutical company.

Analysis of the 50 known lantibiotics suggests that there are possibly six to ten subclasses of lantibiotics as classified by known mechanisms of action, spectra of activity, or structural characteristics. In addition to MU1140-S, we intend to pursue licensing/partnering opportunities for the DPOLT platform technology in order to achieve the synthesis of additional lantibiotics of pharmaceutical interest.

Manufacturing

We have retained Bachem, a leading contract manufacturer, to refine and scale-up GMP production of MU1140-S. Through this relationship, we expect to have access to sufficient amounts of MU1140-S during the first half of 2012 which will enable preliminary preclinical testing to demonstrate equivalence between the synthetic and native molecule.

Additional Area of Development

As part of our past research efforts, we have identified and filed patent applications covering a technology that we may seek to further develop internally or monetize through a sale, license, or partnership in the future. This technology is referred to as CMAT, our biomarker discovery platform.

Biomarker Discovery Platform (CMAT)

Our biomarker discovery platform is based on our Change Mediated Antigen Technology, or CMAT, and was discovered by members of our scientific team while searching for protein targets associated with the diagnosis of periodontal disease. This technology rapidly identifies proteins that are expressed when a cell undergoes any sort of change. Such proteins are excellent targets for medical diagnostics and therapeutic strategies. CMAT is able to identify proteins shed from diseased tissues into bodily fluids such as blood, saliva and urine. We believe that CMAT is faster, more cost-efficient and significantly more sensitive than competing technologies such as differential proteomics and microarrays. In addition, our technology uses the actual diseased host rather than an animal model, so that biomarkers that we discover are more likely to be of high clinical value.

Our In-Licensed Technology Agreements

SMaRT Replacement Therapy

We have exclusively licensed the intellectual property for our replacement therapy technology from the University of Florida Research Foundation, Inc., or 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 and March 17, 2003. 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. The patent covers the genetically altered strain of *S. mutans* which does not produce lactic acid, a pharmaceutical composition for administering the genetically altered strain and the method of preventing tooth decay by administering the strain. See "Our Intellectual Property."

We issued 29,997 shares of our common stock to the UFRF as partial consideration for the initial license.

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 and March 17, 2003. The amended license agreements 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." Our license is for the period of the patent, subject to the performance of terms and conditions contained therein. See "Our Intellectual Property."

Additional Terms of License Agreements

In the amended license agreements for SMaRT Replacement Therapy and MU1140 the UFRF has reserved the right to use and sell products and services for research purposes only. The amended license agreements also provide the UFRF with a license, for research purposes only, to any improvements that we make to the products and processes covered by the patents.

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 20% of all revenues received from the sublicenses, excluding monies received solely for development costs.

We are also obligated to make minimum annual royalty payments to the UFRF for the term of the amended license agreement in the amount of $50,000 by the end of each year for each license agreement. The minimum royalty payments are required to be paid in advance on a quarterly basis. For the SMaRT Replacement Therapy and MU1140 minimum royalty payments, we must pay the UFRF an aggregate of $100,000 which is required to be paid in equal quarterly installments of $25,000.

Under the terms of the amended license agreements, in each calendar year and in addition to the royalty payment obligations, we are obligated to spend, or cause to be spent, an aggregate of $1,000,000 on the research, development, and regulatory prosecution of our SMaRT Replacement Therapy and MU1140 technologies combined, until a product which is covered wholly or partially by the claims of the patent, or is manufactured using a process which is covered wholly or partially by the claims of the patent, is sold commercially. If we fail to make these minimum research and development expenditures, the UFRF may terminate our license agreement.

We must also pay all patent costs and expenses incurred by the UFRF for the preparation, filing, prosecution, issuance and maintenance of the patent.

We have agreed to indemnify and hold the UFRF harmless from any damages caused as a result of the production, manufacture, sale, use, lease, consumption or advertisement of the product.

We are required to maintain liability insurance coverage appropriate to the risk involved in marketing our products. Our liability insurance has been renewed through March 2013, however, there is no assurance that we can obtain continued coverage on reasonable terms.

The amended license agreements further provide that the U.S. government funded research grant No. RO1 DE04529 during the course of or under which the licensed inventions covered by the patent were conceived. As such the U.S. government is entitled, as a right, to a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced the inventions of such patents for governmental purposes.

In order to protect our license rights and their patents, we or the UFRF may have to file lawsuits and obtain injunctions. If we do that, we will have to spend large sums of money for attorney fees in order to obtain the injunctions. Even if we do obtain the injunctions, there is no assurance that those infringing on our licenses or the UFRF's patents will comply with the injunctions. Further, we may not have adequate funds available to prosecute actions to protect or to defend the licenses and patents, in which case those infringing on the licenses and patents could continue to do so in the future**.**

Texas A&M License Agreement

In December 2011, the Company completed an exclusive licensing agreement with Texas A&M University (College Station, TX) ("Texas A&M") for access to new analogs 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 a new patent application with the US Patent Office to secure the intellectual property related to these new lantibiotic analogs (US Provisional Patent Application Serial No. 61,603,661, on February 27, 2012, entitled "Variants of the Lantibiotic MU1140 and Other Lantibiotics with Improved Pharmacological Properties and Structural Features". We have had a longstanding relationship with Dr. James Leif Smith, one of the co-authors of the patent application. Dr. Smith is an Assistant 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 (up to our 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 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 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.

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 determination by a court that the patent rights are invalid.

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 preclinical 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 preclinical testing and clinical trials.

Preclinical tests include laboratory evaluation of the product candidate, its formulation and stability, as well as animal studies. The FDA requires that preclinical tests be conducted in compliance with GLP regulations. The results of preclinical 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, preclinical 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 preclinical 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:

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. Recently, 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 experience in this market area. LPT3-04 appears to work through a novel mechanism of increasing, specifically, the rate of white fat cell apoptosis, or programmed cell death. Therefore, LPT3-04 could not only compete in this marketplace as a novel, stand alone approach to weight management, but it should also be complimentary to many existing products promoted for weight loss. As such, our weight loss agent should be attractive for licensing by an existing company in this field in order to obtain an advantage over other competitors with products that address only one or more of the common modes for promoting the reduction in body mass of its users. The overweight problem affects not only humans but occurs at an alarming frequency in the companion pet population. Again, there are a host of diet plans and aids for helping pets to lose weight, but the opportunities for an additive effect with the incorporation of LPT3-04 into existing pet diets, makes our agent an attractive acquisition candidate for established firms 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. Very recently, a University of California, Los Angeles spin-out C3 Jian announced that it was working on therapeutic candidates designed to specifically target *S. mutans* within oral plaque. 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.

MU1140-S and Other Lantibiotics

MU1140-S 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. Commercial success of MU1140-S technology will depend on our ability and/or the ability of our licensees and partners to compete effectively in all of these areas, against other companies with existing and pipeline antibiotics to be commercialized in the future. Producers of antibiotic products include many large, global pharmaceutical companies, who have much greater financial and technical resources than us.

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, particularly our patents. We also need to operate without infringing the proprietary rights of third parties.

License Agreements

We have exclusively licensed the intellectual property for our SMaRT Replacement Therapy and MU1140 technologies from the UFRF. The patents to which our exclusive UFRF license applies are U.S. Patent No. 5,607,672, "Replacement Therapy for Dental Caries," and U.S. Patent No. 5,932,469, "Antimicrobial Polypeptide, Nucleic Acid and Methods of Use" (including derivative patents: 6,391,285, 6,475,771, 6,964,760 and 7,067,125) in addition to many corresponding international patents and applications. In addition, we have exclusively licensed intellectual property for site directed mutagenesis of MU1140 and its effect on bacterial activity for which we have filed a U.S. patent application No. 61,603,661. See "Our In-licensed Technology Agreements."

Patents

We attempt to protect our technology and products through patents and patent applications. We have built a portfolio of patents and applications covering certain of our technologies. We have rights to ten issued U.S. patents and we have twelve U.S. patent applications on file with the U.S. PTO directed toward our products and technologies, including patents exclusively licensed from the UFRF. Our pending 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. 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 patents and patent applications we have with respect to our products and technologies are set forth below:

- **Consumer Products.** We filed five U.S. patent applications on our probiotic technology. One patent has issued: US Patent No. 7,931,892 for Composition and Methods for the Maintenance of Oral Health. Four applications are pending: U.S. patent application serial number 12/482,881, filed June 11, 2009; U.S. patent application serial number 13.017214, filed January 31, 2011, U.S. patent application serial number 13/178,706, filed July 8, 2011, and U.S. patent application serial number 13/302,006, filed November 22, 2011. These applications were internationally filed as PCT/US04/025899 on August 10, 2004, PCT/US09/047040, filed on June 11, 2009, PCT/US11/20826, filed January 11, 2011, and PCT/US11/61784, filed November 11, 2011. We also filed a U.S. patent application entitled "Methods for Regulating Weight and Size of Animals" (U.S. patent application serial number 11/265,414, filed November 2, 2005). This application was internationally filed as PCT/US05/39657 on November 2, 2005. A related application entitled "Methods of Treatment of Lipomas and Sarcomas" was filed as a PCT application on February 18, 2010 (PCT/US10/24562).
- **Biomarker Discovery.** In our Biomarker Discovery division we acquired the rights to our platform technology in November 2006 in connection with our acquisition of IviGene Corporation. We own patents and applications directed toward the identification and isolation of polynucleotides expressed during the process of infection: *In Vivo* Induced Antigen Technology-U.S. Patent No. 7,033,748, filed March 6, 2002, and U.S. Patent No. 8,034,571; filed April 8, 2002 (internationally filed as PCT/US00/21340 on August 4, 2000); and U.S. patent application serial number 12/327,056, filed December 3, 2008; *In Vivo* Induced Genes of *Mycobacterium tuberculosis*, U.S. patent application serial number 12/293,497 filed on September 2, 2009 (internationally filed as PCT/US07/63850, on March 13, 2007); Compositions for Detection and Treatment of Colorectal Cancer, PCT/US09/050938, filed July 17, 2009, and filed in the U.S. as U.S. patent application serial number 13/054667 on March 2, 2011.
- **Antibiotics.** In our Antibiotics division we have filed two patent applications directed at the intellectual property surrounding the DPOLT solid/liquid phase peptide synthesis platform technology, as well as associated areas of lantibiotics technology, in the U.S. (Pat. No. 7,521,529 filed August 11, 2006; U.S. Pat. Appl. 12/413,551, filed March 28, 2009) and internationally (PCT/US06/31510 filed August 11, 2006; PCT/US10/028620 filed March 25, 2010). In addition, we have the exclusive license for our MU1140 lantibiotic technology from the UFRF. In November 2011, the Company completed a licensing agreement with Texas A&M University (College Station, TX) for access to new analogs 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. Under the terms of the licensing agreement, we filed a new patent application with the US Patent Office to secure the intellectual property related to these new lantibiotic analogs (US Provisional Patent Application Serial No. 61,603,661, filed on February 27, 2012, entitled "Variants of the Lantibiotic MU1140 and Other Lantibiotics with Improved Pharmacological Properties and Structural Features".

- **Biologics.** We have licensed our SMaRT Replacement Therapy technology, and the use of recombinant Streptococcus strains to combat dental caries, from the UFRF. On February 27, 2012, we filed a patent application for improved replacement therapy for dental caries with an application number 61603693.

We also have applications pending and/or allowed in Australia, Canada, China, Hong Kong, Israel, Japan, Mexico, New Zealand, South Africa, South Korea, as well as in the European Patent Office. 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.

The recently passed Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act provide a 12-year data exclusivity period within the U.S. FDA for new biologics. We believe that our SMaRT Replacement Therapy technology would qualify for this exclusivity.

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™. Oragenics™ is among our non-registered trademarks. We currently have pending with the U.S. PTO, applications for registration of the marks for KJ2™, KJ3™, and JH145™. We also hold U.S. trademark registrations for EVORAKID®, EVORAPRO®, EVORAPLUS ®, EVORAPET®, TEDDY'S PRIDE ® and PROBIORA3 ®. We hold a European Community trademark registration for PROBIORA3 ®. Finally, we have applications pending and/or allowed for key oral care probiotics brand marks in an additional 13 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. 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.

Tax Credit

On November 1, 2010, we received notification that we were awarded federal grant funding for three of its therapeutic development programs under the Qualifying Therapeutic Discovery Project. The Qualifying Therapeutic Discovery Project, was recently enacted by Congress as part of the Patient Protection and Affordable Care Act of 2010, which was designed to provide grants or tax credits to qualified biotechnology companies that demonstrate the potential to either 1) develop new therapies to treat areas of unmet medical needs; 2) prevent, detect or treat chronic or acute diseases and conditions; 3) reduce long-term health care costs in United States; or 4) significantly advance the goal of curing cancer within the 30 year period beginning on May 21, 2010. We applied for funding on three of its programs: Prevention of Tooth Decay using Smart Replacement Therapy, Novel Antibiotics for the Treatment of Healthcare Associated Infections and Rapid and Sensitive Identification of Novel Diagnostic Biomarkers for Cancer and Infectious Diseases. We received a non-taxable cash grant award totaling $733,437 under the program. A payment of $371,219 was made to us in November 2010 and remaining grant award amount of $362,218 was received in February, 2011.

Research and Development Costs

We have spent $2,449,178 and $2,014,784 on research and development of our technologies during the years ended December 31, 2011 and 2010, respectively.

Employees

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

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 require additional financing to operate beyond June 2012, in order to continue growing our oral care probiotics business, as well as complete the development of and to commercialize our LPT3-04 Weight Loss, SMaRT Replacement Therapy and MU1140-S product candidates and we do not know if additional financing will be available to us when and if needed, or, if available, on terms that we find acceptable, particularly given the current and potential future strain in the financial and credit markets.

We do not have sufficient capital to sustain our operations beyond June 2012 and we are seeking financing. Our operations have required substantial capital funding since inception and we expect to continue to need substantial amounts to grow ProBiora3 sales, and to develop and commercialize our LPT3-04 Weight Loss, SMaRT Replacement Therapy and MU1140-S product candidates. We require additional funding and may be unable to raise capital on attractive terms, which would force us to significantly delay, scale back or discontinue the development or commercialization of our product candidates. Changing circumstances may cause us to use capital significantly faster than we currently anticipate, and we may incur higher expenses than currently expected because of circumstances beyond our control. If we are not able to raise additional capital and we are not generating positive cash flow from our ProBiora3 products and are unable to commercialize our product candidates, we may be unable to pursue further development of our product candidates, be forced to divest our product candidates prior to maximizing their potential value, be unable to maintain the licenses for our SMaRT Replacement Therapy and MU1140-S product candidates, or be forced to significantly scale back or cease our operations.

On January 23, 2012, we amended the outstanding unsecured revolving credit agreement (the “Credit Facility”) with the Koski Family Limited partnership, or KFLP, to add an additional $750,000 of available borrowings, which we immediately borrowed. With the $750,000 of additional debt, our principal indebtedness under the Credit Facility was $8.25 million.

On March 23, 2012, we entered into an Exchange of Notes for Equity Agreement (the “Debt Exchange Agreement”) with the KFLP. Pursuant to the terms of the Debt Exchange Agreement, we issued 6,285,619 shares of common stock and warrants to acquire 1,571,405 shares of common stock to the KFLP in exchange for the cancellation of an aggregate of $8,737,011 of indebtedness owed to the KFLP under our existing unsecured revolving Credit Facility with the KFLP. The outstanding indebtedness, consisted of $8,250,000 in principal owed on twelve separate promissory notes previously issued by the Company to the KFLP under the Credit Facility and accrued interest through March 23, 2012 (the closing date) of $487,011. The Credit Facility was terminated and the previously issued promissory notes thereunder were cancelled. The warrants are exercisable immediately at a price per share of $2.00 and expire three (3) years from the date of issuance.

On March 23, 2012, we also entered into a new loan agreement (the “Loan Agreement”) with the KFLP. It provides us with up to $2.5 million in secured funding in two advances of $1,250,000 each with the first advance occurring on March 23, 2012 and the second advance able to be made within 30 days thereafter, subject to the continued accuracy of representations and warranties made by us and that no material adverse events have occurred in connection with our business. Borrowings under the Loan Agreement mature in three years and bear interest at the rate of 5.0% and are secured by select assets of ours relating to or connected with the ProBiora3, SMaRT Replacement Therapy, MU1140 and LPT3-04 technologies. The loan amount is subject to automatic conversion upon a subsequent qualified equity financing by us of $5,000,000 (excluding any converted debt amount). Pursuant to the Loan Agreement we also issued a warrant to the KFLP to acquire 599,520 shares of the Company common stock. The warrants are exercisable immediately at a price per share of $2.00 and expire three (3) years from the date of issuance.

While we believe funding from the Loan Agreement will be sufficient to sustain our operations through June 2012, we have no other committed sources of capital and do not know whether additional financing will be available to us when and if needed, or, if available, that the terms will be acceptable to us, particularly if the financial and credit markets continue to be constrained.

We may seek additional financing through public or private equity offerings or through arrangements with strategic third parties. If we raise additional financing by issuing equity securities, further dilution to existing stockholders may result. For example, as of March 23, 2012 we had borrowed $8,250,000 under the Credit Facility and we exchanged such amount plus accrued interest of $487,011 for the issuance of 6,285,619 shares of our common stock to the KFLP at the same time we entered into the new Loan Agreement with the KFLP. While such exchange caused dilution to our existing holders, we no longer owe any amounts under the Credit Facility. We also issued to the KFLP warrants on March 23, 2012 to purchase an aggregate of 2,170,925 shares of common stock at an exercise price of $2.00 per share on March 23, 2012 which if exercised would cause additional dilution. In addition, as a condition to providing additional financing to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. If we raise additional financing through arrangements with strategic third parties, we may be required to relinquish rights to or sell certain of our product candidates or products that we would not otherwise relinquish or sell.

We may also seek additional financing through long-term debt and lines of credit or through the issuance of debt securities. If we raise additional financing through borrowing or the issuance of debt securities, our debt service obligations may be significant. If we are unable to generate sufficient cash to meet these debt service obligations, we will need to use existing cash or liquidate assets in order to fund these obligations and to repay our debt, which could force us to delay or terminate our research, development and commercialization efforts.

We are dependent upon our Loan Agreement with our largest shareholder, the KFLP, for funding.

In January 2012, we borrowed the remaining $750,000 under our Credit Facility with the KFLP and as of March 23, 2012 our total borrowings under the Credit Facility of $8,250,000 along with accrued interest of $487,011 were exchanged into 6,285,619 shares of common stock issued to the KFLP. While we no longer owe any amounts to the KFLP under the Credit Facility and the Credit Facility is no longer available as of March 23, 2012, we have borrowed an additional $1,250,000 under our new Loan Agreement with the KFLP and have the ability to receive another advance of $1,250,000 within 30 days of the Loan Agreement. However, we have no other committed sources of capital and do not know whether additional financing will be available to us when and if needed, or, if available, that the terms will be acceptable to us, particularly if the financial and credit markets continue to be constrained.

We may not be able to generate sufficient cash or raise sufficient capital to repay our secured indebtedness and if we are unable to repay our secured indebtedness, we could lose our intellectual property rights in our ProBiora3, SMaRT Replacement Therapy, MU1140 and LPT3-04 technologies which are material assets of the Company.

Our Loan Agreement with the KFLP matures in three years and select material assets of the Company relating to or connected with our ProBiora3, SMaRT Replacement Therapy, MU1140 and LPT3-04 technologies have been pledged as collateral to secure our borrowings under the Loan Agreement. This secured indebtedness could impede us from raising the additional equity or debt capital we need to continue our operations even though the amount borrowed under the Loan Agreement automatically converts into equity upon a qualified equity financing of at least $5 million. Our ability to repay the loan will depend largely upon our future operating performance and we cannot assure you that our business will generate sufficient cash flow or that we will be able to raise the additional capital necessary to repay the loan. If we are unable to generate sufficient cash flow or are otherwise unable to raise the funds necessary to repay the loan when it becomes due, the KFLP could institute foreclosure proceedings against our material intellectual property assets and we could be forced into bankruptcy or liquidation which could in turn significantly diminish the value of your common stock.

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

Since our inception, we have incurred operating losses and negative cash flow from operating activities. To achieve and maintain profitability, we must successfully develop, obtain regulatory approval for, manufacture, market and sell, or license, partner or sell the rights to, one or more of the product candidates we either license or own. Furthermore, our cash burn rate and expenses have increased significantly due to our commercialization initiatives with our ProBiora3 products. We expect to continue to incur losses for the foreseeable future as we expand our sales and marketing capabilities for our ProBiora3 products and continue our preclinical testing, clinical trials and research and development activities.

Net losses have totaled $7,678,868 and $7,805,165 for the years ended December 31, 2011 and 2010, respectively. We have experienced losses from operations during the last two years and have an accumulated deficit of $40,995,916 as of December 31, 2011. We have used cash in our operating activities of $5,494,758 and $6,448,434 for the years ended December 31, 2011 and 2010, respectively. Our accounts payable and accrued expenses have also increased due to operational changes instituted in

connection with the launch of our consumer products, costs incurred for patents, and for accrued interest relating to the borrowings under our credit facility with a related party in 2011. We have a working capital deficit of $8,328,004 (a deficit of $8,592,964 when the current cash reserved for DPOLT research is excluded), and $127,518 ($603,175, when the current cash reserved for DPOLT research is excluded) as of December 31, 2011 and 2010, respectively.

Our auditor has expressed substantial doubt about our ability to continue as a going concern.

In light of our recurring losses, accumulated deficit and negative cash flow, the report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2011 contains an explanatory paragraph raising substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that may be necessary in the event we are unable to continue as a going concern. If we are unable to establish to the satisfaction of our independent registered public accounting firm that the net proceeds from our financing efforts will be sufficient to allow for the removal of this going concern qualification, we may need to significantly modify our operational plans for us to continue as a going concern.

Our success will also depend on our ability to significantly increase sales of our ProBiora3 products which is currently our only source of product revenue and has 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. Net sales of our ProbBiora3 products were $1,229,510 and $1,128,895 for the years ended December 31, 2011 and 2010, respectively. If we are unable to generate significant revenues from our ProBiora3 products our business, financial condition and results of operations will be materially adversely affected.

Our success will depend on our ability to partner or sub-license our SMaRT Replacement Therapy and MU1140-S product candidates and their subsequent successful commercialization.

Our SMaRT Replacement Therapy and MU1140-S product candidates are both in early stage development and will require partners with deep 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 are currently conducting a second Phase 1 clinical trial to examine the safety and genetic stability of an attenuated version of the SMaRT strain in humans. Currently our clinical trials for our SMaRT Replacement Therapy product candidate will be completed on schedule, if at all. 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-S product candidate, we have performed extensive preclinical testing using native MU1140 and expect to pursue the preclinical testing of MU1140-S, including *in vitro* and animal models, during 2012. 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 SMaRT Replacement Therapy and MU1140-S product candidates. If our SMaRT Replacement Therapy or MU1140-S 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 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 profitability 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 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 ProBoira3 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 SMaRT Replacement Therapy and MU1140, our licenses to these product candidates may be terminated and we will be unable to commercialize these products candidates.

We hold our SMaRT Replacement Therapy and MU1140 product candidates under licenses from the University of Florida Research Foundation, Inc., or UFRF. Under the terms of the licenses, we must spend at least $1,000,000 per year on development of those product candidates until the first commercial sale of products derived from those product candidates has occurred. In addition, we must pay $25,000 per quarter as minimum royalties to the UFRF under our license agreements. The UFRF may terminate our licenses to SMaRT Replacement Therapy and MU1140 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. 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.

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 royalty 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. 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. We have contracted with multiple GMP-certified manufacturers to produce our

active ingredient, ProBiora3, under GMPs. We believe our arrangements with our contract manufacturers have the capacity to meet our current and expected future manufacturing 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. 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 profitability**.**

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

We do not have the internal capability to manufacture our ProBiora3 products or our LPT3-04 Weight Loss, SMaRT Replacement Therapy and MU1140-S product candidates under GMPs, as required by the FDA and other regulatory agencies. In order to continue to develop our product candidates, apply for regulatory approvals for our SMaRT Replacement Therapy and MU1140-S product candidates, and commercialize our ProBiora3 and LPT3-04 products and other product candidates, we will need to contract with third parties that have, or otherwise develop, the necessary manufacturing capabilities.

There are a limited number of manufacturers that operate under GMPs that are capable of manufacturing our ProBiora3 products and SMaRT Replacement Therapy product candidate. Furthermore, manufacturing MU1140-S on a commercial scale has not yet been achieved, so there are additional technical skills needed for the manufacture of MU1140-S 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 ProBiora3 products or our development stage product candidates, such as LPT3-04, 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 preclinical 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 ProBiora3 products ourselves in the future, we have no experience in the manufacture of pharmaceutical or biological products for clinical trials or commercial purposes. If we decide to manufacture products, we would be subject to the regulatory requirements described above. In addition, we would require substantial additional capital and would be subject to delays or difficulties encountered in manufacturing pharmaceutical or biological products. Regardless of the manufacturer of our products, we will be subject to continuing obligations regarding the submission of safety reports and other post-market information.

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

Our antibiotic product candidate, MU1140-S, is a synthetic form of MU1140 produced by our strain of *S. mutans*. 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 preclinical testing. In addition, we developed the DPOLT synthetic chemistry methodology to allow large-scale commercial production of the MU1140-S antibiotic. However, this methodology may not be feasible for cost effective, large scale manufacture. If we are not able to utilize this methodology 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. We have recently retained Bachem to refine and scale-up GMP production of MU1140-S. The manufacturing of MU1140-S is a highly exacting and complex process. Manufacturing MU1140-S on a commercial scale has not yet been achieved so there are additional risks. Third-party manufacturers must have additional technical skills and must take multiple steps to attempt to control the manufacturing processes.

Our ProBiora3 products and our LPT3-04 Weight Loss, SMaRT Replacement Therapy and MU1140-S 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 LPT3-04 Weight Loss, SMaRT Replacement Therapy and MU1140-S 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 the LPT3-04 Weight Loss Agent, SMaRT Replacement Therapy and MU1140-S 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, if approved for the treatment of tooth decay, 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 we have incurred significant turnover in key positions in the last six months.

Our performance is substantially dependent on the continued services and on the performance of our senior management and scientific team, who have extensive experience and specialized expertise in our business. Our performance also depends on our ability to retain and motivate our other key employees. In May 2011, we hired Dr. John Bonfiglio as Chief Executive Officer and in February 2012, we hired Mr. Michael Sullivan, CPA as our Chief Financial Officer. The loss of the services of these key employees could harm our ability to develop and commercialize our product candidates. We have no key man life insurance policies. We have employment agreements with Dr Bonfiglio and Mr. Sullivan. The term of each of these employment agreements is for an indefinite period and will end when the employment relationship is terminated by either party for any or no reason.

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 our SMaRT Replacement Therapy and MU1140-S 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 SMaRT Replacement Therapy or MU1140-S product candidates, we must demonstrate through preclinical testing and clinical trials that our products are safe and effective for use in humans. To date, the testing of our SMaRT Replacement Therapy product candidate has been undertaken solely in animals and a limited number of humans. Studies have proven our genetically altered strain of *S. mutans* to be effective in preventing tooth decay in animals. It is possible that our strain of *S. mutans* will be shown to be less effective in preventing tooth decay in humans in clinical trials. If our SMaRT Replacement Therapy product candidate is shown to be ineffective in preventing tooth decay in humans, we will be unable to commercialize and generate revenues from this product candidate. To date the testing of the antibiotic substance, MU1140, has been undertaken solely in the laboratory and in animals. We have not yet conducted human studies of MU1140-S. It is possible that when these studies are conducted, they will show that MU1140-S is ineffective or harmful in humans. If MU1140-S is 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 our SMaRT Replacement Therapy and MU1140-S 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 MU1140-S and SMaRT Replacement Therapy 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 continue our operations.

As we continue our MU1140-S and SMaRT Replacement Therapy product candidates, we intend to either license these product candidates to, or partner with, one or more major pharmaceutical companies 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. 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; and
- the burden of complying with foreign laws.

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 portfolio is protected by ten issued U.S. patents and twelve filed U.S. patent applications, including patents exclusively licensed from the University of Florida Research Foundation, Inc., or the UFRF. 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. 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 preclinical 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.

We plan to discuss with the FDA whether the clinical hold for the non-attenuated SMaRT strain can be lifted after the completion of our second Phase 1 clinical trial using the attenuated strain, because we believe the results from the trial may address the FDA's concerns with the non-attenuated SMaRT strain. However, there is no guarantee that our 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. If the FDA does not lift the clinical hold on the non-attenuated SMaRT strain, we or a partner cannot commence our anticipated third Phase 1 trial and we may not be able to conduct the clinical trials necessary to obtain 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 SMaRT Replacement Therapy and MU1140-S product candidates are subject to substantial government regulation, including the regulation of preclinical 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 SMaRT Replacement Therapy and MU1140-S product candidates and our ongoing research and development, preclinical 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 preclinical testing and clinical trials and an extensive regulatory approval process before they can be marketed in the United States or internationally.

The FDA accepted our protocols to conduct Phase 1 human clinical trials of our SMaRT Replacement Therapy product candidate. If we fail to maintain regulatory approval for the clinical trials of our SMaRT Replacement Therapy, if the FDA fails to lift the clinical hold on our IND for the non-attenuated version of the SMaRT strain, or if we fail to obtain regulatory approval for our MU1140-S product candidate, we may have to cease further development. Clinical trials on our SMaRT Replacement Therapy and MU1140-S product candidates are expected to take several years to fully complete. The commencement or completion of preclinical 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 preclinical 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 our SMaRT Replacement Therapy or MU1140-S product candidates, or will otherwise satisfy regulatory requirements. Our preclinical 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 preclinical studies or clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical 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 product candidates. If they do not, we will be unable to generate significant revenues from our product candidates and our business, financial condition and results of operations will be materially adversely affected.

The commercial success of our ProBiora3, LPT3-04, MU1140-S and SMaRT Replacement Therapy, and other product candidates 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

KFLP, together with members of the Koski family, have a controlling interest in our outstanding shares of common stock.

As of April 4, 2012 the KFLP, together with members of the Koski family, beneficially own approximately 81.5% (which reflects the March 23, 2012 transactions between the KFLP and the Company) of our outstanding shares of common stock, including outstanding warrants to acquire 2,170,925 shares of our common stock that we issued to the KFLP in connection with our Debt Exchange Agreement and Loan Agreement.

Christine L. Koski and Robert C. Koski, share voting and investment powers with two other Koski family members as general partners of the KFLP and serve on our Board of Directors. As a result, the Koski family will be able to affect the outcome of, or exert significant influence over, all matters requiring shareholder approval, including the election and removal of directors and any change in control. 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, the Koski family could cause us to enter into transactions or agreements that we would not otherwise consider.

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 acquiror;
- 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 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.

Our common stock is not listed on a national U.S. securities exchange and the application of the "penny stock" rules could adversely affect the market price of our common stock as well as increase your transaction costs to sell those shares.

Our common stock trades on the OTC Bulletin Board which generally has significantly less liquidity than securities traded on a national securities exchange, not only in the number of shares that can be bought and sold, but also through delays in the timing of transactions, reduction in securities analyst and news media coverage, and lower market prices than might otherwise be obtained. As a result, purchasers of shares of our common stock may find it difficult to resell their shares at prices quoted in the market or at all. In addition, if at any time the trading price of our stock is below $5.00 per share it is subject to the SEC's "penny stock" rules. Because the "penny stock" rules impose certain requirements on brokers, they may be less willing to execute transactions in our securities. Furthermore, because of the limited market and generally low volume of trading in our common stock, our common stock is more likely to be affected by broad market fluctuations, general market conditions, fluctuations in our operating results, changes in the market's perception of our business, and announcements made by us, our competitors or parties with whom we have business relationships. Our ability to issue additional securities for financing or other purposes, or to otherwise arrange for any financing we may need in the future, may also be materially and adversely affected by the fact that our securities are not traded on a national securities exchange.

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

Since our initial public offering in June 2003 and through April 4, 2012 our stock price has fluctuated from $90.00 to $0.75 per share. The trading price of our common stock has been, and may 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. 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.

Trading on the OTC Bulletin Board may be volatile and sporadic, which could depress the market price of our common stock and make it difficult for our stockholders to resell their shares.

Our common stock is quoted on the OTC Bulletin Board service of the Financial Industry Regulatory Authority (FINRA). Trading in stock quoted on the OTC Bulletin Board is often thin and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with our operations or business prospects. This volatility could depress the market price of our common stock for reasons unrelated to operating performance. Moreover, the OTC Bulletin Board is not a stock exchange, and trading of securities on the OTC Bulletin Board is often more sporadic than the trading of securities listed on a quotation system like Nasdaq or a stock exchange like Amex. Accordingly, shareholders may have difficulty reselling any of their shares.

Oragenics shareholders face market liquidity risk

The daily trading volume of Oragenics shares is relatively low. An order for the purchase or sale of a large number of Oragenics shares could significantly affect the price at which the order is executed.

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

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. Under our new Loan Agreement, the amounts borrowed are subject to automatic conversion into equity securities upon the successful completion of an offering by the Company raising a minimum of $5.0 million.

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. As of March 31, 2012, there were 12,170,795 shares of our common stock outstanding, with another 2,477,213 shares of common stock issuable upon exercise of warrants to investors, 770,173 shares issuable upon exercise of options outstanding and an additional 233,228 shares available for option grants under our 2002 Amended and Restated Stock Option Plan ("Stock Incentive Plan"). The issuance of shares of our common stock under our Stock 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 private placements. Such shares are available for resale as well as certain of the shares of common stock issuable upon exercise of the warrants. We have also issued shares of our common stock in the private placement and financing transaction which are deemed to be "restricted securities," as that term is defined in Rule 144 promulgated under the Securities Act of 1933, as amended, or Securities Act, and such shares may be resold pursuant to the provisions of Rule 144. The resale of shares acquired from us in private transactions could cause our stock price to decline significantly.

In addition, 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 could issue additional common stock, which might dilute the book value of our common stock.

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. Such stock issuances could be made at a price that reflects a discount or a premium from the then-current trading price of our common stock. In addition, in order to raise capital, we may need to issue securities that are convertible into or exchangeable for a significant amount of our common stock. 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. You may incur additional dilution if 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.

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 2. PROPERTIES.

In October 2009, we began leasing the office space located at 3000 Bayport Drive, Suite 685, Tampa, Florida 33607. This new location has become our principal executive office and is also being used for sales and marketing and some administrative matters. The office space is approximately 3,150 square feet and the annual lease cost is $63,312 which includes insurance, utilities and taxes. The lease term expires January 2013. Lease payments are capped during the term with the exception of taxes and insurance exceeding 3%. In addition to our Tampa location we continue to lease our research facility located at 13700 Progress Boulevard, Alachua, Florida 32615. This lease was renewed for a three-year period beginning December 2011 and expires November 2014. 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, 2011 were $108,758 which includes insurance, taxes and utilities. Lease payments are capped during the term which expires in November 2014. We expect the location in Alachua, Florida to continue to be used primarily as our research and laboratory space. There were no leasehold improvements in 2011 and 2010.

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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 has been quoted on the over-the counter (OTC) Bulletin Board under the ticker symbol "ORNI," since December 2008. OTC Bulletin Board quotations reflect inter-dealer prices without retail mark-up, markdown, or commissions and may not necessarily represent actual transactions. The following sets forth the high and low bid quotations reflected on the OTC Bulletin Board for the periods applicable in the last two fiscal years.

Period	2011		2010	
	High	Low	High	Low
First quarter	$5.00	$3.00	$20.40	$6.00
Second quarter	$6.50	$2.00	$14.60	$6.80
Third quarter	$3.75	$1.50	$ 9.60	$5.00
Fourth quarter	$2.50	$0.75	$ 8.50	$2.95

On April 4, 2012, the closing bid price of the common stock, as reported by the OTC Bulletin Board, was $0.82. As of April 4, 2012, there were approximately 92 registered holders of our common stock according to our records as maintained by our transfer agent. The number of record holders does not reflect the number of beneficial owners of the common stock for whom shares are held by banks, brokerage firms and others.

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.

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 a nutraceutical company primarily focused on the development of oral health probiotic products for humans and pets.

We have developed and are commercializing a variety of probiotic products that 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, or GRAS. We sell our ProBiora3 products through multiple distribution channels. We continue to seek improvement in the performance of our oral care probiotics business. As a result of such efforts:

- We received the Frost and Sullivan Award for excellence in Oral Care Probiotics;
- To better serve our customers, we have begun to qualify new delivery systems which will enable us to deliver ProBiora3 to new markets and end-users; and
- We refocused our channel efforts, successfully limiting exposure to capital-intensive areas such as mass retail and increasing efforts in cost-effective, focused markets such as dental offices.

Our SMaRT Replacement Therapy

Within oral health, we are also developing our biopharmaceutical product candidate, SMaRT Replacement Therapy. 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. 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. We commenced a second Phase 1 clinical trial for SMaRT Replacement Therapy during the first quarter of 2011, which we expect to conclude in second half of 2012.

Our Antibiotics

We are also seeking to develop novel antibiotics, through our pharmaceutical product candidate, MU1140-S, and we intend to use our patented, novel organic chemistry platform DPOLT to create additional antibiotics for therapeutic use. While developing SMaRT Replacement Therapy, members of our scientific team discovered that the SMaRT bacterial strain produces MU1140, a molecule belonging to the novel class of antibiotics known as lantibiotics. MU1140 has proven active preclinically against Gram positive bacteria responsible for a number of HAIs. We are in the process of scaling up production of our synthetic form of MU1140, or MU1140-S, and expect to commence preclinical testing in 2012 as our capital resources permit. The key technology behind the production of MU1140-S is our Differentially Protected Orthogonal Lanthionine Technology platform, or DPOLT, which is a patented, novel organic chemistry platform that we believe will enable the first ever commercial scale, cost-effective production of any of the 50 known lantibiotics. We intend to seek a partner for the DPOLT platform technology in order to create a pipeline of lantibiotics for therapeutic use.

Our Weight Loss Agent-LPT3-04

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. LPT3-04 consumption in the required amounts has been shown to be safe in humans. Due to the natural sweetness of LPT3-04 and the relatively large amounts of it that need to be consumed on a daily basis to achieve the desired weight loss effect, current product development efforts are focused on incorporating the compound into bars, milkshakes, and other food products. We are positioning our LPT3-04 weight loss agent for licensing following the successful completion of the proof-of-concept human clinical trial. As a result of our efforts to date in developing LPT3-04:

- Our LPT3-04 product yielded successful clinical results, paving the way for a potential newly commercialized product and/or partnership.
- We have submitted a patent application for the use of LPT3-04 for weight regulation with the United States Patent and Trademark Office, or U.S. PTO.

Other Technologies

Additionally, we are developing non-core technologies that originated from the discoveries of our scientific team, including CMAT, which is a biomarker discovery platform, which we believe could provide significant potential opportunities for us.

We have recently repositioned the Company towards increasing our focus and efforts – both financially and operationally on our probiotics business. We expect to focus on our oral health probiotic business to improve market awareness and provide for the potential for increased future sales. We expect to devote a substantial portion of our limited available resources to our oral health probiotic business as we continue the research and development and clinical trials for our other product candidates toward the goal of outlicensing such product candidates. In addition, we expect to devote resources to the protection of our intellectual property and the general and administrative support of our operations.

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, 2011, 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, 2011 and 2010, respectively our net revenues were $1,444,447 and $1,308,910.

As of December 31, 2011, we had an accumulated deficit of $40,995,916 and we have yet to achieve profitability. We incurred net losses of $7,678,868 and $7,805,165 for the years ended December 31, 2011 and 2010, respectively. We expect to incur significant and increasing operating losses for the foreseeable future as we seek to advance our product candidates through preclinical testing and clinical trials to ultimately obtain regulatory approval and eventual commercialization. We are continuing our efforts to raise additional capital. The report of our independent registered public accounting firm with respect to our financial statements appearing in our Form 10-K contains an explanatory paragraph stating that our operating losses and negative cash flows from operations since inception, and our need to raise additional financing and/or financial support prior to July 2012 in order to continue to fund our operations, raise substantial doubt about our ability to continue as a going concern. 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.

Recent Developments

Financing

On January 23, 2012, we entered into a Fifth Amendment (the “Fifth Amendment”) to an unsecured revolving credit agreement (the “Credit Facility”) with the Koski Family Limited Partnership. The Fifth Amendment increased the available borrowing under the Credit Facility by $750,000 from $7,500,000 to $8,250,000. On January 23, 2012, we drew down on the Credit Facility, as amended, to borrow $750,000. All other terms of the Credit Facility remained the same.

On March 23, 2012, we entered into an Exchange of Notes for Equity Agreement (the “Debt Exchange Agreement”) with the Koski Family Limited Partnership (“KFLP”), an accredited investor and our largest shareholder. Pursuant to the terms of the Debt Exchange Agreement, we issued 6,285,619 shares of common stock and warrants to acquire 1,571,405 shares of common stock to the KFLP in exchange for the cancellation of an aggregate of $8,737,011 of indebtedness owed to the KFLP under our existing unsecured revolving credit facility (the “Credit Facility) with the KFLP. The outstanding indebtedness, consisted of $8,250,000 in principal owed on twelve separate promissory notes previously issued by us to the KFLP under the Credit Facility and accrued interest through March 23, 2012 (the closing date) of $487,011. The Credit Facility was terminated and

the previously issued promissory notes thereunder were cancelled. The conversion was based upon a stock price of $1.39 which represented a 15% discount to the thirty day average closing price of our common stock prior to the date of approval by our disinterested directors. The warrants are exercisable immediately at a price per share of $2.00 and expire three (3) years from the date of issuance.

On March 23, 2012, we also entered into a new loan agreement (the "Loan Agreement") with the KFLP. It provides us with up to $2.5 million in secured funding in two advances of $1,250,000 each with the first advance occurring on March 23, 2012 and the second advance able to be made within 30 days thereafter, subject to the continued accuracy of representations and warranties made by us and that no material adverse events have occurred in connection with the our business. Borrowings under the Loan Agreement mature in three years and bear interest at the rate of 5.0% and are secured by select assets of the Company relating to or connected with the ProBiora3, SMaRT Replacement Therapy, MU1140 and LPT3-04 technologies. The loan amount is subject to automatic conversion upon a subsequent qualified equity financing by the Company of $5,000,000 (excluding any converted debt amount). Pursuant to the Loan Agreement we also issued a warrant to the KFLP to acquire 599,520 shares of our common stock. The warrants are exercisable immediately at a price per share of $2.00 and expire three (3) years from the date of issuance.

Oral Health Probiotic Business

We continued our efforts to broaden the distribution of our ProBiora3 products and in 2011, we established distribution for our EvoraPro product through Benco Dental, Henry Schein Dental, and Patterson Dental. We continue to sell our full suite of products to a number of distributors, both domestically and internationally.

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 also included sales of our ProBiora3 products. Sales of our ProBiora3 products were $1,229,510 and $1,128,895 for the years ended December 31, 2011 and 2010, respectively. Because of our efforts to increase the distribution of our ProBiora3 products, we expect net revenues to continue to increase in the near future. However, our success will depend on a number of factors, including our ability to continue to engage in marketing efforts related to our ProBiora3 products.

We expect that our 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 we may receive upon 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. 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 preclinical 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 non-clinical 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) preclinical 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. Preclinical research and development

costs consist of our research activities, preclinical studies, related personnel costs and laboratory supplies, and other costs such as rent, utilities, depreciation and stock-based compensation. While we are currently focused on advancing each of our product development programs, our future research and development expenses will depend on the clinical success of each product candidate, 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 and capital requirements.

Our current strategy is to reduce expenditures in R&D related to all non-probiotic projects. These non-probiotic projects are currently expected to be taken to the point where they can be licensed or partnered with larger pharmaceutical companies. We expect our research and development expenses related solely to the probiotics programs to increase in the future while costs related to other areas will continue to decrease until we partner or license them.

Our research and development expenses were $2,449,178 and $2,014,784 for the years ended December 31, 2011 and 2010, respectively.

Subject to available capital, we plan to increase our research and development expenses in the future as we continue the advancement of our clinical trials and preclinical product development programs for our SMaRT Replacement Therapy and MU1140-S product candidates. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates 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 before 2013.

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 will increase for, among others, the following reasons:

- the 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, expanded infrastructure and higher consulting, legal, accounting and investor relations costs associated with being a public company.

Other Income and (Expense)

Other income and expense includes local business taxes, and loss from abandoned public offering in 2010, 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 convertible revolving note payable to shareholder and short term notes payable.

Income Taxes

As of December 31, 2011 and 2010, we have net operating loss carryforwards of approximately $36,480,000 and $30,150,000, respectively, to offset future federal and state income taxes. We also have research and development and investment tax credit carryforwards of approximately $551,000 and $491,000 as of December 31, 2011 and 2010, 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 2032 and 2022, 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 carryfowards were 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. We consider an accounting estimate to be critical if it requires assumptions to be made that were uncertain at the time the estimate was made; and changes in the estimate or different estimates that could have been made could have a material impact on our results of operations or financial condition. The principal areas of estimation reflected in the financial statements are stock-based compensation, valuation of warrants, 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. Grant revenues are recognized as the reimbursable expenses are incurred over the life of the related grant. Grant revenues are deferred when reimbursable expenses have not been incurred.

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. Product returns are limited to specific mass retail customers for expiration of shelf life or unsold product over a period of time. We maintain a return policy that allows our customers to return product within a specified period of time prior to and subsequent to the expiration date of the product. 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 is only one mass retail customer account and two dental distributers 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.

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 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, 2011 and 2010 was $65,214 and $255,814, respectively.

Consigned Inventory

The Company has authorized a consignment inventory arrangement with one of its mass retail customers in March 2010. As of December 31, 2011 and 2010, the Company has $29,147 and $64,999 of inventory on consignment located at the retailers' stores and warehouses, which is included in our inventory reserve. Once consignment inventory has been sold by this customer, the customer notifies the Company of the sale and the Company records revenue in that accounting period. In 2010, the Company authorized the replenishment of consignment inventory based on orders placed by the customer. The Company is provided with monthly reports of consignment sales activity and balances.

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 dates. Stock-based compensation expense is recorded over the requisite service period in which the grantee provides services to us, to the extent the options or warrants do not vest at the grant date and are subject to forfeiture.

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 May 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2011-04 *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*. The ASU expands Accounting Standards Codification ("ASC") 820's existing disclosure requirements for fair value measurements and makes other amendments that could change how the fair value measurement guidance in ASC 820 is applied. The ASU is effective for the Company with the reporting period beginning January 1, 2012. The adoption of this ASU is not expected to have an impact on the Company's financial statements or disclosures.

No other new accounting pronouncements issued or effective during 2011 have had or are expected to have had an impact on the Company's financial statements.

Results of Operations:

	Years ended December 31		Three months ended December 31	
	2011	2010	2011	2010
Revenue	$ 1,444,447	$ 1,308,910	$ 396,590	$ 298,157
Cost of sales	713,627	911,793	155,422	438,215
Operating expenses:				
Research and development	2,449,178	2,014,784	842,191	641,536
Selling, general and administrative	5,628,005	6,285,004	1,214,470	1,492,854
Total operating expenses	8,077,183	8,299,788	2,056,661	2,134,390
Loss from operations	(7,346,363)	(7,902,671)	(1,815,493)	(2,274,448)
Other income (expense):				
Interest income	1,044	3,657	338	521
Interest expense	(332,349)	(33,859)	(124,167)	(28,866)
Loss from abandoned public offering	—	(603,012)	—	(603,012)
Local business tax	(1,200)	(2,717)	—	(148)
Total other income, net	(332,505)	(635,931)	(123,829)	(631,505)
Loss before income taxes	(7,678,868)	(8,538,602)	(1,939,322	(2,905,953)
Income tax benefit	—	733,437	—	733,437
Net Loss	$(7,678,868)	$(7,805,165)	$(1,939,322)	$(2,172,516)

For the Three Months Ended December 31, 2011 and 2010

Net Revenues. We generated net revenues of $396,590 for the three months ended December 31, 2011 compared to $298,157 in the same period in 2010; an increase of $98,433. The increase was primarily attributable to ProBiora3 product sales and grant revenue, net of a decrease in the sales return allowance.

Cost of Goods Sold. Cost of goods sold was $155,422 for the three months ended December 31, 2011 compared to $438,215 in the same period in 2010; a decrease of $282,793. The decrease was attributable to a decrease in the scrap expenses related to inventory reserves in 2010. Cost of goods in 2011 sold includes the production and manufacturing costs of our ProBiora3 products sold of $100,420, shipping and processing expenses of $42,330, and scrap expense of $12,672. In 2010, we had production and manufacturing costs of our ProBiora3 products sold of $116,484, shipping and processing expenses of $36,347, and scrap expense of $285,384. Scrap expenses represent product rework charges, inventory adjustments, inventory reserves of $12,672 and $255,814 during 2011 and 2010, respectively, associated with expected inventory replacement costs, and damaged inventory.

Research and Development. Research and development expenses were $842,191 for the three months ended December 31, 2011 compared to $641,536 in the same period in 2010; an increase of $200,655, or 31.3%. The increase was primarily attributed to an increase in patent costs of $158,631 and option expense of $137,266 related to restricted stock issued to our former Chief Scientific Officer, Dr. Jeffrey Hillman pursuant to his commitment to provide certain assistance to us in connection with his retirement and options issued to employees, offset by a decrease in clinical trial expense of $88,48l.

Selling, General and Administrative. Selling, general and administrative expenses were $1,214,470 for the three months ended December 31, 2011 compared to $1,492,854 in the same period in 2010; a decrease of $278,384, or 18.6%. This decrease was due to reductions in advertising and marketing expenses of $240,156, salary and fringe costs of $141,699 as a result of a decrease in staffing levels and a decrease in travel expense of $17,972; partially offset by increases in stock-based compensation expense of $109,373 and legal and professional support service fee of $6,329.

Other Income (Expense). Other income (expense) was $(123,829) for the three months ended December 31, 2011 compared to ($631,505) in the same period in 2010; a change of $507,675. The change was primarily attributable to expenses of $603,012 we recognized in 2010 associated with the filing of a registration statement for our contemplated public offering (which we withdrew prior to the end of the year), offset by an increase in interest expense of $95,301 in 2011 as compared to 2010 related to additional borrowings in the current period.

For the Years Ended December 31, 2011 and 2010

Net Revenues. We generated net revenues of $1,444,447 for the year ended December 31, 2011 compared to $1,308,910 for the year ended December 31, 2010; an increase of $135,507. The increase in net revenues was primarily attributable to increased ProBiora3 product sales. The increase in net revenues also included a $39,851 increase in grant revenues.

Cost of Goods Sold. Cost of goods sold was $713,627 for the year ended December 31, 2011 compared to $911,793 for the year ended December 31, 2010; a decrease of $198,166. This decrease was primarily attributable to a decrease in scrap of $254,852 in 2011 as compared to 2010. Cost of goods in 2011 sold also includes shipping and warehouse processing expenses of $157,291, and scrap expense of $139,815. In 2010, we had shipping and warehouse processing expenses of $145,049 and scrap expense of $394,667. Scrap expenses represent product rework charges, inventory adjustments, and inventory reserves of $65,214 and $255,814 in 2011 and 2010, respectively, associated with expected inventory replacement costs, and damaged inventory.

Research and Development. Research and development expenses were $2,449,178 for the year ended December 31, 2011 compared to $2,014,784 for the year ended December 31, 2010; a increase of $434,394, or 31.6%. The increase was primarily attributable to increases in clinical trial expense of $251,534, of stock compensation of $100,984 and patent expense of $256,316, which were offset by a decrease in consulting expense of $248,779. The increased clinical trial costs were a result of the commencement of our second phase 1 clinical trial for our SMaRT Replacement Therapy and expenses for our weight loss product (LPT3-04) clinical trials.

Selling, General and Administrative. Selling, general and administrative expenses were $5,628,005 for the year ended December 31, 2011 compared to $6,285,004 for the year ended December 31, 2010; a decrease of $656,999, or 10.5%. The decrease was due to reduced consulting fees of $496,480 as a result of cost cutting actions taken in the latter half of 2010, advertising and marketing expense savings of $874,458 due to the withdrawal from the mass retail channel in the first quarter of 2011, and accounting and professional support service fee savings of $128,646. These general and administrative expenses savings were partially off-set by increased non-employee director compensation expenses of $663,657 which was attributable to stock based awards to such directors, increased employee stock based awards expense of $101,088, increased recruiting and relocation fees of $71,963 and increased depreciation expense of $51,085.

Other Income (Expense). Other income and expense was $(332,505) for the year ended December 31, 2011 compared to ($635,931) for the year ended December 31, 2010; a change of $303,426. The change was primarily attributable to expenses of $603,012 we recognized in 2010 associated with the filing of a registration statement for our contemplated public offering (which we withdrew prior to the end of the year) offset by an increase in interest expense in 2011 of $298,490 as compared to 2010 related to the increased borrowings under the convertible revolving note payable to shareholder.

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,	
	2011	2010
Net cash used in operating activities	$(5,494,758)	$(6,448,434)
Net cash used in investing activities	—	(88,084)
Net cash provided by financing activities	5,534,394	6,367,029
Net increase (decrease) in cash and cash equivalents	$ 39,636	$ (169,489)

Our operating activities used cash of $5,494,758 and $6,448,434 for the years ended December 31, 2011 and 2010, respectively. The use of cash in all periods primarily resulted from our net losses adjusted for non-cash items and changes in operating assets and liabilities. We had negative working capital of $8,328,004 and $127,518 as of December 31, 2011 and 2010, respectively.

Our investing activities used cash of $0 and $88,084 for the years ended December 31, 2011 and 2010, respectively. The cash used in 2010 was in connection with investing activities primarily related to purchases of equipment.

Our financing activities provided cash of $5,534,394 and $6,367,029 for the years ended December 31, 2011 and 2010, respectively. The cash provided by financing activities in the year ended December 31, 2011 was primarily due to the release of restrictions on cash and borrowings under a convertible revolving note payable from a shareholder, partially offset by reductions in short term notes payable. The cash provided by financing activities in the year December 31, 2010 was primarily due to the release of restrictions on cash, borrowings under a convertible revolving note payable from a shareholder and short term notes payable, and proceeds from issuance of common stock, offset by reductions in long term revolving note payable to shareholder.

Set forth below is a description of our various financing activities for the periods reflected in this report:

December 2009 Private Placement

On December 30, 2009, we issued a total of 500,813 shares of restricted common stock in the initial closing of a private placement to accredited investors including the Koski Family Limited Partnership, or KFLP, our largest shareholder (the "December 2009 Private Placement"), for initial proceeds of $2,504,062. The shares were sold at $5.00 per share. The initial closing proceeds of $2,504,062 included the cancellation at closing of $54,062 in outstanding obligations we owed to Dr. Jeffrey Hillman, our Chief Scientific Officer, for compensation that had been deferred. Approximately half of the total investment, or $1,250,000, was made by the KFLP. In conjunction with, and as a condition to the initial closing of the December 2009 Private Placement, we also issued 200,000 shares of our common stock to the KFLP at $5.00 per share, which was the same price per share paid by the participating accredited investors, in exchange for the cancellation of the KFLP's $1,000,000 secured promissory note we previously issued to the KFLP in connection with a June 2009 private placement in which the KFLP initially acquired control of the Company (the "June 2009 Private Placement").

Approximately $1,000,000 of the total proceeds from the December 2009 Private Placement were committed to further our development of the DPOLT synthetic chemistry platform, essential to the production of our lead antibiotic, MU1140, subject to the goals set forth by the two-year NSF SBIR Phase II grant that we received on February 15, 2008. Such allocation enabled us to be eligible to receive up to an additional $500,000 matching grant from the NSF, which grant was subsequently awarded in June 2010.

On January 13, 2010, we completed the $3,004,062 private placement contemplated by the December 2009 Private Placement and issued another 100,000 shares of common stock at a price per share of $5.00 to the accredited investors for $500,000. Of this amount, the KFLP again participated in half of the remainder of the aggregate investment by acquiring 50,000 shares for $250,000.

May 2010 Note Financing

On May 28, 2010, we entered into an unsecured promissory note with a conversion provision (the "May 2010 Note") to the KFLP pursuant to which we borrowed $1,000,000 from the KFLP. Interest on the May 2010 Note accrued at the rate of LIBOR plus 6.0% and the principal of the May 2010 Note, together with all accrued interest thereon, was due and payable the earlier of: (i) the closing date of a registered public offering of newly issued equity securities by us resulting in cash proceeds to us, other than in connection with employee option plans, or (ii) the May 24, 2011 maturity date; provided, however, that in the event we completed a subsequent private offering of equity securities prior to the May 24, 2011 maturity date, we could elect to convert the principal of the May 2010 Note into the same equity securities being sold in the private offering at the same price and terms to the KFLP.

July 2010 Financing Transaction

On July 5, 2010, we entered into a common stock purchase agreement (the "July 2010 Financing Transaction") with the KFLP. At the closing of this financing transaction on July 30, 2010 we issued 250,000 shares of our common stock to the KFLP at a price of $8.00 per share. The $2,000,000 aggregate consideration paid by the KFLP consisted of (i) $1,000,000 cash and (ii) the exchange and cancellation of the outstanding May 2010 Note issued to the KFLP on May 28, 2010. Accrued interest on the May 2010 Note through closing was waived by the KFLP. Concurrent with the July 2010 Financing Transaction and as part thereof, we entered into an unsecured revolving credit agreement (the "Credit Facility") with the KFLP. Pursuant to the Credit Facility, we are able to borrow up to $2,000,000 from the KFLP at LIBOR plus 6.0%. The term of the Credit Facility was initially for 12 months commencing August 1, 2010.

On each of September 13, 2010 and November 8, 2010, we borrowed $1,000,000 under the Credit Facility and executed a revolving unsecured promissory note (the "September 2010 Promissory Note" and the "November 2010 Promissory Note") in such amounts initially to mature on July 30, 2011.

On January 24, 2011, we entered into a First Amendment to the Credit Facility (the "First Amendment") to increase the available borrowing from $2,000,000 to $2,500,000 and simultaneously therewith we drew on the Credit Facility as amended by the First Amendment to borrow the additional $500,000 in available funds and executed another revolving unsecured promissory note (the "January 2011 Promissory Note") initially due on July 30, 2011.

On February 4, 2011, we entered into a Second Amendment (the "Second Amendment") to the Credit Facility. As a result of the Second Amendment, we are able to borrow up to an additional $2,500,000 from the KFLP. Future draws under the Credit Facility, as amended, are limited to $500,000 per month commencing no earlier than March 2011. Under the Second Amendment, the due date of the amounts then outstanding under the Credit Facility, (the September 2010 Promissory Note, November 2010 Promissory Note and January 2011 Promissory Note) were extended by one year from July 30, 2011 to July 30, 2012. The interest rate remained at LIBOR plus 6.0%. The Second Amendment further provided for the automatic conversion of any amounts borrowed and outstanding under the Credit Facility into securities that we may issue in subsequent securities offerings. Any automatic conversion of amounts outstanding under the Credit Facility would be on the same terms of any such offering. In addition, the Second Amendment provided the KFLP with the right to put any undrawn available amounts under the Credit Facility, as amended, to us and thereby have a note issued to the KFLP.

On each of March 15, 2011, April 5, 2011, May 5, 2011, June 3, 2011, and July 8, 2011 we borrowed an additional $500,000 under the Credit Facility, as amended, and executed a revolving unsecured promissory note in such amounts that mature on July 30, 2012.

On June 29, 2011, we entered into a Third Amendment (the "Third Amendment") to the Credit Facility. As a result of the Third Amendment, we increased our availability under the Credit Facility by $2,000,000 from $5,000,000 to $7,000,000. Future draws of the $2,000,000 in increased availability provided by the Third Amendment to the Credit Facility are limited to $1,000,000 increments beginning no earlier than August 2011 and October 2011, respectively. All other terms of the Credit Facility remained the same.

On each of August 1, 2011 and October 5, 2011, the Company borrowed an additional $1,000,000 under the Credit Facility, as amended by the Third Amendment, and executed a revolving unsecured promissory note in such amounts that mature on July 30, 2012.

On December 9, 2011, we entered into a Fourth Amendment (the "Fourth Amendment") to the Credit Facility. The Fourth Amendment increased the available borrowing under the Credit Facility by $500,000 from $7,000,000 to $7,500,000. On December 9, 2011, the Company drew down on the Credit Facility, as amended, to borrow $500,000 in the newly available funds. All other terms of the Credit Facility remained the same.

On January 23, 2012, we entered into a Fifth Amendment (the "Fifth Amendment") to the Credit Facility. The Fifth Amendment increased the available borrowing under the Credit Facility by $750,000 from $7,500,000 to $8,250,000. On January 23, 2012, we drew down on the Credit Facility, as amended, to borrow $750,000. All other terms of the Credit Facility remained the same.

On March 23, 2012, we entered into an Exchange of Notes for Equity Agreement (the "Debt Exchange Agreement") with the Koski Family Limited Partnership ("KFLP"), an accredited investor and our largest shareholder. Pursuant to the terms of the Debt Exchange Agreement, we issued 6,285,619 shares of common stock and warrants to acquire 1,571,405 shares of common stock to the KFLP in exchange for the cancellation of an aggregate of $8,737,011 of indebtedness owed to the KFLP under our existing unsecured revolving credit facility (the "Credit Facility) with the KFLP. The outstanding indebtedness, consisted of $8,250,000 in principal owed on twelve separate promissory notes previously issued by us to the KFLP under the Credit Facility and accrued interest through March 23, 2012 (the closing date) of $487,011. The Credit Facility was terminated and the previously issued promissory notes thereunder were cancelled. The warrants are exercisable immediately at a price per share of $2.00 and expire three (3) years from the date of issuance.

On March 23, 2012, we also entered into a new loan agreement (the "Loan Agreement") with the KFLP. It provides us with up to $2.5 million in secured funding in two advances of $1,250,000 each with the first advance occurring on March 23, 2012 and the second advance able to be made within 30 days thereafter, subject to the continued accuracy of representations and warranties made by us and that no material adverse events have occurred in connection with the our business. Borrowings under the Loan Agreement mature in three years and bear interest at the rate of 5.0% and are secured by select assets of us relating to or connected with the ProBiora3, SMaRT Replacement Therapy, MU1140 and LPT3-04 technologies. The loan amount is subject to automatic conversion upon a subsequent qualified equity financing by the Company of $5,000,000 (excluding any converted debt amount). Pursuant to the Loan Agreement we also issued a warrant to the KFLP to acquire 599,520 shares of our common stock. The warrants are exercisable immediately at a price per share of $2.00 and expire three (3) years from the date of issuance.

Other Financings

On March 17, 2010, we entered into a short-term note payable for $50,637 with an interest rate of 5.75% to finance product liability insurance. Payments on this note are made evenly based on a straight line amortization over a ten-month period with the final payment due on January 10, 2011.

On July 9, 2010, we entered into a non-interest bearing short-term note payable for $22,188 to finance a portion of our new enterprise resource planning system. Payments on this note began July 9, 2010 and are made quarterly with the final payment due on April 1, 2011.

On July 20, 2010 we entered into a short-term note payable for $63,835 with an interest rate of 5.75% to finance directors' and officers' liability insurance. Payments on this note begin on August 24, 2010 and are made evenly based upon a straight line amortization over a ten-month period with the final payment due on July 24, 2011.

On July 31, 2010, we entered into a short-term note payable for $85,185 bearing interest at 7.5% to finance a portion our new enterprise resource planning system. Principal and interest payments on this note begin August 31, 2010 and are made evenly based on a straight line amortization over a 17-month period with the final payment due on December 31, 2011.

On March 3, 2011, we entered into a short-term notes payable for $48,988 bearing interest at 5.48% to finance product liability insurance. Payments on this note are made evenly based on a straight line amortization over a ten-month period with the final payment due on January 10, 2012.

On July 12, 2011, we entered into a short-term note payable for $77,751 bearing interest at 4.75% to finance a portion of the directors' and officers' liability insurance. Principal and interest payments on this note begin August 24, 2011 and are made evenly based on a straight line amortization over an 11-month period with the final payment due on June 24, 2012.

On March 10, 2012, we entered into a short-term note payable for $50,037 bearing interest at 6.17% to finance the product liability insurance. Principal and interest payments on this note begin April 10, 2012 and are made evenly based on a straight line amortization over an 10-month period with the final payment due on January 10, 2013.

Grants

On June 10, 2010, we were awarded the matching $500,000 grant from the NSF to support an SBIR Phase II grant previously awarded in 2008 for further development of our DPOLT platform. On each of June 17, 2010, February 25, 2011, and March 29, 2012, we received $125,000 related to this NSF awarded SBIR II Phase II grant for the company's DPOLT platform. Proceeds from the financing are to be allocated to further the development of our DPOLT platform, essential to the production of our lead antibiotic, MU1140, subject to the goals set forth by the NSF SBIR Phase II grant received by us. The remaining of these grant funds are expected to be provided to us by June 2012.

Tax Credit

On November 1, 2010, we received notification that we were awarded federal grant funding for three of its therapeutic development programs under the Qualifying Therapeutic Discovery Project. The Qualifying Therapeutic Discovery Project, was recently enacted by Congress as part of the Patient Protection and Affordable Care Act of 2010, which was designed to provide grants or tax credits to qualified biotechnology companies that demonstrate the potential to either 1) develop new therapies to treat areas of unmet medical needs; 2) prevent, detect or treat chronic or acute diseases and conditions; 3) reduce long-term health care costs in United States; or 4) significantly advance the goal of curing cancer within the 30 year period beginning on May 21, 2010. We applied for funding on three of its programs: Prevention of Tooth Decay using Smart Replacement Therapy, Novel Antibiotics for the Treatment of Healthcare Associated Infections and Rapid and Sensitive Identification of Novel Diagnostic Biomarkers for Cancer and Infectious Diseases. We received a non-taxable cash grant award totaling $733,437 under the program. A payment of $371,219 was made to us in November 2010 and remaining grant award amount of $362,218 was received in February 2011.

Future Capital Requirements

Our capital requirements for 2012 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 each of our technologies including continued increases in costs related to research, preclinical testing and clinical studies, as well as significant costs associated with our capital raising efforts and being a public company. We will require substantial funds to conduct research and development and preclinical 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.

In addition, the report of our independent registered public accounting firm with respect to our financial statements for the year ended December 31, 2011 included in our Annual Report on Form 10-K contains an explanatory paragraph stating that our operating losses and negative cash flows from operations since inception, and our need to raise additional financing and/or financial support prior to July 2012 in order to continue to fund our operations, raise substantial doubt about our ability to continue as a going concern. If we are unable to raise sufficient capital we will need to significantly modify our operational plans in order for us to continue as a going concern.

Our current available cash and cash equivalents are insufficient to satisfy our liquidity requirements. We believe our existing cash and cash equivalents, together with the available borrowings under our Loan Agreement and grant funds will allow us to fund our operating plan through June 2012. We will need to raise capital through the additional sale of equity or debt securities. We continue to seek the additional required 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 require additional capital beyond our currently forecasted amounts, such as, for example, if we determine to proceed independently with a Phase 3 clinical trial for our SMaRT Replacement Therapy. 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 pharmaceutical products, 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 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 preclinical and clinical trials;
- 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;
- the cost of manufacturing our ProBiora3 products and product candidates and any products we successfully commercialize;
- our ability to establish strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- 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.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Tax Loss Carryforwards

As of December 31, 2011 and 2010, we have net operating loss carryforwards of approximately $36,480,000 and $30,150,000, respectively, to offset future federal and state income taxes. We also have research and development and investment tax credit carryforwards of approximately $551,000 and $491,000 as of December 31, 2011 and 2010, 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 2032 and 2022, 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 KFLP. As a result, our historical loss carryforwards through June 2009 will be limited to $172,000 per year over the next 20 years, or limited to an aggregate amount of up to $3,440,000 of such historical loss carryforwards over such period of time, and the remaining balance of our historical loss carryforwards prior to June 2009 will 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 the June 2009 Private Placement transaction are expected to add to our loss carryforwards and to be fully available to us.

At December 31, 2011 and 2010, we recorded a 100% valuation allowance against our deferred tax assets of approximately $14,315,000 and $11,769,000, 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-23 at the end of this report and the supplementary data is not applicable.

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

Not Applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Management's evaluation of the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act was performed under the supervision and with the participation of our senior management, including our former Chief Executive Officer and Chief Financial Officer. The purpose of disclosure controls and procedures is to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our former Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures.

During 2010, we disclosed and identified several material weaknesses in our internal controls. Since that time we have been working on remediation of the identified material weaknesses and have provided updates in our periodic reports**.** Management believes progress has been made during the year ended December 31, 2011 to remediate material weaknesses in the internal control over financial reporting. However, based on the continued existence of material weaknesses, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2011, disclosure controls and procedures were not effective. 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, 2011 Form 10-K fairly presented, in all material respects, our financial position, results of operations, and cash flows for the periods presented in conformity with GAAP.

As previously disclosed and referenced above, the matters involving internal controls and procedures that our management identified and considered to be material weaknesses that have not yet been satisfactorily remediated are: (1) limited documentation of our system of internal control, (2) insufficient personnel to employ segregation of duties and (3) lack of formal written policies and procedures for accounting and financial reporting with respect to the requirements and application of GAAP and SEC disclosure requirements and related documentation. These deficiencies and weaknesses were largely attributable to the significant lack of available financial resources.

Management's Remediation Initiatives

Although management has not fully remediated the material weaknesses mentioned above, management believes progress is being made as we continue the engagement with a consulting firm specializing in Sarbanes-Oxley Section 404 compliance to assist us in the implementation of internal controls for financial reporting and disclosure and our remediation efforts. During 2011, the consulting firm completed an analysis of the Company's first, second and third quarter controls and reported that of 68 reporting controls tested there were no deficiencies identified. Management will continue to monitor and evaluate these and other factors affecting our internal controls as our resources and available liquidity permit. Until such time, our internal controls over financial reporting may be subject to additional material weaknesses and deficiencies that we have not yet identified. Management is responsible for and is committed to achieving and maintaining a strong control environment, high ethical standards, and financial reporting integrity. This commitment continues to be communicated to, and reinforced with, our employees.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be

effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Because of the inherent limitations of internal control, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

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

Limitations on the Effectiveness of Controls

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

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

Chief Executive Officer and Chief Financial Officer Certifications

Appearing after the Signatures section of this report there are Certifications of the Chief Executive Officer and the Chief Financial Officer. The Certifications are 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 Certifications and this information should be read in conjunction with the Section 302 Certifications 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 Chief Executive Officer and the Chief Financial Officer, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2011. 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*. Based on our assessment, we believe that, as of December 31, 2011, the Company's internal control over financial reporting was not effective based on those criteria.

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.

Management

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

Name	Age	Position
Dr. Frederick W. Telling	60	Chairman and Director
Dr. John N. Bonfiglio Ph.D.	57	President, Chief Executive Officer and Director
Robert C. Koski	53	Director
Christine L. Koski	54	Director
Charles L. Pope	60	Director
Dr. Alan W. Dunton	57	Director
Michael Sullivan	56	Chief Financial Officer, Secretary and Treasurer
Dr. Martin Handfield	41	Vice President of Research and Development
Dr. Robert Zahradnik	67	Vice President of Operations

Directors of the Company

Dr. Frederick W. Telling. Dr. Telling was elected Chairman of the Board of Directors on February 4, 2011. He has served as a Director since June 2010. Dr. Telling retired from Pfizer Inc. in June 2007 after 30 years of service. At Pfizer Dr. Telling served as its Corporate Vice President and Vice President of Corporate Strategic Planning and Policy since October 1994. Dr. Telling also serves as a director and member of the Compensation Committee and Audit Committee at Cell Therapeutics Inc. (NASDAQ: CTIC), a public company based in Seattle, Washington. Dr. Telling also serves on the boards of various civic and non-profit organizations. Dr. Telling holds a B.A. degree in History and Economics from Hamilton College and a MA degree in Industrial and Labor Relations and a PhD in Economics and Public Policy from Cornell University.

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

Dr. John N. Bonfiglio. Dr. Bonfiglio has served as our President, Chief Executive Officer and Director since May 2011. Prior to joining the Company, Dr. Bonfiglio served as the Chief Executive Officer, President and Director of Transdel Pharmaceuticals (a public company :TDLPE.OB) between October 2010 and May 13, 2011. Previously Dr. Bonfiglio served as the President and Chief Executive Officer of Argos Therapeutics from January 2007 to February 2010. From November 2005 to December 2006, he served as an independent consultant to two medical device companies, a therapeutic company and a medical communications company. From January 2003 to October 2005, he served as the Chief Executive Officer of The Immune Response Corporation, a public company and immuno-pharmaceutical company focused on developing products to treat autoimmune and infectious diseases. From 2001 to 2002, he was the Chief Operating Officer and Executive Vice President of Cypress Biosciences, a public company (NASDAQ: CYPB) providing therapeutics and personalized medicine services. From 1997 to 2001, he served as the Chief Executive Officer and President of Peregrine Pharmaceuticals, Inc., a public biopharmaceutical company (NASDAQ: PPHM) developing first-in-class monoclonal antibodies for the treatment of cancer and viral infections. Dr. Bonfiglio has also held senior management positions with Baxter Healthcare and Allergan, Inc. Dr. Bonfiglio received his bachelor of sciences degree in chemistry from State University of New York at Stony Brook in 1976, later earning his masters degree and a doctorate in synthetic organic chemistry from University of California at San Diego in 1978 and 1980 respectively. He later went on to serve as a postdoctoral fellow in organometallic chemistry at the University of California at Berkeley in 1981, earning his masters in business administration from Pepperdine University in 1992.

We believe that Dr. Bonfiglio’s qualifications to serve as a director include his 27 years of executive experience in the pharmaceutical, medical device and healthcare businesses, his experience in raising funds and completing licensing transactions for his prior companies and his experience on other company boards.

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

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

Christine L. Koski. Ms. Koski has served as a Director since June 2009 and as the Chairperson of our Board of Directors from June 2009 until February 2011 when director Telling was appointed to succeed Ms. Koski. Ms. Koski also serves as President and CEO of nMetrics, LLC, a provider of web-based scheduling system software. Prior to joining nMetrics in September 2006, Ms. Koski founded Koski Consulting Group, Inc. in June 2001 to advise start-up companies in the areas of business strategy and marketing. In addition to her positions at nMetrics and Oragenics, Ms. Koski serves as a director at Sun Hydraulics Corporation (NASDAQ: SNHY), a manufacturer of high performance hydraulic valves and solutions, and Cheltec, Inc., a specialty chemical company. Ms. Koski is a managing partner of the Koski Family Limited Partnership, which beneficially owns a controlling interest in the Company. Ms. Koski is a member of the nonprofit National Association of Corporate Directors. Ms. Koski holds an Executive MBA degree from Southern Methodist University's Cox School of Business and a B.S. degree in Chemistry from St. Lawrence University. Ms. Koski is the sister of our Director, Robert Koski.

Ms. Koski brings to the Board over a decade of experience as an executive officer and as a director of other privately held and public technology-based companies. Through her extensive executive management and board experience, Ms. Koski has developed the leadership, business judgment and consensus-building skills necessary to effectively execute her duties as director. Her strong expertise and background in management and marketing and track record as an accomplished executive have provided her with the business acumen and skills necessary to serve the company as it moves forward in commercializing its technology.

Charles L. Pope. Mr. Pope has served as a Director since June 2010. Mr. Pope currently serves as the Chief Financial Officer of Palm Bancorp, Inc. since June 2009. From September 2007 through June 2009, Mr. Pope served as the Chief Financial Officer of Aerosonic Inc., a manufacturer of aviation products. Mr. Pope served as the Chief Financial Officer of Reptron Inc., a manufacturer of electronic products, from March 2005 through June 2007. From March 2002 to February 2005, Mr. Pope served as Chief Financial Officer of SRI/Surgical Express, Inc. From February 2001 to March 2002 Mr. Pope served as Chief Financial Officer of Innovaro, Inc. (formerly UTEK Corporation). Prior to this time, Mr. Pope served as a Partner in the Audit and Financial Advisory Consulting Divisions and was a Partner in the Accounting and SEC Directorate at PricewaterhouseCoopers LLP. Mr. Pope also serves on the board of directors of Inuvo, Inc. in Clearwater, Florida and Innovaro Inc. in Tampa, Florida, both of which are public companies. Mr. Pope holds a B.S. degree in Economics and Accounting from Auburn University and is a Certified Public Accountant in Florida.

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

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

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

Resignation of Certain Executive Officers

On February 4, 2011 David Hirsch resigned as our President and Chief Executive Officer and director to pursue other opportunities. In connection with Mr. Hirsch's resignation, his employment agreement was terminated and we entered into a separation and release agreement with Mr. Hirsch which provided for the payment of severance in the amount of $112,500 over six months in accordance with the Company's normal payroll practices. Mr. Hirsch was entitled to the immediate payment of his accrued vacation which totaled $10,961.

On October 31, 2011, our founder and Chief Scientific Officer, Dr. Jeffrey Hillman retired from full time services to the Company and resigned from his executive positions with the Company and as a director. Pursuant to the terms of a separation agreement Dr. Hillman received an award of 120,000 restricted shares of the Company's common stock subject to performance conditions as well as time based vesting. The performance based vesting relates to the completion of certain work-in-progress concerning the Company's intellectual property and the time vesting is equal over a three year period with the restricted shares being subject to earlier vesting upon a change of control. The separation agreement also provides for the amendment of Dr. Hillman's outstanding stock option agreements to (a) vest any unvested options and (b) extend the exercise period of such options for one year post separation of employment until October 31, 2012. No severance payments were made to Dr. Hillman.

On January 27, 2012, Mr. Brian Bohunicky resigned as our Chief Financial Officer, Secretary and Treasurer to pursue other opportunities. In connection with Mr. Bohunicky's resignation, we entered into a separation and release agreement with Mr. Bohunicky which provided for the payment of severance in the amount of $100,000 over six months in accordance with the Company's normal payroll practices. Mr. Bohunicky's employment agreement was terminated in connection with the separation and release agreement.

Executive Management

John N. Bonfiglio Ph.D.

The biography of Dr. Bonfiglio is included above under the Section "Directors of the Company."

Michael Sullivan, CPA

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

Key Employees

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

Dr. Robert Zahradnik

Dr. Zahradnik has served as our Vice President of Operations since December 2011. Dr. Zahardnik served as the Vice President of Product Development from October 2009 to November 2011. Between February 2008 and April 2008 and July 2009 to September 2009 Dr. Zahradnik served as a consultant to the Company. Prior to that he served the Company in a variety of capacities. Dr. Zahradnik was previously our President and Chief Executive Officer. In addition Dr. Zahradnik served as our Secretary, Treasurer and Interim Chief Financial Officer. Dr. Zahradnik served as a member of our Board of Directors between November 1996 and December 2007 except for the period between July 2005 when he resigned from the Board so we would satisfy regulatory requirements with regards to independent directors. Dr. Zahradnik again served on our board of directors

between July 2006 and December 2007 when he was appointed back on the Board to fill the vacancy left by our former chief executive officer and director. From July 2000 until its merger with Oragenics in November 2006, Dr. Zahradnik was a Director of iviGene Corporation, Alachua, Florida. IviGene was engaged in the business of developing vaccines and therapeutics. From September 1999 to June 2005, Dr. Zahradnik was general manager of ProHealth, Inc., Batesville, Arkansas. ProHealth, Inc. is a manufacturer of nutritional supplements and household and skin care products. From February 1993 to June 2005, Dr. Zahradnik was a partner and general manager of Professional Dental Technologies and Therapeutics, Batesville, Arkansas, an oral pharmaceutical manufacturer. From February 1986 until June 2003, Dr. Zahradnik was the Chief Executive Officer and Chairman of the Board of Directors of Advanced Clinical Technologies, Inc., Medfield, Massachusetts, a medical diagnostic manufacturer and technical consulting firm. Dr. Zahradnik is a graduate of Penn State University with a Bachelor of Science degree in Chemistry and Boston University with a PhD in Physical Chemistry.

Board of Directors and Committees

Board of Directors

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

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

On February 4, 2011 Mr. David Hirsch resigned as President and Chief Executive Officer, and Dr. Frederick Telling was elected to succeed Christine Koski as Chairperson of the Board of Directors. On March 31, 2011, Dr Alan Dunton joined our Board of Directors as an independent director. On May 25, 2011, Dr. John Bonfiglio, was appointed as our President and Chief Executive Officer and added as a Director to the Board. On October 12, 2011, our founder and Chief Scientific Officer, Dr. Hillman retired and in connection herewith, resigned as Chief Scientific Officer and as a Director of the Company.

Director Independence

Since our securities are not listed on a national securities exchange or in an inter-dealer quotation system, we are not currently required to comply with director independence requirements. Notwithstanding the foregoing, historically we have determined director independence in accordance with the rules of a designated exchange. Accordingly, in determining whether our Directors are independent, we intend to comply with the rules of the NASDAQ Capital Market. We also expect to continue to comply with securities and other laws and regulations regarding the independence of directors, including those adopted under Section 301 of the Sarbanes-Oxley Act and Rule 10A-3 under the Securities and Exchange Act of 1934 with respect to the independence of Audit Committee members. The NASDAQ Capital Market listing standards define an “independent director” generally as a person, other than an officer of a company, who does not, in the view of the company’s Board of Directors, have a relationship with the company that would interfere with the director’s exercise of independent judgment. The Board has determined that each of the following directors, is independent within the meaning of the NASDAQ Capital Market listing standards:

Frederick W. Telling

Charles L. Pope

Alan W. Dunton

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

Due to the March 23, 2012 Debt Exchange Agreement and Loan Agreement transactions (the “KFLP Financing Transactions”) between the Company and the Koski Family Limited Partnership (‘KFLP”) pursuant to which the KFLP became a secured creditor and increased its beneficial ownership in the Company to over 80% and Directors Robert C. Koski and Christine L. Koski’s relationship to the KFLP as general partners, the Board of Directors recently concluded that Christine L. Koski and Robert C. Koski could no longer be considered to be independent directors under the NASDAQ listing standards.

As a result, the Board of Directors made changes to the members of its Compensation Committee and Nominating Committee. The Compensation Committee now consists of Dr. Telling, Mr. Pope, as independent director members, and Ms. Koski, with Dr. Telling serving as Chair. The Nominating Committee now consists of independent directors, Dr. Alan Dunton and Mr. Pope, and Mr. Koski, with Dr. Dunton serving as Chair. Ms. Koski was re-appointed to the Compensation Committee and Mr. Koski was re-appointed to the Nominating Committee as non-independent directors under the exception contained in the NASDAQ listing requirements pursuant to which a non-independent director can serve on a nominating committee or compensation committee under exceptional and limited circumstances for no longer than two years. The Board determined that due to Ms. Koski's extensive prior involvement with our compensation practices as a member of our Compensation Committee, her re-appointment to the Compensation Committee was required by the best interests of the Company and its shareholders. The Board determined that due to Mr. Koski's extensive prior involvement with our director recruitment process as a member of the Nominating Committee, his re-appointment to the Nominating Committee was required by the best interests of the Company and its shareholders. Notwithstanding such re-appointments of Ms. Koski and Mr. Koski, a majority of each of the Company's Compensation Committee and Nominating Committee consist of independent directors.

Audit Committee Financial Expert

The audit committee is comprised of three non-employee, independent members of the board of directors, Mr. Charles Pope (chair), Dr. Frederick Telling and Dr. Alan Dunton. The board of directors has determined that all of the audit committee members are able to read and understand fundamental financial statements. In addition, the board of directors has determined that Mr. Pope is an "audit committee financial expert" as that term is defined in Item 407(d)(5) of Regulation S-K promulgated under the Securities and Exchange Act of 1934.

Code of Ethics

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

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires the Company's officers and Directors and any persons who beneficially own more than ten percent of the Company's Common Stock to file reports of ownership and changes in ownership of such securities with the Securities and Exchange Commission Officers, Directors and beneficial owners of more than ten percent of the Common Stock are required by applicable regulations to furnish the Company with copies of all Section 16(a) forms they file. Based solely on its review of copies of forms furnished to the Company and written representations from the executive officers, directors and holders of ten percent or more of the Company's Common Stock, the Company believes, all persons subject to the reporting requirements with regard to the Common Stock complied with the applicable filing requirements during 2011.

ITEM 11. EXECUTIVE COMPENSATION.

Compensation of Directors

On June 4, 2010, commensurate with the appointment of two new independent Directors, the Board approved changes to the Company's Board compensation to be paid to non-employee Directors. Such changes primarily related to the reinstating of a cash fee component to the Director compensation program for non-employee directors. On March 11, 2011, the Board again approved revisions to the Board compensation program. The revision consisted of the addition of one per board meeting fee for each non-employee director for any board meetings in excess of one per quarter. On November 14, 2011, the Board added a long term incentive component for the non-employee directors to the director compensation program. As revised by the foregoing, the Director compensation program consists of the following:

Non-employee directors

Cash Compensation. The Director compensation program changes provide that all non-employee Directors will receive an annual base fee for service on the Board of $24,000. In addition, the Chairperson of the Board and of our Audit Committee, Compensation Committee and Nominating Committee will also receive annual fees of $25,000, $20,000, $15,000 and $10,000, respectively. All non-employee Directors serving on committees (other than as the Chairperson) shall receive an annual fee of $5,000 in connection with such committee service. In addition all non-employee Directors shall receive a per board meeting fee of $2,000 for each board meeting in excess of one per quarter. All fees for Board service are to be paid quarterly in arrears.

Equity Compensation. Equity compensation is to be issued to Directors upon joining our Board. Non-employee Directors receive a stock option for the purchase of 5,000 shares of our common stock at an exercise price per share equal to the fair market value per share on date they became a Director, which will immediately vest and be exercisable. As part of the Director compensation program, the Board may also make discretionary equity based awards from time to time under the Company's existing Amended and Restated 2002 Stock Option and Incentive Plan (the "Stock Incentive Plan").

Long-term Incentive Component. On November 14, 2011, the Compensation Committee and Board of Directors approved a change in the Company's director compensation program to add a long term performance based equity incentive based component for the non-employee directors. (the "Non-Employee Director LTIP Program"). The Non-Employee Director LTIP Program is an incentive program designed to motivate the non-employee director participants to achieve the Company's financial and other performance objectives and to reward them if, and when, those objectives are met. The Non-Employee Director LTIP Program included a one time retention award to each non-employee director of common stock from the Company's Stock Incentive Plan. In addition, the Non-Employee Director LTIP Program provides for the award of shares of common stock as compensation to non-employee directors of the Company. The shares will be issued to non-employee directors during the term of the Non-Employee Director LTIP Program, subject to the satisfaction of applicable performance goals (as described below). The non-employee director participants are eligible to receive shares of common stock if they continue to serve the Company as directors C through the first to occur of either of the following: (i) the Company's achievement, on or before December 31, 2013 (the "Termination Date"), of the various "Performance Goals" set forth below, or (ii) the effective date of a "Change in Control" of the Company that occurs at any time on or before the Termination Date.

The performance periods for the Non-Employee Director LTIP Program run from January 1, 2012 through December 31, 2013. Awards will be credited to participants, up to target levels, to the extent that the performance goals are satisfied, as determined by the Compensation Committee. Upon the occurrence of a "Performance Vesting Date" with respect to a "Performance Goal," a participant will be entitled to receive a number of shares of Common Stock determined by multiplying (1) the award percentage (each, an "Award Percentage") corresponding to that particular Performance Goal as set forth in their award agreement by (2) the total number of outstanding shares of Common Stock, determined on a non-fully diluted basis, as of that particular applicable Performance Vesting Date. For purposes of an award, the "Performance Vesting Date" with respect to a Performance Goal shall be the day on which the Compensation Committee of the Company's Board of Directors certifies and determines, in its reasonable discretion, that the applicable Performance Goal has been achieved. Participants are required to remain directors of the Company through the date on which the Compensation Committee makes a final determination under the Non-Employee Director LTIP Program with respect to the satisfaction of the performance goals during the performance period.

The Non-Employee Director LTIP Program provides for awards upon the Company achieving any of the following performance goals: (i) achievement of Company fiscal year sales equal or greater than $10,000,000; (ii) achievement of Company fiscal year sales equal or greater than $20,000,000; (iii) achievement by the Company of cash flow positive in any fiscal quarter; (iv) achievement by the Company of earnings per share in any fiscal year equal or greater than $0.02 per share of Company stock; (v) Achievement of price per share of Company stock equal to $10.00; (vi) Achievement of price per share of Company stock equal to $20.00; (vii) licensing of any science technology which results in upfront cash receipt of $2M; or (viii) capital raise by the Company of $5,000,000 in both fiscal years or a $10,000,000 in a single raise.

In the event a Change in Control of the Company occurs, a participant will be entitled to receive the full amount of the shares with respect to any Performance Goal as to which the related Performance Vesting Date did not occur prior to the date of the Change in Control as though the Performance Goal had been fully achieved as of the time of the Change in Control except with respect to the Share Appreciation Goals which will depend on the price per share of any change in control transaction. The term "Change in Control" for purposes of an award shall mean: a "Corporate Transaction" as defined in the Company's Stock Incentive Plan.

The award percentages for each non-employee director for the achievement of each designated Performance Goal are the same for each non-employee director as follows:

Non-Emp. Director	$10M Sales	$20M Sales	Positive CF	EPS Goal	$10 Share Appreciation	$20 Share Appreciation	License Technology	Company Capital Raise
	0.11%	0.09%	0.11%	0.16%	0.11%	0.06%	0.09%	0.16%

As a result of the addition of the Non-Employee Director LTIP Program, on November 14, 2012 each non-employee director (Dr. Frederick Telling, Charles Pope, Dr. Alan Dunton, Robert Koski and Christine Koski) received an immediate Retention Award of 6,400 shares under the Stock Incentive Plan.

Assuming a Change of Control event during the Non-Employee Director LTIP Program period, and based upon the current level of the Company's outstanding shares of common stock, each non-employee director would be entitled to receive an aggregate of 108,300 shares (assuming that all performance awards would be included as vested upon a change in control). A copy of the form of long term incentive plan award agreement for non-employee directors ("LTIP Director Award Agreement") approved by the Committee and Board is incorporated herein by reference to the Form 10-K.

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

Employee Directors

Consistent with past practice, the Director compensation program provides that employee Directors receive no additional compensation in connection with their board service.

The following table sets forth the compensation of our non-employee Directors in 2011.

Director Compensation Table

Name	Fees earned or paid in cash(1)	Stock Awards (2)	Option awards(3)	All other compensation(4)	Total
Dr. Frederick W. Telling	$ 75,000	$ 9,600	$187,917	—	$272,517
Robert C. Koski	$ 45,000	$42,270	—	—	$ 87,270
Christine L. Koski	$ 40,000	$ 9,600	—	—	$ 49,600
Charles L. Pope	$ 55,000	$ 9,600	$187,917	—	$252,517
Dr. Alan Dunton	$ 23,750	$ 9,600	$204,117	—	$237,467

(1) Amounts represent cash compensation earned by Directors during 2011 in connection with their Board service.

(2) On November 14, 2011, the Company adopted a change to its director compensation program simultaneously with adding long term incentive program for the Company's executive officers. See "Director Compensation — Long-Term Incentive Component." In connection with such program each non-employee director was awarded an immediate retention award of 6,400 shares of our common stock. The aggregate grant date fair value was computed in accordance with FASB ASC Topic 718. In addition to the foregoing, the amount for Robert C. Koski, includes an award of 10,000 shares of restricted common stock made to Mr. Koski for his services as a liaison between the Board and Management during the vacancy of the Company's office of President and Chief Executive Officer earlier in the year.

(3) The compensation amount reflected with respect to the option awards represents the 2011 compensation expense associated with outstanding option grants to our non-employee directors. Upon joining our Board of Directors in April 2011, Dr. Dunton as a non-employee Director was granted options to acquire 5,000 shares of our common stock at $3.30 per share in accordance with our Director compensation program. In addition, our independent audit committee members (Dr. Dunton, Dr. Telling and Mr. Pope) were granted options to acquire 50,000 shares of our common stock in May, 2011 at an exercise price of $5.00 per share in accordance with the discretionary component of our director compensation program. Twenty-five thousand of the shares vested immediately with the remaining twenty-five thousand vesting on the anniversary of the grant date. The amounts reflected in the table with respect to these awards represent the 2011 compensation expense associated with such grants and do not reflect compensation actually received by the named directors. The Company uses a Black-Scholes option pricing model to estimate the fair value of the stock option grant. The use of a valuation model requires the Company to make certain assumptions with respect to selected model inputs. The average expected life is based on the contractual term of the option and on the simplified approach provided by SAB 107. The risk-free interest rate is based on the U.S. Treasury zero-coupon issues equal to the expected life assumed at the date of the grant.

(4) No other compensation was paid to the non-employee Directors except for reimbursement for travel expenses to Board meetings, which did not exceed $10,000 individually or in the aggregate for our non-employee Directors.

Executive compensation

Summary Compensation Table

The following table sets forth the aggregate compensation in 2011 and 2010 for services in all capacities paid or accrued by the Company to our most highly compensated officers and our former Principal Executive Officers ("PEO") who earned more than $100,000 in total salary and bonus during the fiscal year ended December 31, 2011 (the "Named Executive Officers").

Name and principal position	Year	Salary	Bonus	Stock Awards (8)	Option awards (8)	All other compensation (9)	Total
John N. Bonfiglio Ph.D.	2011	$168,718	$16,333	$43,500	$421,046	$ 4,550	$654,147
Chief Executive Officer[1]	2010	$ —	$ —	$ —	$ —	$ —	$ —
Principal Executive Officer, PEO							
Michael Sullivan[2]	2011	$ —	$ —	$ —	$ —	$ —	$ —
Chief Financial Officer	2010	$ —	$ —	$ —	$ —	$ —	$ —
Dr. Martin Handfield[3]	2011	$171,000	$ —	$14,850	$ 2,104	$ 5,130	$193,084
Vice President of Research	2010	$171,000	$ —	$ —	$ —	$ 5,130	$176,130
and Development							
Dr. Robert Zahradnik[4]	2011	$135,000	—	$14,850	$ 1,653	$ 4,050	$155,553
Vice President of Operations	2010	$135,000	—	—	—	$ 4,050	$139,050
Former Officers:							
David Hirsch[5]	2011	$ 21,346	$ —	$ —	$ —	$ 123,963	$145,309
Former PEO	2010	$225,000	$ —	$ —	$ —	$ 6,750	$231,750
Brian J. Bohunicky[6]	2011	$200,000	$ —	$51,870	$ 29,233	$ 6,000	$287,103
Chief Financial Officer	2010	$200,000	$ —	$ —	$ —	$ 6,000	$206,000
Dr. Jeffrey D. Hillman[7]	2011	$166,667	$ —	$40,227	$ —	$ 29,356	$236,250
Chief Scientific Officer	2010	$200,000	$ —	$ —	$ —	$ 6,000	$206,000

(1) Dr. Bonfiglio became our President and Chief Executive Officer on May 25, 2011 and as such he did not earn any compensation during 2010. We entered into an employment agreement with Dr. Bonfiglio. See "Employment Contracts and Change of Control Agreements" for a discussion of the terms of Dr. Bonfiglio's employment agreement with us. Upon commencing employment with us on May 25, 2011 Dr. Bonfiglio's annual salary was set at $ 280,000 and he was awarded options to acquire 125,800 shares of our common stock at an exercise price of $4.76 per share (the closing price on the grant date). Of these options, 78,625 vested immediately and the remaining 47,175 vest over three years on the anniversary date of the grant. In addition, on September 28, 2011 Dr. Bonfiglio was granted options to acquire 39,200 shares of common stock at an exercise price of $1.50 per share (the closing price on the grant date). The options vest equally on an annual basis over a three year period. Option awards to Dr. Bonfiglio were made pursuant to our Stock Incentive Plan. Pursuant to the terms of Dr. Bonfiglio's employment agreement the Board of Directors adopted a bonus plan for the achievement of certain financial and other performance objectives. See "Employment Contracts and Change in Control Arrangements —Chief Executive Bonus Plan," for discussion of the bonus plan. Under the bonus plan Dr. Bonfiglio was awarded a bonus of $16,333 for 2011. In addition to the bonus plan, Dr. Bonfiglio's employment agreement required the adoption of an equity based award program tied to certain performance goals. On November 14, 2011, the Company adopted a long-term performance-based incentive program and broadened its applicability to other designated officers and employees (the "Executive LTPB Program"). See "Executive Long-Term Performance-Based Incentive Program" below for a summary of the Executive LTPB Program. Dr. Bonfiglio received 29,000 shares of our common stock under the Executive LTPB Program as an immediate retention award. The retention award shares vested immediately. In addition, as part of Dr. Bonfiglio's employment agreement we agreed to reimburse Dr. Bonfiglio for up to $30,000 in relocation and temporary living expenses. We reimbursed $20,305 in such expenses during 2011 which are not reflected in the above table.

(2) Mr. Sullivan became our Chief Financial Officer on February 6, 2012 and as such he did not serve the Company in any capacity during 2011 or 2010.

(3) Dr. Handfield was awarded stock options on September 28, 2011, to acquire 16,800 shares of common stock under our Stock Incentive Plan at an exercise price of $1.50 (the closing price on the grant date). These options vest equally on an annual basis over a three year period. Dr. Handfield was also included as one of the designated participants in the Executive LTPB Program and as such he received 9,900 shares as an immediate retention award under our Stock Incentive Plan which vested immediately.

(4) Dr. Zahradnik was awarded stock options on September 28, 2011, to acquire 13,200 shares of common stock under our Stock Incentive Plan at an exercise price of $1.50 (the closing price on the grant date). These options vest equally on an annual basis over a three year period. Dr. Zahradnik was also included as one of the designated participants in the Executive LTPB Program and as such he received 9,900 shares as an immediate retention award under our Stock Incentive Plan, which vested immediately.

(5) On February 4, 2011 Mr. Hirsch resigned as our President and Chief Executive Officer and Director to pursue other opportunities. We entered into a separation and release agreement with Mr. Hirsch which provides for the payment of six months' severance to Mr. Hirsch based upon his annual salary. The amount under salary represents that portion of Mr. Hirsch's salary applicable to the time he served as our President and Chief Executive Officer. Included in the amount listed under All Other Compensation is $112,500 in severance payments and $10,961 in accrued but unused vacation pay paid to Mr. Hirsch.

(6) Mr. Bohunicky was awarded 10,000 shares of restricted stock on March 11, 2011 half of which vested in six months and half of which vested on the anniversary of the award. Mr. Bohunicky was also awarded stock options on March 11, 2011 to acquire 20,000 shares of common stock under our Stock Incentive Plan at an exercise price of $3.60 (the closing price on the date of grant). One-third of these options vest on the first anniversary of the date of grant, with an additional one-third becoming exercisable on each of the following two anniversaries of the date of grant. Mr. Bohunicky was awarded stock option on September 28, 2011, to acquire 28,000 shares of common stock under our Stock Incentive Plan at an exercise price of $1.50 (the closing price on the date of grant). These options vest equally on an annual basis over three years. Mr. Bohunicky was also included as one of the designated participants in the Executive LTPB Program and as such he received 12,800 shares as an immediate retention award under our Stock Incentive Plan which vested immediately. We also reimbursed Mr. Bohunicky for $15,000 of expenses associated with his contemplated relocation to the location of our primary corporate headquarters. Such reimbursements are not reflected in the above table.

(7) Dr. Hillman retired from full time service to us, effective October 31, 2011. Included in Stock Awards, is $40,227 in compensation associated with the issuance to Dr. Hillman of 120,000 shares of restricted common stock relating to Dr. Hillman's continued assistance with the writing and filing of certain patent applications and the documentation of certain production process. Included in All Other Compensation for 2011, is $24,356 of accrued but unused vacation pay.

(8) The amounts in this column represent the aggregate grant date fair value computed in accordance with Financial Accounting Standards Board Accounting Standards Codification, Topic 718, Compensation—Stock Compensation (ASC 718). Under SEC rules relating to executive compensation disclosure, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Fair values relating to share grants have been determined under ASC 718 and were calculated using the common stock closing price on the date of grant and multiplying that price by the number of shares subject to the share grant. The equity-based compensation expense relating to the stock grants is recognized over the requisite service period of the grant. For option awards, we utilize the Black-Scholes option pricing model to determine the fair value on the date of the grant multiplied by the number of options subject to the option grants in accordance with ASC 718. The stock-based compensation expense relating to the stock option grants is recognized over the requisite service period of the grant and the amounts included in the Option Awards column do not reflect compensation actually received by the named executive officers. For information on the assumptions used to calculate the fair value of stock option grants, refer to Footnote 1, "Organization and Significant Accounting Policies" in our financial statements for the year ended December 31, 2011.

(9) Our Simple IRA retirement plan requires us to match employee contributions up to the first 3% of compensation earned and amounts presented also include our matching contribution and the amounts in this column represent such contributions. This column excludes certain payments for personal benefits for Mr. Hirsch and Dr. Hillman that did not exceed $10,000 individually or in the aggregate.

Incentive Awards

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

During the year ending December 31, 2011, we granted options and restricted stock awards to our named executive officers. A description of these awards is set forth in the footnotes to the Summary Compensation Table above. These awards were made pursuant to individual award agreements substantially similar to the form of stock option agreement attached as an exhibit to our Stock Incentive Plan which has been previously filed with the SEC, or in the case of restricted stock, pursuant to a restricted stock award agreement. In connection with the awards contemplated pursuant to the Executive LTPB Program, the performance awards criteria are set forth in separate award agreements with each designated participant, a form of which has also been previously filed with the SEC.

Outstanding Equity Awards at Fiscal Year End

The following table provides information concerning unexercised options, stock that has not vested, and equity incentive plan awards outstanding as of December 31, 2011:

	Option Awards					Stock Awards	
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive Plan awards: number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date	Number of Shares or Units of Stock That Have Not Vested	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights that Have Not Vested
Dr. John N. Bonfiglio	78,625			4.76	5/24/2021		
Principal Executive		47,175(1)		4.76	5/24/2021		
Officer		39,200(1)		1.50	9/27/2021		
Dr. Martin Handfield	15,000			10.40	9/18/2018		
Vice President of	8,333(1)	4,167(1))		5.40	12/1/2019		
Research and		4,275(2)		5.40	12/1/2019		
Development	2,500			5.40	12/12/2019		
		16,800(1)		1.50	9/27/2021		
Dr. Robert Zahradnik	6,667(1)	3,333(1)		5.40	12/12/2019		
Vice President of		3,375(2)		5.40	12/12/2019		
Operations		13,200(1)		1.50	9/27/2021		
Former Officers:							
David Hirsch(3)	—	—	—	—	—		
Chief Executive Officer							
Dr. Jeffrey D. Hillman(4)	35,000		—	17.00	10/31/2012		
Chief Scientific Officer	45,000			5.40	10/31/2012		
						120,000	
Brian J. Bohunicky(5)	16,667	8,333(1)		5.40	12/12/2019		
Chief Financial Officer		20,000(1)		3.60	3/11/2021		
		28,000(1)		1.50	9/27/2021		
							5,000

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

(2) Represents awards that vest upon the first calendar quarter in which we report a net profit in a Form 10-Q Report or a Form 10-K Report. These awards expire on the earlier of (i) December 1, 2019 or (ii) such date we cease to be required to file quarterly or annual reports with the Securities and Exchange Commission.

(3) All outstanding option awards made to our former Chief Executive Officer David Hirsch, were forfeited due to the lack of exercise following Mr. Hirsch's resignation from the Company.

(4) Options awarded to our founder and former Chief Scientific Officer were amended in connection with his retirement from the Company to accelerate the vesting of all unvested outstanding options and to extend the exercise date to one year following the effective date of his retirement of October 31, 2011. In addition, Dr. Hillman received an award of 120,000 shares of restricted common stock which is subject to performance conditions and time vesting. The performance based vesting relates to the completion of certain work-in-progress concerning Company intellectual property and the time vesting is equal over a three year period with the restricted shares being subject to earlier vesting upon a change of control.

(5) Our former Chief Financial Officer Mr. Bohunicky received 10,000 shares of restricted stock half of which vested within six months and the remaining 5,000 shares reflected in the table were forfeited due to his resignation prior to the vesting of the remaining 5,000 shares.

Employment Contracts and Change in Control Arrangements

Dr. John Bonfiglio, President and Chief Executive Officer— Executive Employment Agreement.

On May 23, 2011, we entered into an Executive Employment Agreement with Dr. Bonfiglio. Under the terms of Dr. Bonfiglio's Executive Employment Agreement, Dr. Bonfiglio's employment with us became effective May 25, 2011 and he receives an annual base salary of not less than $280,000 and will be eligible for bonuses of up to 50% of his annual salary based on appropriate Company based, and individual based, targets determined in the discretion of the Compensation Committee as approved by the full Board of Directors.

Dr. Bonfiglio will be eligible to participate in the medical insurance and other benefits available to all employees except his annual vacation will be set at four (4) weeks. In connection with Dr. Bonfiglio's employment we agreed to pay for two weeks of hotel and rental car expenses for Dr. Bonfiglio's initial two weeks of employment with us as well as reimburse Dr. Bonfiglio of up to $30,000 in expenses associated with his relocation and temporary living expenses.

In connection with Dr. Bonfiglio's commencement of employment, he was awarded stock options to acquire 125,800 shares of common stock under our Stock Incentive Plan, at an exercise price of $4.76, which was the closing price on the grant date, May 25, 2011. Of the options granted 78,625 vest immediately and are exerciseable over ten (10) years. The remaining 47,175 options vest at an even amount over the next three years on the anniversary date of grant. Dr. Bonfiglio is also eligible for additional equity awards based upon the Executive LTPB Program we developed, which contains awards that are tied to the achievement of Company objectives.

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

If Dr. Bonfiglio dies during the term of his employment, the estate of Dr. Bonfiglio shall be paid his salary as it would have accrued over a period of thirty days after Dr. Bonfiglio's death. We shall also extend his right to exercise vested stock options for six months provided such extension is permitted under the Stock Incentive Plan. In the event Dr. Bonfiglio becomes disabled (as defined in the then applicable short and long-term disability insurance policies) we shall pay to Dr. Bonfiglio his salary as it would have accrued over a period of 30 days after he became so disabled and we shall extend his right to exercise vested stock options for six months provided such extension is permitted under the Stock Incentive Plan.

The Executive Employment Agreement also includes non-disclosure and Company ownership of development provisions, as well as a provision providing for us to defend and indemnify Dr. Bonfiglio if he is named as a defendant in any lawsuit regarding any action taken within the scope of employment.

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

Family Limited Partnership, including its members and their immediate families, including spouses and their children; provided, such sale would qualify as a "change in ownership" "change in effective control" or "change in the ownership of substantially all of the assets" of the Company as these terms are defined in Treasury Regulation Section 1.409A-3(i)(5).

Chief Executive Bonus Plan

On August 29, 2011, our Board of Directors adopted an executive bonus plan for 2011 for our President and Chief Executive Officer, Dr. John Bonfiglio. The executive bonus plan was an incentive program designed to motivate our CEO to achieve our financial and other performance objectives and to reward the CEO if, and when, those objectives were met. Dr. Bonfiglio's employment agreement with the Company required the adoption of a bonus plan and provides for a target bonus of up to 50% of his annual base salary ("Bonus Target"). The bonus payable to Dr. Bonfiglio would be based on the achievement of the following:

(i) up to 40% of the targeted bonus for Company performance objectives related to the Company's revenue and non-GAAP operating profit as compared to the Company's operating plan between July and December 2011;

(ii) up to 25% of the targeted bonus for Company performance objectives related to raising capital;

(iii) up to 15% of the targeted bonus for individual performance objectives concerning the development of long and short term strategic plans approved by the Board; and

(iv) up to 20% of the targeted bonus for meeting specified science objectives tied to licensing, validation testing, and study enrollment.

Based upon the assessment of the above factors the Compensation Committee determined to award Dr. Bonfiglio a bonus of $16,333 for 2011. Achievement of each factor would be measured independently, and a minimum threshold for each factor must be met for any credit to be given to that factor. The Board set a minimum threshold, target objective for annual revenue and non-GAAP operating profit. Accordingly, the bonuses earned could range from zero to 100% of Dr. Bonfiglio's Bonus Target and would vary depending on the extent to which actual performance meets, exceeds or falls short of the goals approved by the Board.

Employment Agreements—Mr. Sullivan and Dr. Handfield

We have entered into employment agreements with our key employees, including Mr. Michael Sullivan and Dr. Martin Handfield (the "Employment Agreements"). The annual base salaries provided in the Employment Agreements are $180,000 and $171,000 for Mr. Sullivan and Dr. Handfield, respectively, and are payable in installments consistent with our normal payroll practices. Mr. Sullivan and Dr. Handfield are also eligible under the Employment Agreements to receive annual bonuses during the term at the discretion of the Compensation Committee and the Board of Directors with Mr. Sullivan's employment agreement providing for such a discretionary bonus of up to 25% of his base salary.

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

If the executive officer or key employee dies during the term of employment with us, the estate of the employee shall be paid the salary of the employee as it would have accrued over a period of thirty days after the executive officer's death. We shall also extend the executive officer or key employee's right to exercise vested stock options for six months provided such extension is permitted under the Stock Incentive Plan. In the event the executive officer or key employee becomes disabled (as defined in the then applicable short and long-term disability insurance policies) we shall pay to the executive officer or key

employee his salary as it would have accrued over a period of 30 days after the executive or key employee became so disabled and we shall extend the executive officer or key employee's right to exercise vested stock options for six months provided such extension is permitted under the Stock Incentive Plan.

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

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

Employment Relationship—Dr. Zahradnik

We do not have an employment agreement with Dr. Zahradnik. His employment with the Company is at will and he receives benefits generally available to our employees.

Our founder and former Chief Scientific Officer, Dr. Jeffrey Hillman

In connection with Dr. Hillman's retirement effective October 31, 2011, our employment agreement with Dr. Hillman was terminated. We entered into a separation agreement with Dr. Hillman. Pursuant to the terms of the separation agreement Dr. Hillman received an award of 120,000 restricted shares of the Company's common stock subject to performance conditions as well as time based vesting. The performance based vesting relates to the completion of certain work-in-progress concerning the Company's intellectual property and the time vesting is equal over a three year period with the restricted shares being subject to earlier vesting upon a change of control. The separation agreement also provides for the amendment of Dr. Hillman's outstanding stock option agreements to (a) vest any unvested options and (b) extend the exercise period of such options for one year post separation of employment until October 31, 2012.

Our former Chief Executive Officer and President, David Hirsh

On February 4, 2011 Mr. Hirsch resigned from the Company and we entered into a separation and release agreement with Mr. Hirsch that provided for the payment of six months' severance and his employment agreement with us was terminated.

Our former Chief Financial Officer, Secretary and Treasurer, Brian Bohunicky

On January 27, 2012 Mr. Bohunicky resigned as Chief Financial Officer, Secretary and Treasurer of the Company and we entered into a separation and release agreement with Mr. Bohunicky that provided for the payment of six months severance and his employment agreement with us was terminated.

Executive Long-Term Performance Based Incentive Program

On November 14, 2011, the Compensation Committee of our Board of Directors as well as our Board of Directors approved a long-term performance-based incentive program (the "Executive LTPB Program") to be administered under the Company's Stock Incentive Plan. The Executive LTPB Program is an incentive program designed to motivate the participants, including the Company's CEO to achieve the Company's financial and other performance objectives and to reward them if, and when, those objectives are met. The Company believed it was in the best interest of the Company to: (i) develop a culture of achievement and performance; (ii) align the incentive structure to the long term goals of the Company; (iii) promote retention; (iv) promote achievement of targeted results; (v) use equity proactively and as an appropriate incentive; and (vi) employ variable compensation based upon performance goals.

Executive Officer Participants-Long Term Incentive Plan. The Company's President and Chief Executive Officer, Dr. John Bonfiglio's, employment agreement with the Company required the adoption of an equity based plan tied to certain performance goals. The Executive LTPB Program is intended by the Company to meet the employment agreement requirement. Accordingly, Dr. Bonfiglio, is a designated participant in the Executive LTPB Program, as well as certain other designated executive officers and employees.

General Terms. The Executive LTPB Program provides for the award of shares of common stock as a bonus to designated executive officers and employees of the Company. The shares will be issued to participants during the term of the Executive LTPB Program, subject to the satisfaction of applicable performance goals (as described below). Participants are eligible to receive a bonus payable in shares of common stock if they continue to be employed by the Company through the first to occur of either of the following: (i) the Company's achievement, on or before December 31, 2013 (the "Termination Date"), of the various "Performance Goals" set forth below, or (ii) the effective date of a "Change in Control" of the Company that occurs at any time following the date of this Agreement and on or before the Termination Date.

Retention Award. The Executive LTPB Program included an immediate retention award to be made to the designated participants, which was payable in shares of common stock of the Company, as a retention award (a "Retention Award"). The Retention Award was determined by multiplying (i) the approved award percentage for the Retention Award by (2) the total number of outstanding shares of Common Stock, determined on a non-fully diluted basis. Total retention awards issued by the Company were 93,600 shares.

Performance and Vesting. The performance periods for the Executive LTPB Program run from January 1, 2012 through December 31, 2013. Future Awards will be credited to participants, up to target levels, to the extent that the performance goals are satisfied, as determined by the Compensation Committee. Upon the occurrence of a "Performance Vesting Date" with respect to a "Performance Goal," a participant will be entitled to receive a number of shares of Common Stock determined by multiplying (1) the award percentage (each, an "Award Percentage") corresponding to that particular Performance Goal as set forth in their award agreement by (2) the total number of outstanding shares of Common Stock, determined on a non-fully diluted basis, as of that particular applicable Performance Vesting Date. For purposes of an award, the "Performance Vesting Date" with respect to a Performance Goal shall be the day on which the Compensation Committee of the Company's Board of Directors certifies and determines, in its reasonable discretion, that the applicable Performance Goal has been achieved. Participants are required to remain employees of the Company through the date on which the Compensation Committee makes a final determination under the Executive LTPB Program with respect to the satisfaction of the performance goals during the performance period.

Performance Goals. The Executive LTPB Program provides for awards upon the Company achieving any of the following performance goals: (i) achievement of Company fiscal year sales equal or greater than $10,000,000; (ii) achievement of Company fiscal year sales equal or greater than $20,000,000; (iii) achievement by the Company of cash flow positive in any fiscal quarter; (iv) achievement by the Company of earnings per share in any fiscal year equal or greater than $0.02 per share of Company stock; (v) Achievement of price per share of Company stock equal to $10.00; (vi) Achievement of price per share of Company stock equal to $20.00; (vii) licensing of any science technology which results in upfront cash receipt of $2,000,000; or (viii) capital raise by the Company of $5,000,000 in both fiscal years or a $10,000,000 in a single raise.

Change of Control. In the event a Change in Control of the Company occurs, a participant will be entitled to receive the full amount of the shares with respect to any Performance Goal as to which the related Performance Vesting Date did not occur prior to the date of the Change in Control as though the Performance Goal had been fully achieved as of the time of the Change in Control except with respect to the Share Appreciation Goals which will depend on the price per share of any change in control transaction. The term "Change in Control" for purposes of an award shall mean: a "Corporate Transaction" as defined in the Company's Stock Incentive Plan.

Award Agreement and Participants. An award agreement will be delivered to each participant under the Executive LTPB Program, which shall set forth the percentage award of shares to be awarded to the participant upon achievement of the Performance Goals and the terms thereof. New participants may be added to the Executive LTPB Program following the beginning of the performance period. A copy of the form of long term incentive plan award agreement for employee participants approved by the Committee and Board has been previously filed with the SEC and is referenced as an exhibit to this Form 10-K.

The share based awards payable to our executive officer and designated participants will be based on the achievement of the performance goals listed above and tied to certain pre-determined and approved percentages. The specific percentages for Dr. Bonfiglio's awards upon achievement of the specific Performance Goals as well as those of Dr. Handfield and Dr. Zahradnik are as follows:

Executive	$10M Sales	$20M Sales	Positive CF	EPS Goal	$10 Share Appreciation	$20 Share Appreciation	License Technology	Company Capital Raise
Dr. John Bonfiglio	0.50%	0.40%	0.50%	0.70%	0.50%	0.30%	0.40%	0.70%
Dr. Martin Handfield	0.17%	0.13%	0.17%	0.23%	0.17%	0.10%	0.13%	0.23%
Dr. Robert Zahradnik	0.17%	0.13%	0.17%	0.23%	0.17%	0.10%	0.13%	0.23%

Under the Executive LTPB Program, and pursuant thereto on November 14, 2011, Dr. Bonfiglio, Dr. Handfield and Dr. Zahradnik were immediately awarded the Retention Awards in share amounts of 29,000 9,900 and 9,900 shares, respectively under the Stock Incentive Plan. The closing price of the Company's common stock on November 14, 2011, the date of the awards, was $1.50.

Assuming a Change of Control event during the Executive LTPB Program period, and based upon the current level of the Company's outstanding shares of common stock, Dr. Bonfiglio, Dr. Handfield and Dr. Zahradnik would be entitled to receive an aggregate of 486,831, 161,872 and 161,872 shares respectively, (assuming that all performance awards would be included as vested upon a change in control).

Our Chief Financial Officer, Mr. Sullivan is not currently designated as a participant in the Executive LTPB Program.

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

The following table sets forth, as of March 31, 2012, certain information concerning the beneficial ownership of each class of our voting securities by: (i) each person known by us to own beneficially 5% or more of the outstanding shares of our common stock, (ii) each of our Directors and named executive officers, and (iii) all executive officers and Directors as a group.

The number of shares beneficially owned by each 5% shareholder, Director or named executive officer is determined under rules of the SEC and the information is not necessarily indicative of beneficial ownership for any other purpose. Under those rules, beneficial ownership includes any shares to which the individual has sole or shared voting power or investment power and also any shares that the individual has the right to acquire within 60 days after March 31, 2012 through the exercise of any stock option, warrant or other right, or conversion of any security. Unless otherwise indicated, each person has sole investment and voting power (or shares such power with his or her spouse) with respect to the shares set forth in the following table. The inclusion in the table below of any shares deemed beneficially owned does not constitute an admission of beneficial ownership of those shares.

Name and address(1)	Number of shares beneficially owned	Percentage of ownership(2)
5% shareholders		
Koski Family Limited Partnership(3)	11,686,3428	81.5%
George T. Hawes(4)	667,285	5.4%
Directors and officers		
Dr. John Bonfiglio (5)	124,600	1.0%
Christine L. Koski(3)(6)	10,697,610	74.6%
Robert C. Koski(3)(7)	10,755,610	75.0%
Charles L. Pope(8)	61,400	*
Dr. Alan Dunton(8)	61,400	*
Dr. Frederick W. Telling(8)(9)	71,400	*
Michael Sullivan (10)	15,000	*
All Directors and officers as a group 7 persons) (11)	11,540,476	78.6%

* less than one percent

(1) Except as indicated, the address of the person named in the table is c/o Oragenics, Inc., 3000 Bayport Drive, Suite 685, Tampa, Florida 33607.

(2) For each person and group included in this table, percentage ownership is calculated by dividing the number of shares beneficially owned by such person or group by the sum of 12,170,795 shares of common stock outstanding as of March 31, 2012, plus the number of shares of common stock that such person has the right to acquire within 60 days.

(3) Based upon information provided by the Koski Family Limited Partnership, or KFLP, in the amendment to its Schedule 13D filing with the SEC on April 5, 2012, includes (i) 8,075,619 shares held directly by the KFLP and 2,170,925 shares able to be acquired based upon outstanding warrants, and (ii) 451,066 shares held by KFLP partner Christine Koski, 11,400 shares held by KFLP partner Robert Koski, 10,000 shares held by KFLP partner Koski Management, Inc. (solely owned by Beverly Koski), 469,666 shares held by KFLP partner, Thomas Koski, and 497,666 shares held in trusts which Robert Koski serves as sole trustee (See Note 7 below). Christine L. Koski, Robert C. Koski, Thomas L. Koski and Beverly Koski (as sole owner of Koski Management, Inc.) share voting and investment powers as general partners of the KFLP. The address for the KFLP is 3525 Turtle Creek Boulevard, Unit 19-B, Dallas, Texas 75219.

(4) Based solely upon information provided by Mr. Hawes in his Form 5, Form 4s and Schedule 13D filings with the SEC. The number of shares includes 539,397 shares owned directly, (as reflected on Form 4 filed October 13, 2010) and 127,888 shares issuable pursuant to currently exercisable warrants, and excludes 5,000 shares of common stock and warrants to purchase 5,250 shares of common stock owned by Mr. Hawes' wife for which he disclaimed beneficial ownership. Mr. Hawes' address as reflected in Schedule 13D/A is 390 Plandome Road, Suite 222, Manhasset, New York 11030.

(5) Includes 30,250 shares held directly and 94,350 shares able to be acquired pursuant to outstanding stock option awards.

(6) In addition to the 8,075,619 shares reflected as being directly owned by the KFLP and the 2,170,925 shares able to be acquired pursuant to warrants, described in Note 3, the share amounts include 451,066 shares owned directly by Ms. Koski (which includes 6,400 shares of our common stock issued to Ms. Koski as a Director).

(7) In addition to the 8,075,619 shares reflected as directly owned by the KFLP and the 2,170,925 shares able to be acquired pursuant to warrants, described in Note 3, the share amounts include: (i) 11,400 shares owned directly by Mr. Koski (which includes 6,400 shares of our common stock issued to Mr. Koski as a Director) and (ii) 497,666 shares owned by trusts for which Mr. Koski serves as sole trustee as follows: the Robert Clayton Koski Trust for the benefit of Anthony James Hunter (100,000 shares); The Robert Clayton Koski Trust for the benefit of Hunter Buchanan Koski (100,000 shares); The Robert Clayton Koski Trust for the benefit of Clayton Ward Bennett (100,000 shares); and The Robert Clayton Koski Trust for the benefit of Robert Edward Koski (100,000 shares) and the Robert Clayton Koski Trust for the benefit of Elyse Margaux Koski (97,666 shares).

(8) Includes (i) 5,000 option shares able to be acquired upon the exercise of currently exercisable stock options granted pursuant to our Director compensation program upon initially becoming Directors, (ii) 50,000 option shares granted to each of our independent, non-employee directors serving on our audit committee and (iii) 6,400 shares awarded pursuant to a change in the director compensation program to provide long term incentives which includes an immediate retention award component.

(9) Includes 10,000 shares owned directly by Dr. Telling.

(10) Represents currently excerciseable stock options and excludes 30,000 shares pursuant to stock options not currently exerciseable.

(11) Excludes 10,000 shares owned directly by Koski Management, Inc. (solely owned by Beverly Koski) and 469,666 shares owned directly by Thomas Koski, neither of which are directors or employees of the Company, but both of which are general partners of the KFLP. If such shares are included the beneficial ownership percentage of the group would be 81.5%.

Equity Compensation Plan Information

We maintain an equity-based compensation plan—the Amended and Restated 2002 Stock Option and Incentive Plan (as amended, the "Stock Incentive Plan"). A description of our equity based compensation plan can be found in Note 10 of the Notes to Financial Statements. The Stock Incentive Plan has been approved by our shareholders. The following table sets forth the number of shares of our common stock subject to outstanding options and rights under the Stock Incentive Plan, the weighted-average exercise price of outstanding options, and the number of shares remaining available for future award grants under the Stock Incentive Plan as of December 31, 2011 (in thousands, except exercise price):

As a result of the recent KFLP Financing Transaction and the share issuance resulting from the KFLP Financing Transaction, if there is a change of control at the Company as contemplated by the Long-Term Performance Based Incentive Program the Company would not have sufficient shares under its Stock Incentive Plan to meet the share issuances contemplated thereby. Accordingly, the Company would need to seek an amendment to its Stock Incentive Plan to add additional shares.

	Equity Compensation Plan Information		
	(a)	(b)	(c)
Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	725,173	$ 4.85	273,228
Equity compensation plans not approved by security holders[1]	—	—	—
Total	725,173	$ 4.85	273,228

(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 306,388 shares of common stock outstanding at a weighted average exercise price of $19.14 per share, 288,888 of which were issued in connection with a private placement in June 2008 and warrants to acquire 2,170,925 shares of common stock to the KFLP in connection with our Debt Exchange Agreement and Loan Agreement consummated on March 23, 2012, at an exercise price of $2.00 per share.

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

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

Financing Transactions

December 2009 Private Placement

On December 30, 2009, we issued a total of 500,813 shares of restricted common stock in the initial closing of a private placement to accredited investors including the Koski Family Limited Partnership, or KFLP, our largest shareholder (the "December 2009 Private Placement"), for initial proceeds of $2,504,062. The shares were sold at $5.00 per share. The initial closing proceeds of $2,504,062 included the cancellation at closing of $54,062 in outstanding obligations we owed to Dr. Jeffrey Hillman, our former director and Chief Scientific Officer, for compensation that had been deferred. Approximately half of the total investment, or $1,250,000, was made by the KFLP. In conjunction with, and as a condition to the initial closing of the December 2009 Private Placement, we also issued 200,000 shares of our common stock to the KFLP at $5.00 per share, which was the same price per share paid by the participating accredited investors, in exchange for the cancellation of the KFLP's $1,000,000 secured promissory note we previously issued to the KFLP in connection with a June 2009 private placement in which the KFLP initially acquired control of the Company (the "June 2009 Private Placement").

Approximately $1,000,000 of the total proceeds from the December 2009 Private Placement were committed to further our development of the DPOLT synthetic chemistry platform, essential to the production of our lead antibiotic, MU1140, subject to the goals set forth by the two-year NSF SBIR Phase II grant that we received on February 15, 2008. Such allocation enabled us to be eligible to receive up to an additional $500,000 matching grant from the NSF, which grant was subsequently awarded in June 2010.

Contemporaneously with the initial closing of the December 2009 Private Placement, the KFLP also elected to exercise warrants it received as part of the June 2009 Private Placement to purchase 50,000 shares of our common stock. The warrants were exercised through the payment by the KFLP of the warrant exercise price of $2.00 per share. Additionally, Christine Koski and Robert Koski, as directors, each exercised previously issued options to purchase 5,000 shares of our common stock at the option exercise price of $2.00 per share. These options were granted to Christine Koski and Robert Koski when they became non-employee directors on June 30, 2009 in connection with our non-employee director compensation program.

On January 13, 2010, we completed the $3,004,062 private placement contemplated by the December 2009 Private Placement and issued another 100,000 shares of common stock at a price per share of $5.00 to the accredited investors for $500,000. Of this amount, the KFLP again participated in half of the remainder of the aggregate investment by acquiring 50,000 shares for $250,000.

May 2010 Note Financing

On May 28, 2010, we entered into an unsecured promissory note with a conversion provision (the "May 2010 Note") to the KFLP pursuant to which we borrowed $1,000,000 from the KFLP. Interest on the May 2010 Note accrued at the rate of LIBOR plus 6.0% and the principal of the May 2010 Note, together with all accrued interest thereon, was due and payable the earlier of: (i) the closing date of a registered public offering of newly issued equity securities by us resulting in cash proceeds to us, other than in connection with employee option plans, or (ii) the May 24, 2011 maturity date; provided, however, that in the event we completed a subsequent private offering of equity securities prior to the May 24, 2011 maturity date, we could elect to convert the principal of the May 2010 Note into the same equity securities being sold in the private offering at the same price and terms to the KFLP.

July 2010 Financing Transaction and Credit Facility

On July 5, 2010, we entered into a common stock purchase agreement (the "July 2010 Financing Transaction") with the Koski Family Limited Partnership, or KFLP. At the closing of this financing transaction on July 30, 2010 we issued 250,000 shares of our common stock to the KFLP at a price of $8.00 per share. The $2,000,000 aggregate consideration paid by the KFLP consisted of (i) $1,000,000 cash and (ii) the exchange and cancellation of the outstanding May 2010 Note issued to the KFLP

on May 28, 2010. Accrued interest on the May 2010 Note through closing was waived by the KFLP. Concurrent with the July 2010 Financing Transaction and as part thereof, we entered into an unsecured revolving credit agreement (the "Credit Facility") with the KFLP. Pursuant to the Credit Facility, we are able to borrow up to $2,000,000 from the KFLP at LIBOR plus 6.0%. The term of the Credit Facility was initially for 12 months commencing August 1, 2010.

On each of September 13, 2010 and November 8, 2010, we borrowed $1,000,000 under the Credit Facility and executed a revolving unsecured promissory note for such amounts initially to mature on July 30, 2011.

On January 24, 2011, we entered into a First Amendment to the Credit Facility (the "First Amendment") to increase the available borrowing from $2,000,000 to $2,500,000 and simultaneously therewith we drew on the Credit Facility as amended by the First Amendment to borrow the additional $500,000 in available funds and executed another revolving unsecured promissory note initially due on July 30, 2011.

On February 4, 2011, we entered into a Second Amendment (the "Second Amendment") to the Credit Facility. As a result of the Second Amendment, we are able to borrow up to an additional $2,500,000 from the KFLP. Future draws under the Credit Facility, as amended, are limited to $500,000 per month commencing no earlier than March 2011. Under the Second Amendment, the due date of the amounts then outstanding under the Credit Facility, (the September 2010 Promissory Note, November 2010 Promissory Note and January 2011 Promissory Note) were extended by one year from July 30, 2011 to July 30, 2012. The interest rate remained at LIBOR plus 6.0%. The Second Amendment further provided for the automatic conversion of any amounts borrowed and outstanding under the Credit Facility into securities that we may issue in subsequent securities offerings. Any automatic conversion of amounts outstanding under the Credit Facility would be on the same terms of any such offering. In addition, the Second Amendment provides the KFLP with the right to put any undrawn available amounts under the Credit Facility, as amended, to us and thereby have a note issued to the KFLP.

On each of March 15, 2011, April 5, 2011, May 5, 2011, June 3, 2011, and July 8, 2011 we borrowed an additional $500,000 under the Credit Facility, as amended, and executed a revolving unsecured promissory note in such amounts that matures on July 30, 2012.

On June 29, 2011, we entered into a Third Amendment (the "Third Amendment") to the Credit Facility. As a result of the Third Amendment, we increased our availability under the Credit Facility by $2,000,000 from $5,000,000 to $7,000,000. Future draws of the $2,000,000 in increased availability provided by the Third Amendment to the Credit Facility are limited to $1,000,000 increments beginning no earlier than August 2011 and October 2011, respectively. All other terms of the Credit Facility remained the same.

On each of August 1, 2011 and October 5, 2011, the Company borrowed an additional $1,000,000 under the Credit Facility, as amended, and executed a revolving unsecured promissory note in such amounts that matures on July 30, 2012.

On December 9, 2011, we entered into a Fourth Amendment (the "Fourth Amendment") to the Credit Facility. The Fourth Amendment increased the available borrowing under the Credit Facility by $500,000 from $7,000,000 to $7,500,000. On December 9, 2011, the Company drew down on the Credit Facility as amended to borrow $500,000 in the newly available funds. All other terms of the Credit Facility remained the same.

On January 23, 2012, we entered into a Fifth Amendment (the "Fifth Amendment") to the Credit Facility. The Fifth Amendment increased the available borrowing under the Credit Facility by $750,000 from $7,500,000 to $8,250,000. On January 23, 2012, we drew down on the Credit Facility, as amended, to borrow $750,000. All other terms of the Credit Facility remained the same.

Conversion of Credit Facility Indebtedness and new Loan Agreement

On March 23, 2012, we entered into an Exchange of Notes for Equity Agreement (the "Debt Exchange Agreement") with the KFLP. Pursuant to the terms of the Debt Exchange Agreement, we issued 6,285,619 shares of common stock and warrants to acquire 1,571,405 shares of common stock to the KFLP in exchange for the cancellation of an aggregate of $8,737,011 of indebtedness owed to the KFLP under our existing unsecured revolving Credit Facility with the KFLP. The outstanding indebtedness, consisted of $8,250,000 in principal owed on twelve separate promissory notes previously issued by us to the KFLP under the Credit Facility and accrued interest through March 23, 2012 (the closing date) of $487,011. The Credit Facility was terminated and the previously issued promissory notes thereunder were cancelled. The warrants are exercisable immediately at a price per share of $2.00 and expire three (3) years from the date of issuance.

On March 23, 2012, we also entered into a new loan agreement (the "Loan Agreement") with the KFLP. It provides us with up to $2.5 million in secured funding in two advances of $1,250,000 each with the first advance occurring on March 23, 2012 and the second advance able to be made within 30 days thereafter, subject to the continued accuracy of representations and warranties made by the Company and that no material adverse events have occurred in connection with our business. Borrowings under the Loan Agreement mature in three years and bear interest at the rate of 5.0% and are secured by our select assets of relating to or connected with the ProBiora3, SMaRT Replacement Therapy, MU1140 and LPT3-04 technologies. The loan amount is subject to automatic conversion upon a subsequent qualified equity financing by us of $5,000,000 (excluding any converted debt amount). Pursuant to the Loan Agreement we also issued a warrant to the KFLP to acquire 599,520 shares of our common stock. The warrants are exercisable immediately at a price per share of $2.00 and expire three (3) years from the date of issuance.

Since our directors Christine L. Koski and Robert C. Koski, share voting and investment powers with two other family members as general partners of the KFLP, the Debt Exchange Agreement and the Loan Agreement were approved by the Company's disinterested directors.

Relationships

During the years ended December 31, 2011 and 2010, we paid $270,702 and $226,760, respectively, (which included approximately $96,909 and $162,501, respectively, in costs reimbursements associated with maintaining our intellectual property) to a law firm that employs the daughter-in-law of our former director and Chief Scientific Officer, Dr. Jeffrey Hillman, as a lawyer and from which firm we received intellectual property related legal services.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

Audit and Other Fees

The following table presents fees incurred for professional audit services rendered by our independent registered public accounting firm, Mayer Hoffman McCann P.C. for the audits of our financial statements for the years ended December 31, 2011 and December 31, 2010, and quarterly reports on Form 10Q for 2011 and 2010 and fees for other services rendered by other accounting firms whom assisted on special projects during those periods.

Type of Fees	2011	2010
Audit Fees (1)	$125,000	$110,000
Audit-Related Fees (2)	0	89,721
Tax Fees (3)	7,105	3,500
All Other Fees (4)	62,025	36,180
Total	$194,130	$239,401

(1) *Audit Fees*: These fees consist of aggregate fees billed or to be billed by Mayer Hoffman McCann P.C. for professional services rendered in connection with their audits of the Company's 2011 and 2010 annual reports on Form 10-K and the review of the financial statements included in the 2011 and 2010 Company's Quarterly Reports on Form 10-Q.

(2) *Audit-Related Fees*: There were fees billed by Mayer Hoffman McCann P.C. and RSM McGladrey, Inc., for assurance and related services that are reasonably related to the performance of the audit or review of the Company's financial statements, registration statements and grant applications that are not reported above under the caption "Audit Fees."

(3) *Tax Fees*: There were fees billed by CBIZ Kirkland, Russ, Murphy & Tapp for professional services for tax compliance and tax advice.

(4) *All Other Fees*: There were fees billed by Taylor White Consulting firm in connection with the professional services associated with the Company's compliance with the Sarbanes-Oxley Act of 2002 filings for small businesses and the valuation of the Company's stock option awards in accordance with FASB Accounting Standards Codification.

Pre-Approval Policies and Procedures

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

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

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

1. The financial statements and accompanying report of independent registered public accounting firm are set forth immediately following the signature page of this report on pages F-1 through F-23.
2. All financial statement schedules are omitted because they are inapplicable, not required or the information is included elsewhere in the financial statements or the notes thereto.
3. The exhibits required to be filed by this report or able to be incorporated by reference are listed in the “Exhibit Index” following the financial statements.

(b) Other Exhibits

Exhibits required by Item 601 of Regulation S-K are submitted (or incorporated by reference) and listed in a separate section herein immediately following the “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: April 16, 2012

ORAGENICS, INC.

By: /s/ John N. Bonfiglio
John N. Bonfiglio, Chief Executive Officer,
and Principal Executive Officer

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ John N. Bonfiglio John N. Bonfiglio	Principal Executive Officer, Chief Executive Officer and Director	April 16, 2012
/s/ Michael Sullivan Michael Sullivan	Principal Financial Officer, Chief Financial Officer (Principal Accounting Officer)	April 16, 2012
/s/ Christine L. Koski Christine L. Koski	Director	April 16, 2012
/s/ Robert C. Koski Robert C. Koski	Director	April 16, 2012
/s/ Frederick W. Telling Frederick W. Telling	Chairman and Director	April 16, 2012
/s/ Charles L. Pope Charles L. Pope	Director	April 16, 2012
/s/ Alan W. Dunton Alan W. Dunton	Director	April 16, 2012

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Financial Statements

Oragenics, Inc.

Financial Statements

Years ended December 31, 2011 and 2010

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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, 2011 and 2010 and the related statements of operations, changes in shareholders' equity (deficit), 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, 2011 and 2010, 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.

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

April 13, 2012

/s/ Mayer Hoffman McCann P.C.

Certified Public Accountants

Clearwater, Florida

Oragenics, Inc.
Balance Sheets
December 31, 2011 and 2010

	2011	2010
Assets		
Current assets:		
Cash and cash equivalents	$ 171,739	132,103
Restricted cash	264,960	475,657
Accounts receivables, net	92,644	122,972
Income tax receivable	—	362,218
Inventory, net	475,592	266,628
Prepaid expenses and other current assets	113,331	139,883
Total current assets	1,118,266	1,499,461
Property and equipment, net	148,686	228,202
Total assets	$ 1,266,952	1,727,663
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,740,216	1,514,885
Short term notes payable	53,092	98,906
Deferred revenue	152,962	13,188
Convertible revolving note payable to shareholder	7,500,000	—
Total current liabilities	9,446,270	1,626,979
Revolving note payable to shareholder	—	2,000,000
Total liabilities	9,446,270	3,626,979
Shareholders' equity (deficit):		
Preferred stock, no par value; 20,000,000 shares authorized; none issued and outstanding	—	—
Common stock, $0.001 par value; 50,000,000 shares and 15,000,000 shares authorized at December 31, 2011 and 2010, respectively; 5,894,176 and 5,663,076 shares issued and outstanding at December 31, 2011 and December 31, 2010, respectively.	5,894	5,663
Additional paid-in capital	32,810,704	31,412,069
Accumulated deficit	(40,995,916)	(33,317,048)
Total shareholders' equity (deficit)	(8,179,318)	(1,899,316)
Total liabilities and shareholders' equity (deficit)	$ 1,266,952	1,727,663

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, 2011 and 2010

	Year Ended December 31	
	2011	2010
Revenue, net	$ 1,444,447	$ 1,308,910
Cost of sales	713,627	911,793
Operating expenses:		
Research and development	2,449,178	2,014,784
Selling, general and administrative	5,628,005	6,285,004
Total operating expenses	8,077,183	8,299,788
Loss from operations	(7,346,363)	(7,902,671)
Other income (expense):		
Interest income	1,044	3,657
Interest expense	(332,349)	(33,859)
Loss from abandoned public offering	—	(603,012)
Local business tax	(1,200)	(2,717)
Total other expense, net	(332,505)	(635,931)
Loss before income taxes	(7,678,868)	(8,538,602)
Income tax benefit	—	733,437
Net loss	$(7,678,868)	$(7,805,165)
Basic and diluted net loss per share	$ (1.34)	$ (1.42)
Shares used to compute basic and diluted net loss per share	5,717,533	5,511,451

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

Organics, Inc.
Statements of Changes in Shareholders' Equity (Deficit)
For the Years Ended December 31, 2011 and 2010

	Common Stock		Additional Paid In Capital	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount			
Balances at December 31, 2009	5,304,157	$5,304	$28,146,206	$(25,511,883)	$ 2,639,627
Exercise of common stock options	3,000	3	23,997	—	24,000
Issuance of common stock, net of expenses	356,000	356	2,574,644	—	2,575,000
Compensation expense relating to option issuances	—	—	667,222	—	667,222
Fractional shares cash payments from one for twenty reverse split of common stock	(81)	—	—	—	—
Net loss	—	—	—	(7,805,165)	(7,805,165)
Balances at December 31, 2010	5,663,076	$5,663	$31,412,069	$(33,317,048)	$(1,899,316)
Issuance of restricted common stock , net of expenses	140,000	140	(140)	—	—
Compensation expense relating to option issuances	—	—	1,140,324	—	1,140,324
Compensation expense relating to restricted stock	—	—	121,893	—	121,893
Issuance of stock retention awards	93,600	94	140,306	—	140,400
Retirement of treasury stock	(2,500)	(3)	(3,748)	—	(3,751)
Net loss	—	—	—	(7,678,868)	(7,678,868)
Balances at December 31, 2011	5,894,176	$5,894	$32,810,704	$(40,995,916)	$(8,179,318)

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, 2011 and 2010

	Year Ended December 31	
	2011	2010
Cash flows from operating activities:		
Net loss	$(7,678,868)	$(7,805,165)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock retention awards	140,400	—
Non-cash services paid in common stock	—	99,000
Depreciation and amortization	79,516	42,735
Stock-based compensation expense	1,262,217	667,222
Changes in operating assets and liabilities:		
Accounts receivable, net	30,328	39,841
Income tax receivable	362,218	(362,218)
Inventory, net	(208,964)	(134,516)
Prepaid expenses and other current assets	153,290	4,791
Accounts payable and accrued expenses	225,331	1,036,774
Deferred revenue	139,774	(36,898)
Net cash used in operating activities	(5,494,758)	(6,448,434)
Cash flows from investing activities:		
Purchase of property and equipment, net	—	(88,084)
Net cash used in investing activities	—	(88,084)
Cash flows from financing activities:		
Borrowings under note payable to shareholder	—	1,000,000
Borrowings under convertible revolving note payable to shareholder	5,500,000	2,000,000
Payments on short term notes payable	(172,552)	(107,314)
Net proceeds from issuance of common stock	—	1,500,000
Purchase of treasury stock	(3,751)	—
Restricted cash released from common stock proceeds	210,697	1,974,343
Net cash provided by financing activities	5,534,394	6,367,029
Net increase (decrease) in cash and cash equivalents	39,636	(169,489)
Cash and cash equivalents at beginning of year	132,103	301,592
Cash and cash equivalents at end of year	$ 171,739	$ 132,103
Interest paid	$ 5,928	$ 21,968
Non-cash investing and financing activities:		
Borrowings under short term notes payable for prepaid expense	$ 126,738	$ 63,835
Par value of restricted stock granted as stock compensation	$ 140	$ —
Common stock issued in exchange for cancellation of note payable to shareholder	$ —	$ 1,000,000
Borrowings under short term notes payable for purchase of property and equipment	$ —	$ 107,373

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

Oragenics, Inc.
Notes to Financial Statements
December 31, 2011 and 2010

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. The Company is focused on the discovery, development and commercialization of a variety of technologies associated with oral health, broad spectrum antibiotics and other general health benefits.

On August 29, 2011 the Company held its Annual Meeting of Shareholders (the "Meeting"), at which time the shareholders authorized the amendment to the Company's Amended and Restated Articles of Incorporation (the "Amendment") to increase the number of authorized common stock from 15,000,000 to 50,000,000 shares. Following the Meeting, the Amendment was filed with the Secretary of State of Florida on August 30, 2011 and became effective.

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 $1,444,447, incurred a net loss of $7,678,868 and used cash of $5,494,758 in its operating activities during the year ended December 31, 2011. As of December 31, 2011 the Company had an accumulated deficit of $(40,995,916) and cash flows from operations were negative throughout 2011. These factors raise substantial doubt about the Company's ability to continue as a going concern.

During 2010 and 2011, the Company's primary source of debt and equity funding was provided by its largest shareholder, the Koski Family Limited Partnership (the "KFLP"). The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes the working capital at December 31, 2011, together with access to the Loan Agreement with the KFLP will be sufficient to meet the business objectives as presently structured through June 2012. Management recognizes that the Company must generate additional capital resources or consider modifications to its technology development plans to enable it to continue as a going concern. Management's plans include seeking financing, alliances or other partnership agreements with entities interested in the Company's technologies, or other business transactions that would generate sufficient resources to assure continuation of the Company's operations and research and development programs.

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. Without sufficient capital to fund their operations, the Company will be unable to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Reverse Stock Split

On September 24, 2010, the Company effected a 1-for-20 reverse stock split of all of its authorized, issued and outstanding shares of common stock (the "Reverse Stock Split") by filing Articles of Amendment to Amended and Restated Articles of Incorporation with the Secretary of State of Florida. The par value of our common stock remained unchanged. The number of shares and per share amounts included in the financial statements and the accompanying notes have been adjusted to reflect the Reverse Stock Split retroactively. Unless otherwise indicated, all references to number of shares, per share amounts and earnings per share information contained in this report give effect to the Reverse Stock Split.

Oragenics, Inc.
Notes to Financial Statements (continued)
December 31, 2011 and 2010

2. Significant Accounting Policies

Recently Adopted Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2011-04 *Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs*. The ASU expands Accounting Standards Codification ("ASC") 820's existing disclosure requirements for fair value measurements and makes other amendments that could change how the fair value measurement guidance in ASC 820 is applied. The ASU is effective for the Company with the reporting period beginning January 1, 2012. The adoption of this ASU is not expected to have an impact on the Company's financial statements or disclosures.

No other new accounting pronouncements issued or effective during 2011 have had or are expected to have had an impact on the Company's financial statements.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the 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 stock based compensation, valuation of warrants, inventory obsolescence reserve, sales returns and allowances and allowance for doubtful accounts.

Fair Value of Financial Instruments

The fair value of the Company's cash and cash equivalents, accounts payable and accrued expenses approximate their carrying values due to their short-term nature.

Guaranteed Rights of Return

The Company has granted guaranteed rights of return to one mass retail and two dental distributors 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. Once notification has been received and verified, the Company records revenue in that accounting period. The Company had $25,752 and $0 of revenue deferred under guaranteed rights of return arrangements included in deferred revenue in the balance sheets as of December 31, 2011 and 2010, 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 agreement investments and at times deposits are in excess of federally insured limits.

Restricted Cash

As of December 31, 2011 and 2010, the Company had $264,960 and $475,657, respectively, of cash remaining that was restricted pursuant to the Common Stock Purchase Agreement dated December 30, 2009. The Company reserved and allocated $1,000,000 of the proceeds from the December 2009 Private Placement to the expenses incurred to further development of the Company's DPOLT synthetic chemistry platform.

Oragenics, Inc.
Notes to Financial Statements (continued)
December 31, 2011 and 2010

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, 2011 and 2010, the Company has recorded an allowance for doubtful accounts of approximately $156,000 and $149,000, 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, 2011 and 2010 was approximately $65,000 and $256,000, respectively.

Consigned Inventory

The Company has authorized a consignment inventory arrangement with one of its mass retail customers in March 2010. As of December 31, 2011 and 2010, the Company has $29,147 and $64,999, respectively, of inventory on consignment located at the retailers stores and warehouses, which is included in our inventory reserve. Once consignment inventory has been sold by this customer, the customer notifies the Company of the sale and the Company records revenue in that accounting period. The Company authorizes the replenishment of consignment inventory based on orders placed by the customer. The Company is provided with weekly reports of consignment sales activity and balances.

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 (five 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 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 or warrants do not vest at the grant date and are subject to forfeiture.

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.

Oragenics, Inc.
Notes to Financial Statements (continued)
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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. Grant revenues are recognized as the reimbursable expenses are incurred over the life of the related grant. Grant revenues are deferred when reimbursable expenses have not been incurred.

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. Product returns are limited to specific mass retail customers for expiration of shelf life or unsold product over a period of time. We maintain a return policy that allows our customers to return product within a specified period of time prior to and subsequent to the expiration date of the product. 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 is only one active mass retail customer account and 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, 2011 and 2010.

Advertising Expenses

The Company’s policy is to expense advertising and marketing costs as incurred. For the years ended December 31, 2011 and 2010, advertising and marketing expense was $735,245 and $1,615,268, 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 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 preclinical 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 non-clinical 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 and three key suppliers to provide probiotics, blending, warehousing and packaging of its EvoraPlus, EvoraPlus Kids, EvoraPro, and Teddy's Pride products during the years ended December 31, 2011 and 2010, respectively. The majority of cost of sales are from these key suppliers. As of December 31, 2011 and 2010, our accounts payable and accrued expenses for these vendors totaled $108,312 and $107,980, respectively.

Abandoned Public Offering

On December 22, 2010, we withdrew the filing of a registration statement for our contemplated public offering. As of December 22, 2010 we had incurred $603,012 in expenses associated with the offering, which is included in other income (expense) on the accompanying statement of operations for the year ended December 31, 2010.

3. Inventory, net

Inventory, net consists of the following as of December 31, 2011 and 2010:

	2011	2010
Finished goods	$411,724	$ 368,101
Consignment	29,147	64,999
Work-in-process	58,599	71,996
Raw materials	41,336	17,346
Total inventory	540,806	522,442
Less: inventory reserve	(65,214)	(255,814)
	$475,592	$ 266,628

4. Property and Equipment, net

Property and equipment, net consists of the following as of December 31, 2011 and 2010:

	2011	2010
Furniture and fixtures	$ 20,742	$ 20,742
Laboratory equipment	757,882	758,766
Leasehold improvements	476,777	476,777
Office and computer equipment	271,245	271,245
	1,526,646	1,527,530
Accumulated depreciation and amortization	(1,377,960)	(1,299,328)
Property and equipment, net	$ 148,686	$ 228,202

Depreciation and amortization expense for the years ending December 31, 2011 and 2010 was $79,516 and $42,735, respectively.

Oragenics, Inc.
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5. Related Party Transactions

At December 31, 2011 and 2010 deferred payments totaling $25,500 and $34,000, 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. These meeting fees are deferred until such time as management determines that we have sufficient funding to pay them to the former directors. The deferrals of payments to our former directors do not reduce our expenses, but serve to preserve our limited cash resources to the extent necessary to maintain our operations. These amounts are non-interest bearing.

During the years ended December 31, 2011 and 2010, we paid $270,702 and $226,760, respectively, (which included approximately $96,909 and $162,501, respectively, in costs reimbursements associated with maintaining our intellectual property) to a law firm that employs the daughter-in-law of our former director and Chief Scientific Officer, Dr. Jeffrey Hillman, as a lawyer and from which firm we received intellectual property related legal services.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following as of December 31, 2011 and 2010:

	2011	2010
Accounts payable trade	$ 631,274	$ 745,569
Legal fees	376,167	256,478
Vacation	85,655	116,321
Deferred compensation	25,500	34,000
Royalties payable	25,000	25,000
Interest	356,689	30,268
Consulting fees	35,858	33,009
Public offering costs	—	149,163
Sales return allowance	197,923	121,728
Other	6,150	3,349
Total accounts payable and accrued expenses	$1,740,216	$1,514,885

7. Short Term Notes Payable

The Company had the following short-term notes payable as of December 31, 2011 and 2010:

	2011	2010
Product liability insurance financing of $48,988 and $63,835, due in monthly installments of $5,024 and $6,552 including principal and interest at 5.48% and 5.75% through January 10, 2012 and May 24, 2011, respectively.	$ 5,000	$32,299
Directors' and officers' liability insurance financing of $77,751, due in monthly installments of $7,237 including principal and interest at 4.75% through June 24, 2012.	42,828	—
New enterprise resource planning system financing of $85,185 due in monthly installments of principal and interest at 7.5% through December 31, 2011.	5,264	61,060
New enterprise resource planning system financing of $22,188, due in quarterly installments of $5,547, non-interest bearing through April 1, 2011.	—	5,547
Total short-term notes payable	$53,092	$98,906

Oragenics, Inc.
Notes to Financial Statements (continued)
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8. Convertible Revolving Notes Payable to Shareholder

May 2010 Note Financing—On May 28, 2010, we entered into an unsecured promissory note with a conversion provision (the "May 2010 Note") to the Koski Family Limited Partnership (the "KFLP") pursuant to which we borrowed $1,000,000 from the KFLP. Interest on the May 2010 Note accrued at the rate of LIBOR plus 6.0% and the principal of the May 2010 Note, together with all accrued interest thereon, was due and payable the earlier of: (i) the closing date of a registered public offering of newly issued equity securities by us resulting in cash proceeds to us, other than in connection with employee option plans, or (ii) the May 24, 2011 maturity date; provided, however, that in the event we completed a subsequent private offering of equity securities prior to the May 24, 2011 maturity date, we could elect to convert the principal of the May 2010 Note into the same equity securities being sold in the private offering at the same price and terms to the KFLP. The May 2010 Note was repaid through the issuance of common stock in connection with the July 2010 Financing Transaction (See Note 9).

Credit Facility- On July 30, 2010, in connection with the July 2010 Financing Transaction, the Company entered into an unsecured revolving credit facility agreement with the KFLP (the "Credit Facility") Pursuant to the Credit Facility, the Company is able to borrow up to $2,000,000 from the KFLP at LIBOR plus 6.0%. The term of the Credit Facility is for 12 months commencing August 1, 2010. Our continued ability to draw on the Credit Facility is subject to (i) the receipt by the KFLP of a certificate of no adverse change from us in form and substance acceptable to the KFLP, (ii) the receipt by the KFLP of a revolving unsecured promissory note from us in the principal drawn down in the form attached to the Credit Facility and (iii) our compliance with the terms of the Credit Facility.

On each of September 13, 2010 and November 8, 2010, the Company borrowed $1,000,000 under the Credit Facility and executed a revolving unsecured promissory note for such amounts initially to mature on July 30, 2011.

On January 24, 2011, the Company entered into a First Amendment to its Credit Facility (the "First Amendment") to increase the available borrowing from $2,000,000 to $2,500,000 and simultaneously therewith the Company drew on the Credit Facility, as amended, to borrow the additional $500,000 in available funds and executed another revolving unsecured promissory note initially due on July 30, 2011.

On February 4, 2011, the Company entered into a Second Amendment (the "Second Amendment") to its Credit Facility to increase the available borrowings from $2,500,000 to $5,000,000. Future draws under the Credit Facility, as amended, are limited to $500,000 per month commencing no earlier than March 2011. Under the Second Amendment, the due date of the amounts borrowed and outstanding under the Credit Facility, were extended by one year from July 30, 2011 to July 30, 2012. The interest rate remained at LIBOR plus 6.0%. The Second Amendment further provided for the automatic conversion of any amounts borrowed and outstanding under the Credit Facility into Company securities that may be issued by the Company in subsequent securities offerings. Any automatic conversion of amounts outstanding under the Credit Facility would be on the same terms of any such offering. In addition, the Second Amendment provides the KFLP with the right to put any undrawn available amounts under the Credit Facility, as amended, to the Company and thereby have a note issued to the KFLP. The KFLP can exercise its put right to the extent it desires to fully participate, through the automatic conversion provision, in any subsequent offering by the Company.

On each of March 15, 2011, April 5, 2011, May 5,2011, June 3, 2011, and July 8, 2011, the Company borrowed an additional $500,000 under the Credit Facility, as amended, and executed a revolving unsecured promissory notes for such amounts that each mature on July 30, 2012.

On June 29, 2011, the Company entered into a Third Amendment (the "Third Amendment") to its Credit Facility. As a result of the Third Amendment, the Company increased its availability under the Credit Facility by $2,000,000 from $5,000,000 to $7,000,000. Future draws of the $2,000,000 in increased availability provided by the Third Amendment to the Credit Facility are limited to $1,000,000 increments beginning no earlier than August 2011 and October 2011, respectively. All other terms of the Credit Facility remained the same.

On each of August 1, 2011 and October 5, 2011, the Company borrowed an additional $1,000,000 under the Credit Facility, as amended and executed a revolving unsecured promissory note in such amounts that mature on July 30, 2012.

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On December 9, 2011, the Company entered into a Fourth Amendment (the "Fourth Amendment") to its Credit Facility with the KFLP. The entering into of the Fourth Amendment was approved by the Company's Audit Committee and disinterested directors. The Fourth Amendment increased the available borrowing under the Credit Facility by $500,000 from $7,000,000 million to $7,500,000. On December 9, 2011, the Company drew down on the Credit Facility as amended to borrow $500,000 in the newly available funds. All other terms of the Credit Facility remained the same.

As of December 31, 2011 the Company had borrowed an aggregate of $7,500,000 from the KFLP under the Credit Facility, as amended and owed accrued interest of $356,689 to the KFLP with no remaining availability. See Note 16 for subsequent events regarding the further amendment of the Credit Facility followed by the conversion of the outstanding debt owed thereunder into equity and the termination of the Credit Facility.

9. Shareholders' Equity

Common Stock

At our 2010 annual meeting our proposal to amend the Company's articles of incorporation to consummate a reverse stock split of our authorized and outstanding shares of common stock was approved and thereafter our Board of Directors authorized a 1 for 20 reverse stock split of our authorized and outstanding shares of common stock and the Company filed an amendment to its articles of incorporation with the Florida Department of State to effect the reverse stock split.

Restricted Stock Issuance

The Company issued 120,000 restricted shares of common stock to its former Chief Scientific Officer and founder, Dr. Jeffrey Hillman in connection with his retirement from full time services to the Company effective October 31, 2011. The restricted shares are subject to performance conditions as well as time based vesting. The performance based vesting relates to the completion of certain work-in-process concerning Company intellectual property and the time vesting is equal over a three year period with restricted shares being subject to earlier vesting upon a change of control. Dr. Hillman's outstanding stock option agreements were amended to (a) vest any unvested options and (b) extend the exercise period of such options for one year post separation of employment until October 31, 2012. The Company recorded compensation expense of $40,227 for the year ended December 31, 2011 for these restricted shares. At December 31, 2011, 120,000 shares of restricted common stock are non-vested. At December 31, 2011, there was $169,773 of total unrecognized compensation expense related to non-vested restricted common stock that is expected to be recognized over a period of three months.

January 2010 Private Placement

In January 2010, we completed a second closing of a $3,000,000 private placement of common stock that commenced in December 2009 (when the initial closing occurred) pursuant to a common stock Purchase Agreement with accredited investors. In January 2010 the Company issued an additional 100,000 shares of its common stock at a price per share of $5.00 to the additional participating investors. The additional investment amount in January 2010 was $500,000, of which $250,000 was made by the Koski Family Limited Partnership.

July 2010 Financing Transaction

In July 2010, we issued 250,000 shares of our common stock to the KFLP at a price of $8.00 per share in connection with a common stock purchase agreement (the "July 2010 Financing Transaction") we entered into with the KFLP. The $2,000,000 aggregate consideration paid by the KFLP for the shares consisted of (i) $1,000,000 cash and (ii) the exchange and cancellation of the outstanding May 2010 Note issued to the KFLP on May 28, 2010. Accrued interest on the May 2010 Note through closing was waived by the KFLP.

Concurrent with the July 2010 Financing Transaction and as part thereof, the Company entered into the Credit Facility with the KFLP (see Note 8).

Other Share Issuances

In June 2010, we issued 6,000 shares to Athorn Clark partners ("Athorn") at a price per share of $12.50 (based on the value of the services required to be provided by Athorn) in connection with an agreement for Athorn to provide media related services to us.

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Warrants

The Company's outstanding and exercisable warrants as of December 31, 2011 are presented below:

Shares Underlying Warrant Outstanding	Exercise Price	Expiration Date
127,888	$26.00	5/30/2013
161,000	15.00	5/30/2013
5,000	10.00	4/15/2014
12,500	6.00	9/14/2012
306,338		

As of December 31, 2011 there are 306,388 warrants and 725,173 stock options outstanding. If all warrants and stock options were exercised, the total number of outstanding common shares would be approximately 6,925,737 as of December 31, 2011.

Treasury Stock

During 2011, the board of directors authorized and the Company repurchased 2,500 shares of the Company's common stock at an aggregate cost of $3,751. In 2011, we retired all shares of treasury stock. These shares remain as authorized stock; however, they are now considered unissued.

10. 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 most recently, on August 29, 2011. Under the terms of the Stock Incentive Plan, as amended, the Company is authorized to issue options to purchase up to 1,125,000 shares of the Company's common 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, 2011, the Company had 273,228 shares available for future stock option grants under the Stock Incentive Plan.

The purpose of the Stock 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 Stock Incentive Plan authorizes the grant of stock options (incentive and non-statutory), stock appreciation rights and restricted stock. As of December 31, 2011 and 2010, the Company had not awarded any stock appreciation rights under the Stock Incentive Plan. As of December 31, 2010 the Company had not awarded any restricted stock under the Stock Incentive Plan.

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

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

The following table summarizes the assumptions used to estimate the fair value of stock options granted during the years ended December 31, 2011 and 2010:

	2011	2010
Expected dividend yield	0%	0%
Weighted-average expected volatility	145%-146%	146%
Weighted-average risk-free interest rate	2.03%-2.48%	3.15%
Expected life of options	10 years	10 years

Total compensation cost related to stock options was $1,140,324 and $667,222 for the years ended December 31, 2011 and 2010, respectively. As of December 31, 2011, there was $758,978 of unrecognized compensation costs related to stock options , which is expected to be recognized over a weighted average period of 8.16 years.

The following table represents stock option activity as of and for the two years ended December 31, 2011:

	Number of Options	Option Price Per Share	Weighted Average Exercise Price
Outstanding at December 31, 2009	385,967	$5.40 -17.00	$ 17.00
Forfeited	(44,262)	5.40 -14.00	6.77
Granted	41,132	4.00 -14.00	9.23
Exercised	(3,000)	8.00	8.00
Outstanding at December 31, 2010	379,837	$5.40 -17.00	$ 7.86
Forfeited	(151,164)	5.40 -14.80	6.50
Granted	496,500	1.50 -5.00	3.50
Exercised	—		
Outstanding at December 31, 2011	725,173	$1.50 – 17.00	$ 4.85
Exercisable at December 31, 2011	323,537	$4.00 – 17.00	$ 6.76

The total grant date fair value of options vested during the years ended December 31, 2011 and 2010 was approximately $1,085,445 and $305,650, respectively.

Restricted Stock Awards

On March 11, 2011, our Board of Directors and Compensation Committee awarded 10,000 shares of restricted common stock to each of Mr. Brian Bohunicky, our former Chief Financial Officer and to Mr. Robert Koski, our director at a grant date fair value of $3.60 per share. The restricted stock awards were pursuant to the Company's Stock Incentive Plan. Half of the awarded shares vest in six (6) months and the other half on the anniversary date of the award. The Company recorded compensation expense of $65,341 for the year ended December 31, 2011. Compensation expense related to restricted stock awards is a non-cash expense and is included in selling, general and administrative expenses in the accompanying statement of operations. At December 31, 2011, 10,000 shares of restricted common stock are non-vested. At December 31, 2011, there was $6,659 of total unrecognized compensation expense related to non-vested restricted common stock that is expected to be recognized over a period of three months.

Long-Term Performance -Based Incentive Program

Executive LTPB Program

On November 14, 2011, the Compensation Committee of our Board of Directors as well as our Board of Directors approved

a long-term performance-based incentive program (the "Executive LTPB Program") to be administered under the Company's Stock Incentive Plan. The Executive LTPB Program is an incentive program designed to motivate the participants, including the Company's CEO to achieve the Company's financial and other performance objectives and to reward them if, and when, those objectives are met. The Company believed it was in the best interest of the Company to: (i) develop a culture of achievement and performance; (ii) align the incentive structure to the long term goals of the Company; (iii) promote retention; (iv) promote achievement of targeted results; (v) use equity proactively and as an appropriate incentive; and (vi) employ variable compensation based upon performance goals.

The Executive LTPB Program provides for the award of shares of common stock as a bonus to designated executive officers and employees of the Company. The shares will be issued to participants during the term of the Executive LTPB Program, subject to the satisfaction of applicable performance goals (as described below). Participants are eligible to receive a bonus payable in shares of common stock if they continue to be employed by the Company through the first to occur of either of the following: (i) the Company's achievement, on or before December 31, 2013 (the "Termination Date"), of the various "Performance Goals" set forth below, or (ii) the effective date of a "Change in Control" of the Company that occurs at any time following the date of this Agreement and on or before the Termination Date.

The performance periods for the Executive LTPB Program run from January 1, 2012 through December 31, 2013. Future Awards will be credited to participants, up to target levels, to the extent that the performance goals are satisfied, as determined by the Compensation Committee. Upon the occurrence of a "Performance Vesting Date" with respect to a "Performance Goal," a participant will be entitled to receive a number of shares of Common Stock determined by multiplying (1) the award percentage (each, an "Award Percentage") corresponding to that particular Performance Goal as set forth in their award agreement by (2) the total number of outstanding shares of Common Stock, determined on a non-fully diluted basis, as of that particular applicable Performance Vesting Date. For purposes of an award, the "Performance Vesting Date" with respect to a Performance Goal shall be the day on which the Compensation Committee of the Company's Board of Directors certifies and determines, in its reasonable discretion, that the applicable Performance Goal has been achieved. Participants are required to remain employees of the Company through the date on which the Compensation Committee makes a final determination under the Executive LTPB Program with respect to the satisfaction of the performance goals during the performance period.

The Executive LTPB Program provides for awards upon the Company achieving any of the following performance goals: (i) achievement of Company fiscal year sales equal or greater than $10,000,000; (ii) achievement of Company fiscal year sales equal or greater than $20,000,000; (iii) achievement by the Company of cash flow positive in any fiscal quarter; (iv) achievement by the Company of earnings per share in any fiscal year equal or greater than $0.02 per share of Company stock; (v) Achievement of price per share of Company stock equal to $10.00; (vi) Achievement of price per share of Company stock equal to $20.00; (vii) licensing of any science technology which results in upfront cash receipt of $2M; or (viii) capital raise by the Company of $5,000,000 in both fiscal years or a $10,000,000 in a single raise.

Non-Employee Director Compensation Program

Simultaneously with the approval of the Executive LTPB Program, the Compensation Committee also approved a change in the Company's director compensation program to add a similar long-term performance based incentive compensation component for the non-employee directors. These changes were considered by the Compensation Committee to be in the best interest of the Company and necessary to attract and retain highly qualified directors to serve on the Company's board. The full board also ratified and approved the changes to the director compensation program. The long term incentive plan is comparable in all respects to the Executive LTPB Program for the designated executive officers and employee participants, including the Performance Goals.

Retention Awards.

The Executive LTPB Program and similar component to the Non-Employee Director Compensation Program included immediate retention awards to be made to the designated participants and non-employee directors, which were payable in shares of common stock of the Company, as a retention award (the "Retention Awards"). The Company issued an aggregate of 93,600 shares as Retention Awards under the Stock Incentive Plan.

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11. Licenses

The Company has two license agreements with the University of Florida Research Foundation, Inc. ("UFRF") for their technologies. The Company issued 29,997 shares of common stock as partial consideration in 1998. The license agreements provide for, among other things, the Company to make minimum annual research expenditures of $1,000,000 and to adhere to specific milestones. Beginning in 2005, the Company was required to pay minimum royalties on product sales of $50,000 annually per agreement. If the Company fails to perform certain of its obligations, UFRF may terminate the license agreements. The Company's milestones are in compliance with UFRF and the Company had $25,000 of royalties payable to UFRF recorded in the accompanying balance sheets in accounts payable and accrued expenses at December 31, 2011 and 2010, respectively.

In December 2011, the Company completed an exclusive licensing agreement with Texas A&M University (College Station, TX) ("Texas A&M") for access to new analogs of the lantibiotic Mutacin 1140 (MU1140) and other lantibiotics with improved pharmacological properties and structural features.

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 (up to our 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.

12. 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 contributions to the plan. Total matching contributions made by the Company for the years ended December 31, 2011 and 2010 were $41,794 and $40,197, respectively.

13. Income Taxes

The components of the provision for income taxes for the years ended December 31, 2011 and 2010 are as follows:

	2011	2010
Current	$ —	$ (733,437)
Deferred	(2,545,834)	(3,502,706)
Valuation Allowance	2,545,834	3,502,706
Total provision for income taxes	$ —	$ (733,437)

At December 31, 2011 and 2010, 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:

	2011	2010
Deferred tax assets:		
Net operating loss carryforward	$ 13,681,361	$ 11,345,514
Bad debt reserve	58,765	55,914
Inventory reserve	24,540	96,263
Sales return allowance	74,478	45,806
Accrued vacation	32,232	43,771
Deferrals of compensation to Directors & Officers	9,596	12,794
Deferred grant revenue	13,194	—
Uniform capitalization (UNICAP)	6,418	2,486
Non-qualified stock compensation	414,630	166,832
Total deferred tax assets	14,315,214	11,769,380
Less valuation allowance	(14,315,214)	(11,769,380)
Total net deferred taxes	$ —	$ —

Oragenics, Inc.
Notes to Financial Statements (continued)
December 31, 2011 and 2010

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, 2011 and 2010:

	2011	2010
Income tax benefit computed at statutory federal rate of 34%	$(2,610,815)	$(2,903,125)
State income tax benefits, net of federal expense/benefit	(278,743)	(309,951)
Change in valuation allowance	2,545,834	3,052,706
Non-deductible expenses	231,465	133,032
Therapeutic discovery tax credit	—	733,437
Other	112,259	27,338
Total	$ —	$ 733,437

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 $14,315,214 and $11,769,380 has been provided in the accompanying financial statements as of December 31, 2011 and 2010, respectively. The 2011 net change in valuation allowance related to deferred tax assets was an increase of $2,545,834 primarily relating to net operating loss carryforwards. The 2010 net change in valuation allowance related to deferred tax assets was an increase of $3,052,706 primarily relating to net operating loss carryforwards.

At December 31, 2011, the Company has federal and state tax net operating loss carryforwards of approximately $36,480,000. The federal and state tax loss carryforward will expire through 2032, unless previously utilized. The Company also has federal research and development tax credit carryforwards of approximately $551,000. The federal tax credit carryforward will expire through 2022, 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. As a result of the 50% change 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 $172,000. 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, 2011 and 2010, the Company incurred $59,967 and $106,719, 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 2007.

Oragenics, Inc.
Notes to Financial Statements (continued)
December 31, 2011 and 2010

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

Balance as of December 31, 2009	$384,276
Additions based on tax positions related to the current year	106,719
Additions for the tax positions of prior years	—
Reductions for the tax positions of prior years	—
Balance as of December 31, 2010	$490,995
Additions based on tax positions related to the current year	59,967
Additions for the tax positions of prior years	—
Reductions for the tax positions of prior years	—
Balance as of December 31, 2011	$550,962

Included in the balance at December 31, 2011 and 2010, are $550,962 and $490,995, 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 2011 and 2010 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.

On November 1, 2010, we received notification that we were awarded federal grant funding for three of its therapeutic development programs under the Qualifying Therapeutic Discovery Project. The Qualifying Therapeutic Discovery Project, was recently enacted by Congress as part of the Patient Protection and Affordable Care Act of 2010, which was designed to provide grants or tax credits to qualified biotechnology companies that demonstrate the potential to either 1) develop new therapies to treat areas of unmet medical needs; 2) prevent, detect or treat chronic or acute diseases and conditions; 3) reduce long-term health care costs in United States; or 4) significantly advance the goal of curing cancer within the 30 year period beginning on May 21, 2010. We applied for funding on three of its programs: Prevention of Tooth Decay using Smart Replacement Therapy, Novel Antibiotics for the Treatment of Healthcare Associated Infections and Rapid and Sensitive Identification of Novel Diagnostic Biomarkers for Cancer and Infectious Diseases. We received a non-taxable cash grant award totaling $733,437 under the program which was recorded as income tax benefits for the year. As of December 31, 2010, we had recorded income tax receivables totaling $362,218. A payment of $371,219 was made to us in November 2010 and remaining grant award amount of $362,218 was received in February, 2011.

14. Commitments and Contingencies

The Company's Alachua facility is being leased from a real estate developer for a term of three years and was renewed in December 2011. Lease payments are capped during the term with the exception of taxes and insurance exceeding 3%. This operating lease agreement required the Company to pay a deposit of $6,400 and provides for monthly lease payments of $8,993, inclusive of utilities, insurance, sales taxes and real estate taxes. Rent expense under this lease was $108,758 and $97,187 for the years ended December 31, 2011 and 2010. On October 1, 2009 the Company leased office space for Corporate, Sales and Marketing personnel located in Tampa, FL. The lease is for approximately 3,150 square feet and is occupied by ten employees. The lease period for the office space is forty months in the amount of $5,276 per month inclusive of insurance, taxes and utilities. The lease expires on January 31, 2013. Rent expense under this lease was $63,312 for the years ended December 31, 2011 and 2010, respectively.

Oragenics, Inc.
Notes to Financial Statements (continued)
December 31, 2011 and 2010

Future annual minimum payments under all non-cancelable operating leases are as follows as of December 31, 2011:

Year ended December 31:	
2012	$ 175,637
2013	117,596
2014	102,960
	$ 396,193

15. 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.

	2011			
	First	Second	Third	Fourth
Revenue	$ 349,937	$ 347,569	$ 350,351	$ 396,590
Total operating expenses	1,770,347	2,323,126	1,927,049	2,056,661
Net loss	(1,559,013)	(2,373,243)	(1,807,290)	(1,939,322)
Loss per share:				
Basic and Diluted	$ (0.28)	$ (0.42)	$ (0.32)	$ (0.33)

	2010			
	First	Second	Third	Fourth
Revenue	$ 341,483	$ 304,696	$ 364,574	$ 298,157
Total operating expenses	1,890,997	2,186,467	2,087,934	2,134,390
Net loss	(1,747,199)	(2,010,222)	(1,875,228)	(2,172,516)
Loss per share:				
Basic and Diluted	$ (0.32)	$ (0.37)	$ (0.34)	$ (0.38)

Oragenics, Inc.
Notes to Financial Statements (continued)
December 31, 2011 and 2010

16. Subsequent Events

On January 23, 2012, the Company entered into a Fifth Amendment (the "Fifth Amendment") to the Credit Facility with the KFLP, an accredited investor and the Company's largest shareholder (see Note 8). The Fifth Amendment was approved by the Company's Audit Committee and Board of Directors. The Fifth Amendment increased the available borrowing under the Credit Facility by $750,000 from $7,500,000 to $8,250,000. On January 23, 2012, the Company drew down on the Credit Facility as amended to borrow $750,000. All other terms of the Credit Facility remained the same, including but not limited to, the outstanding indebtedness thereunder being due July 30, 2012.

On March 23, 2012, the Company entered into an Exchange of Notes for Equity Agreement (the "Debt Exchange Agreement") with the KFLP, an accredited investor and its largest shareholder. Pursuant to the terms of the Debt Exchange Agreement, the Company issued 6,285,619 shares of common stock and warrants to acquire 1,571,405 shares of common stock to the KFLP in exchange for the cancellation of an aggregate of $8,737,011 of indebtedness owed to the KFLP under its existing unsecured revolving credit facility (the "Credit Facility) with the KFLP. The outstanding indebtedness, consisted of $8,250,000 in principal owed on twelve separate promissory notes previously issued by the Company to the KFLP under the Credit Facility and accrued interest through March 23, 2012 (the closing date) of $487,011. The Credit Facility was terminated and the previously issued promissory notes thereunder were cancelled. The warrants are exercisable immediately at a price per share of $2.00 and expire three (3) years from the date of issuance.

On March 23, 2012, the Company also entered into a new loan agreement (the "Loan Agreement") with the KFLP. It provides the Company with up to $2.5 million in secured funding in two advances of $1,250,000 each with the first advance occurring on March 23, 2012 and the second advance able to be made within 30 days thereafter, subject to the continued accuracy of representations and warranties made by the Company and that no material adverse events have occurred in connection with its business. Borrowings under the Loan Agreement mature in three years and bear interest at the rate of 5.0% and are secured by select assets of the Company relating to or connected with the ProBiora3, SMaRT Replacement Therapy, MU1140 and LPT3-04 technologies. The loan amount is subject to automatic conversion upon a subsequent qualified equity financing by the Company of $5,000,000 (excluding any converted debt amount). Pursuant to the Loan Agreement the Company also issued a warrant to the KFLP to acquire 599,520 shares of its common stock. The warrants are exercisable immediately at a price per share of $2.00 and expire three (3) years from the date of issuance.

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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	
4.2	Securities Purchase Agreement between George Hawes, William Matlack and Oragenics, Inc. dated June 12, 2008 (including form of June 2008 Warrant)	8-K	001-32188	10.1	6/16/08	
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	Standard Exclusive License Agreement with Sublicensing Terms between the Company and the University of Florida Research Foundation, Inc. effective June 22, 2000 (the "Antimicrobial Polypeptide License Agreement")	SB-2	333-100568	10.5	10/16/02	
10.7	First Amendment to the Antimicrobial Polypeptide License Agreement dated September 15, 2000	SB-2	333-100568	10.6	10/16/02	
10.8	Second Amendment to the Antimicrobial Polypeptide License Agreement dated June 10, 2002	SB-2	333-100568	10.7	10/16/02	
10.9	Third Amendment to the Antimicrobial Polypeptide License Agreement dated September 25, 2002	SB-2	333-100568	10.4	10/16/02	

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Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
10.10	Fourth Amendment to the Antimicrobial Polypeptide License Agreement dated March 2003	SB-2/A-3	333-100568	10.36	4/9/03	
10.11	Amended and Restated 2002 Stock Option and Incentive Plan (including Form of Stock Option Agreement)	10-QSB/A	001-32188	10.1	9/29/06	
10.12	First Amendment to Amended and Restated 2002 Stock Option and Incentive Plan	8-K	001-32188	4.2	4/14/08	
10.13	Second Amendment to Amended and Restated 2002 Stock Option and Incentive Plan	8-K	001-32188	10.1	10/30/09	
10.14	Third Amendment to Amended and Restated 2002 Stock Option and Incentive Plan	8-K	001-32188	4.1	09/01/11	
10.15	Fourth Amendment to Amended and Restated 2002 Stock Option and Incentive Plan	10-Q	001-32188	4.5	11/14/11	
10.16	Form of Employee Long Term Incentive Plan Agreement	8-K	001-32188	10.1	11/17/11	
10.17	Form of Director Long Term Incentive Plan Agreement	8-K	001-32188	10.2	11/17/11	
10.18	Lease Agreement between the Company and Hawley-Wiggins LLC dated January 28, 2004; Subordination Agreement dated April 14, 2004; and First Amendment dated November 15, 2004	10-KSB	001-32188	10.46	3/14/05	
10.19	Sublease Agreement between the Company and Astrazenca LP dated October 12, 2009 (3000 Bayport Drive, Suite 685, Tampa, FL 33607)	10-K	001-32188	10.17	3/31/10	
10.20	Lease Agreement between the Company and Hawley-Wiggins LLC dated October 28, 2011 (13700 Progress Blvd, Alachua, FL 32615)					X
10.21	Executive Employment Agreement between the Company and John N. Bonfiglio dated May 25, 2011	8-K	001-32188	10.1	5/26/11	
10.22	Executive Employment Agreement between the Company and Michael Sullivan dated January 28, 2012	8-K	001-32188	10.1	2/2/12	
10.23	Executive Employment Agreement between the Company and Martin Handfield dated May 11, 2010	10-Q	001-32188	10.16	11/14/11	
10.24	Debt Exchange Agreement by and between Oragenics, Inc. and the Koski Family Limited Partnership dated March 23, 2012	8-K	001-32188	10.1	3/26/12	
10.25	Loan Agreement by and between Oragenics, Inc. and the Koski Family Limited Partnership dated March 23, 2012	8-K	001-32188	10.2	3/26/12	
10.26	Security Agreement by and between Oragenics, Inc. and the Koski Family Limited Partnership dated March 23, 2012	8-K	001-32188	10.3	3/26/12	
10.27	Form of Senior Secured Convertible Promissory Note dated March 23, 2012	8-K	001-32188	10.4	3/26/12	

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Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
10.28	License Agreement by and between Oragenics Inc. and Texas A&M University System dated December 20, 2011					X
23.1	Consent of Mayer Hoffman McCann P.C., an independent public accounting firm					X
24.1	Powers of Attorney (included on signature page).					
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).					X
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).					X
101.INS*	XBRL Instance Document					
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					

* Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933 or Section 18 of the Securities Exchange Act of 1934 and otherwise are not subject to liability.

Exhibit 10.20

LEASE

THIS LEASE AGREEMENT ("Lease") made as of the 28th day of October, 2011, by and between HAWLEY-WIGGINS LLC, a Florida limited liability company ("Landlord"), and ORAGENICS INC., a Florida corporation ("Tenant").

FOR AND IN CONSIDERATION of the sum of Ten Dollars ($10.00) receipt of which is hereby acknowledged and the mutual covenants herein contained, the parties hereto agree that Landlord does lease to Tenant and Tenant hereby leases from Landlord as follows:

WITNESSETH:

1. DEFINITIONS:

(a) "Landlord": Hawley-Wiggins L.L.C., a Florida limited liability company
Address: Post Office Box 1857, Alachua, Florida 32616

(b) "Tenant": Oragenics, Inc., a Florida Corporation
Address: 13700 Progress Boulevard, Alachua, Florida 32615

(c) "Premises": A building consisting (which landlord represents consists) of approximately 5,616 square feet of gross rentable area. The Premises are located in the Progress Corporate Park and known as 13700 Progress Boulevard, Alachua, FL 32615.

(d) "Use of Premises": Office and laboratory use.

(e) "Commencement Date": December 1, 2011 and this lease shall expire on November 30, 2014. (unless sooner terminated or extended as provided herein)

(f) "Term": Not less than thirty six (36) months commencing on the Commencement Date, this Lease to end on the last day of the thirty sixth month after the Commencement Date.

(g) "Rent":

(1) "Annual Gross Rent" Shall be per rentable square foot per Lease year as scheduled below:

Lease Year:	Annual Gross Rent/RSF:	Annual Gross Rent:	Monthly Payment Rent:
1	$ 20.00	$112,320.00	$ 9,360.00
2	$ 20.00	$112,320.00	$ 9,360.00
3	$ 20.00	$112,320.00	$ 9,360.00

Rent and other sums payable by Tenant to Landlord under this Lease, plus any applicable tax, shall be paid to Landlord, without deduction or offset at its management office presently located at P.O. Box 1857, Alachua, Florida 32616 or at such other place as Landlord may hereafter specify in writing.

(h) "Security Deposit": The sum of one (1) months' rent. (First year of Lease)($9,360.00) Security Deposit is due and payable upon execution of this Lease. Landlord is currently holding $8,424.00 Security Deposit and is requiring an additional **$936.00** upon execution of Lease.

2. PREMISES AND TERM: Landlord, in consideration of the Rent hereinafter reserved to be paid and of the covenants, conditions and agreements to be kept and performed by Tenant, hereby leases, lets and demises to Tenant, and Tenant hereby leases and hires from Landlord, that certain space called the Premises as described above.

Tenant may terminate this Lease prior to the expiration upon the payment to the Landlord of six (6) month's rent in advance.

3. RENT: Tenant covenants and agrees to pay, without deduction or offset, to Landlord Rent for the Premises as described in the Definitions above, on or before the first (1st) day of the first (1st) full calendar month of the term hereof and on or before the first (1 st) day of each and every successive calendar month thereafter during the full term of this Lease, subject to the adjustments as provided hereinafter along with any applicable tax, at the then current rate. In the event the Commencement Date occurs on a day other than the first (1st) day of a calendar month, the first Rent payment shall be in the amount of the prorated Rent for the calendar month in which the term of this Lease commences, such payment to be due on the Commencement Date. If Tenant shall become due and payable, then Tenant shall also pay to Landlord a late payment service charge of Five Percent (5%) of the rent, excepting such payments that are contested by Tenant.

Whenever under the terms of this Lease any sums of money is required to be paid by Tenant in addition to the Rent herein reserved, whether or not such sum is herein described as "Additional Rent", said sum shall nevertheless, at Landlord's option, if not paid when due, be deemed Additional Rent and shall be collectible as such with the first installment of Rent thereafter falling due hereunder.

3.1 ASSIGNMENT/SUBLETTING: Except as otherwise specified herein, Tenant will not assign this Lease, in whole or in part, nor sublet all or any part of the Premises, nor license concessions or lease departments therein, without first obtaining the written consent of the Landlord, which consent shall not be unreasonably withheld, conditioned or delayed by Landlord. At least thirty (30) days prior to the transfer, Tenant shall furnish Landlord with (a) all documents related to the transfer; (b) all financial statements of the proposed transferee, including, but not limited to, the most recent income, balance sheet and changes in financial position statement (with accompanying notes and disclosures of all material changes thereto) in audited form, if available, and certified as accurate by transferee's certified public accountant, if available; (c) any other relevant information that Landlord has theretofore reasonably requested regarding the proposed transfer; and (d) a statement signed by an authorized officer of an assignee, in the case of an assignment, agreeing that the assignee will be liable for all obligations thereafter arising under this Lease. Within thirty (30) days from receipt of Tenant's request for transfer, Landlord shall respond to Tenant's request.

Consent by Landlord to any assignment or subletting shall not constitute a waiver of the necessity for such consent to any subsequent assignment or subletting and shall not constitute a release of the Tenant hereunder. This prohibition includes any subletting or assignment which would otherwise occur by operation of law, merger, consolidation, reorganization, transfer or other change of Tenant's corporate or proprietary structure.

If, as a result of the transfer, Tenant will receive compensation in excess of the Lease Term Rental and additional Rent due hereunder, Tenant shall pay one hundred percent (100%) of such amounts to Landlord as and when received by Tenant as consideration for the consent to transfer. Tenant also agrees to reimburse Landlord upon demand for Landlord's reasonable costs and fees (including professional fees) for Landlord's consideration of a transfer but such reimbursement shall not exceed One Thousand Dollars ($1,000.00).

3.2 PERSONAL PROPERTY TAXES: Tenant shall be liable for all taxes levied against personal property and trade fixtures placed by Tenant in the Premises.

3.3 TAX ADJUSTMENT: Landlord shall pay all real property (ad valorem) taxes and assessments levied against the Building or the Premises. Notwithstanding the foregoing, Tenant shall pay to Landlord, as Additional Rent (tax adjustment), any increases in taxes payable by Landlord with respect to the Building and the land on which it is situated over the Tax Base as specified in this Lease. "Tax Base" is the ad valorem taxes for the tax year 2011. Tenant will pay to any increase (tax adjustment) over this Tax Base within ten (10) days after demand in one lump sum, or, at Landlord's option, divided by twelve (12) and collected with monthly Rent. This tax adjustment however is capped at no more than three percent (3%) per year. The tax adjustment will be due each anniversary after the initial adjustment and collectible as Additional Rent. In addition, Tenant shall make timely payment of (or reimburse Landlord for) all taxes and assessments levied against or attributable to Tenant's furniture, equipment, supplies, fixtures and other personal property located in the Premises, regardless of whether title to such improvements shall be held by Tenant or Landlord.

3.4 INSURANCE ADJUSTMENT: Landlord shall pay all insurance premiums. Notwithstanding the foregoing, Tenant shall pay to Landlord, as Additional Rent (insurance adjustment), any increases in insurance premiums payable by Landlord with respect to the Building over the Insurance Base as specified in this Lease. "Insurance Base" is the insurance premium for 2011. Tenant will pay to Landlord any increase (insurance adjustment) over this Insurance Base within ten (10) days after demand in one lump sum, or, at Landlord's option, divided by twelve (12) and collected with monthly Rent. This insurance adjustment however is capped at no more than three percent (3%) per year. The insurance adjustment will be due each anniversary after the initial adjustment and collectible as Additional Rent.

Even though the terms of the Lease has terminated or expired and Tenant has vacated the Leased Premises, when a final determination is made of Tenant's share of the taxes adjustments and insurance adjustments for the year in which this Lease terminates, Tenant shall immediately pay any increase due over the estimated Tenant's Share of such taxes and insurance adjustments previously paid, and conversely, any overpayment made shall be immediately rebated by Landlord to Tenant.

4. LANDLORD'S REPAIRS: Landlord, at landlord's expense, shall deliver the Premises to the Tenant in good, sound, and watertight condition. Upon Tenant taking possession of the Leased Premises, Tenant hereby acknowledged that it has accepted the Premises "As is". Landlord shall be responsible for the maintenance and repair of the building structure, plumbing, sewer, electrical, HVAC maintenance, lawn maintenance, dumpster (trash) removal, pest control, termite inspection and Association fees.

5. TENANT'S REPAIRS: Tenant, at Tenant's expense, shall make all ordinary wear and tear repairs and replacements to keep and maintain the premises in good condition. Tenant shall further keep the Premises clean, attractive and free of rubbish, rubble, debris, insects, rodents and other pests. Tenant shall be responsible for any damage as a result of misuse or neglect of the sewer system.

6. TENANT'S ALTERATIONS: Tenant shall have the right, at is sole expense, from time to time, to redecorate the Premises and to make such alterations, additions, improvements and changes in such parts thereof as Tenant shall deem expedient or necessary for tits purposes, subject to Landlord's prior approval; provided, however, that such alterations, additions, improvements and changes when completed shall neither impair the structural soundness nor diminish the value of the Premises. Upon the expiration of this Lease, Tenant may, at its option, remove all such redecorations, alteration, additions, improvements and changes. Tenant shall repair all damage caused by such removal. Notwithstanding the foregoing, all floor and wall coverings, sinks, vanities, light fixtures (other than special decorative lighting fixtures), and the complete electrical, plumbing, air conditioning and heating systems, including ducts, diffusers, grills, controls and all other equipment and parts related to such systems, shall be and remain in the Premises at all times for the benefit of Landlord. All such alterations, additions, or improvements shall be done in accordance with all applicable laws, rules regulations, and orders, including applicable building codes. Landlord shall execute and deliver upon request of Tenant such instrument or instruments embodying the approval of Landlord which may be required by any public or quasi public authority for the purpose of obtaining any licenses or permits for the making of such alterations, additions, improvements, changes and/or installations in, to or upon said Premises and Tenant agrees to pay for such licenses or permits. Tenant will indemnify and hold Landlord harmless from and against all claims by reason of such alterations, additions, or improvements which may be made by Tenant on the Premises, and Tenant shall promptly repair any damage to the Premises caused by any such alterations, additions, improvements, or changes. Anything contained in this Section to the contrary notwithstanding, Tenant shall not make changes to the exterior or structural portions for the Premises without Landlord's prior approval, which approval shall not be withheld or delayed unreasonably.

7. MECHANICS' LIENS: Tenants shall not suffer any mechanics' lien to be filed against the Premises by reason of work, labor, services or materials performed or furnished to Tenant in connection with any alterations, additions, or improvements to the Premises by Tenant hereunder. If any such mechanics' lien shall at any time be filed against the Premises, Tenant shall have the right to contest and any and all such liens; provided, however, that Tenant shall cause the same to be discharged of record by payment, bond, order of a court of competent jurisdiction or otherwise within

thirty (30) days written notice by Landlord. If Tenant shall fail to cause such lien to be discharged within such thirty (30) day period, then, in addition to any other right or remedy, Landlord may, but shall not be obligated to discharge the same by paying the amount claimed to be due or by bonding or other proceeding deemed appropriate by Landlord, and the amount so paid by Landlord and/or all reasonable costs and expense, including reasonable attorney' fees, incurred by Landlord in procuring the discharge of such lien, together with interest thereon at the Default Rate from the date paid until repaid by Tenant to Landlord, shall be deemed to be additional rent for the Premises and shall be due and payable by Tenant to Landlord on the first day of the next following month.

8. UTILITIES: Tenant shall pay all charges for water, gas, heat, electricity, sewer and any other utility used upon or furnished to the Premises. Tenant shall keep the Premises sufficiently heated to avoid the freezing or bursting of all pipes therein. The obligation of Tenant to pay for such utilities shall commence as of the Commencement Date.

9. USE OF PREMISES: Tenant shall use and occupy the Premises for purposes of office and/or laboratory use. Landlord represents that the Premises may lawfully be used for such purposes.

10. TENANT'S COVENANTS: Tenants covenants and agrees as follows:

(a) Tenant shall procure any and all licenses and permits required for Tenant's use of the Premises, and upon the expiration or terminations of this Lease, Tenant shall remove its goods and effects and those of all persons claiming under it and shall yield up the same peaceably to Landlord in good order, repair and condition in all respects, except for damage by fire and casualty, which is either insured against or required to be insured against hereunder, structural defects (not caused by Tenant's use of the Premises), required repairs by landlord, and reasonable wear and tear.

(b) Tenant shall permit Landlord and its agents on reasonable notice and at reasonable times to examine the Premises and to show the Premises to prospective purchasers, mortgagees, and/or tenants (but only during the last twelve (12) months of the term with respect to prospective tenants), provided that landlord shall not thereby unreasonably interfere with the conduct of Tenant's business. During the last three (3) months of the Term of this Lease, Landlord shall have the right to display on the Premises a "for rent" and/or "for sale" sign, which notice shall not be removed, obliterated, or hidden by Tenant.

(c) Tenant shall use and occupy the Premises in a careful, safe and proper manner and shall keep the Premises in a clean, safe and health condition in accordance with local ordinances and lawful directions of proper public officers. Tenant shall not permit the Premises to be used for any unlawful purpose, commit any waste thereof, or commit any nuisance. Notwithstanding the foregoing, Tenants shall have the right to contest the legality of any law, order, rule, regulations or requirement applicable to Tenant's use of the Premises, and Tenant shall indemnify and hold Landlord harmless from any liabilities, suits or penalties that may result from any such contest. Upon the final determination of any such contest, Tenants shall comply with any such law, order, ordinance, rule, regulation or requirements to the extent held to be valid or legal.

(d) (i) Tenant covenants that except in compliance with all laws and regulations, Tenant will not use hazardous substances within the premises as defined by any law or regulation now or

hereafter enacted or promulgated by any governmental authority and that there shall be no hazardous wastes or biomedical materials or waste generated within the Premises as defined by any law or regulation now or hereafter enacted or promulgated by any governmental authority, without Landlord's prior consent. Tenant agrees to manage and dispose of all hazardous substances, hazardous wastes biomedical materials and wastes in accordance with all federal, state and local laws, regulations and rules.

(ii) Tenant agrees not to store any hazardous wastes or biomedical materials or waste within the Premises (except in compliance with all laws and regulations).

(iii) Upon the expiration of the term of the Lease or the earlier termination hereof, Tenant shall remove all hazardous wastes and/or biomedical materials or waste generated by Tenant form any portion of the Premises. Landlord shall have the right to inspect the Premises with regard to the management and disposal of hazardous substances and wastes at all reasonable times during the term of this Lease.

(e) Tenant acknowledges that the leased premises are part of an office park development subject to covenants, conditions and restrictions as recorded in Official Records Book 1588, at Page 2207, as amended, Alachua County, Florida, together with rules and regulations governing the office park which Tenant shall comply with and be subject to.

In addition, the Tenant shall promptly execute and comply with all statutes, ordinances, rules, orders, regulations and requirements of the Federal, State and City Governmental and of any and all their Departments and Bureaus applicable to said premises, for the correction, prevention, and abatement of nuisances or other grievances, in, upon, or connected with said premises during said term; and shall also promptly comply with and execute all rules, orders and regulations of the applicable fire prevention codes for the prevention of fires, at Tenant's own cost and expense.

11. ASSIGNMENT AND SUBLETTING: Tenant shall not assign, transfer, mortgage or encumber this lease in whole or in part, nor sublet all or any part of the Premises, not suffer or permit the occupation of all or any part thereof by any other party, without prior written consent of the Landlord, which consent shall not be unreasonably withheld or delayed. The consent by Landlord to any assignment or subletting shall not constitute a waiver of the necessity for such consent to any subsequent assignment or subletting. (Tenant shall be entitled to assign or sublease this to an affiliated entity provided that Tenant remains liable for performance of the lease).

12. CHANGE IN CONTROL: Any transfers of company interests in Tenant which results in change of control shall be deemed an assignment of this Lease.

13. TENANT TO REMAIN LIABLE: If, at any time during the term of this lease, Tenant sublets all or any part of the Premises or assigns this Lease as provided herein, Tenant shall nevertheless remain fully liable under all the terms and conditions of this lease.

14. FIXTURES: All equipment and all other trade and light fixtures installed by or at the expense of Tenant in or on the Premises shall remain the property of Tenant and Tenant may, but shall not be obligated to, remove the same or any part thereof by the end of the term hereof, and provided that Tenant, at its sole cost and expense, shall make any repairs occasioned by such removal.

15. INDEMNITY: Tenant shall indemnify and hold Landlord harmless from any claims, damages, liabilities and expenses (including attorneys' fees and costs) for damage or injury to any person or any property occurring on the Premises, or any part thereof, arising as a result of the tortuous or negligent acts or commissions of Tenant, its agents, employees, independent contractors and invitees.

16. LIABILITY INSURANCE: During the Term of this lease, Tenant shall maintain comprehensive public liability insurance, including insurance against the assumed or contractual liability of Tenant hereunder, to afford protection to the limit for each occurrence of not less than $1,000,000.00 combined single limit for bodily injury, death and $300,000.00 for damage to the property. The policy carried by Tenant hereunder shall name Landlord (and Landlord's mortgagee) as an additional insured, and such policy shall provide that no cancellation, reduction or other material changes therein shall be effective until at least thirty (30) days after mailing of written notice thereof to Landlord (and Landlord's mortgagee). Certificates evidencing all such insurance shall be delivered to Landlord prior to the Commencement Date, and prior to the expiration of any such policies.

17. PROPERTY INSURANCE; During the term of this lease, Tenant shall maintain all-risk property casualty insurance, written at replacement cost value and with replacement cost endorsement, including coverage against vandalism and malicious mischief, covering all of Tenant's personal property in the Premises (including, without limitation, inventory, trade fixtures, all and floor coverings, furniture and other personal property), and all leasehold improvements installed in the Premises by Tenant.

18. DESTRUCTION OF PREMISES: Upon the performance by the Tenant of all the covenants and agreements hereinabove set forth, in case the leased premises or any part thereof shall at any time be destroyed or so damaged as to be unfit for occupancy or use by the Tenant, then, and in that event, the Landlord shall have to option: (1) to terminate this Lease; (2) to repair and rebuild the said premises remitting rents hereby reserved or a fair and just proportion thereof according to the damage sustained, until the said premises are reinstated and made fit for occupancy and use and in the event the Landlord elects to exercise the option to repair and rebuild, the same shall be done and completed within one hundred eighty (180) days from the date said damage occurred; otherwise, the Tenant shall have the option to terminate this Lease.

19. DAMAGE TO TENANTS PROPERTY: The Tenant assumes all risks of any damage or loss to Tenant's property that may occur by reason of water or the bursting or leaking of any pipes or waste water about said premises, or from any act of negligence of any co-Tenant or occupants of the building, or fire, or hurricane, or other Act of God, or from any cause whatsoever. The Landlord shall not be liable for any damage so incurred.

20. TOTAL TAKING: If the whole of the Premises shall be taken under power of eminent domain by any public or private authority, or conveyed by Landlord to said authority in lieu of such taking, then this Lease shall terminate as of the date of such taking.

21. PARTIAL TAKING: Landlord or Tenant may, at their election, terminate this Lease upon the occurrence of any condemnation or conveyance in lieu of condemnation, which affects any portion of the floor area of the premises. Upon the occurrence of such event, wither party shall give the other party notice of such election within thirty (30) days after receipt of notice of such pending

condemnation. If either party fails to give the other party such written notice within such thirty (30) day period, such party shall be conclusively deemed to have elected not to terminate this Lease. Notwithstanding any termination of this Lease hereunder, Tenant, at its election, may continue to occupy the Premises, subject to the terms of provisions of this lease, for the period between the date of such taking and the date when possession of the Premises shall be taken by the appropriate authority.

22. RESTORATION: If this Lease is not terminated under Section 22 above, Landlord, at Landlord's sole cost and expense, shall promptly negotiate and settle its claim for compensation with the condemning authority and upon receipt of the condemnation award shall promptly restore the remaining portions of the Premises, including any and all improvements made theretofore, to an architectural whole in substantially the same condition that the same were in prior to such taking. Upon any condemnation of a portion of the Premises, the Rent and any other charges payable by Tenant hereunder shall be proportionately reduced based upon the floor area of the Premises remaining after said taking.

23. THE AWARD: All compensation awarded for any taking, whether for the whole or a portion of the Premises, shall be the sole property of Landlord whether such compensation shall be awarded for diminution in the value of, or loss of, the leasehold or for diminution in the value of, or loss of the fee, or otherwise, and Tenant hereby assigns to landlord all of Tenant's right and title to and interest in any and all such compensation; provided, however, Landlord shall not be entitled to and Tenant shall have the sole right to retain any separate award made by the appropriating authority to Tenant for the cost of removal of leasehold improvements, fixtures, and personal improvements installed in the Premises by, or at the expense of, Tenant and for relocation expenses, and any separate award made by the appropriating authority directly to Tenant.

24. RELEASE: In the event of any termination of this Lease as the result of the provisions of Sections 21 or 22 above, Rent and any other charges, if any, paid in advance by Tenant shall be refunded to Tenant, and the Parties, effective as of such termination, shall be released from all liability and obligations thereafter arising under this Lease.

25. EVENTS OF DEFAULT; REMEDIES: If Tenant shall at any time be in default in the payment of rental or any other charges hereunder or in the performance of any of the covenants of this Lease, and Tenant shall fail to remedy such default within (a) fifteen (15) days after receipt of written notice thereof from Landlord if such default is as to payment of Rent, or any other charges payable by Tenant hereunder, or (b) within fifteen (15) days after receipt of written notice thereof if such default is nonmonetary (but Tenant shall not be deemed in default is such default cannot be cured in fifteen (15) days and Tenant commences to remedy such default within said fifteen (15) day period and proceeds therewith with due diligence until completion), or if Tenant shall be adjudged a bankrupt or shall make an assignment for the benefit of creditors, or if a receiver of any property of Tenant in or upon the Premises be appointed in any action, suit or proceeding by or against Tenant and not removed within sixty (60) days after appointment, or if the interest of Tenant in the Premises shall be sold under execution or other legal process, or if the Premises are sublet or this Lease is assigned without Landlord's consent, or if Tenant shall commit waste, Landlord may terminate this Lease, or without terminating this Lease, re-enter the Premises by summary proceedings, proceedings in forcible entry and detainer, eviction, or otherwise and may dispossess Tenant.

26. LANDLORD'S RIGHT TO RELIEF: If Tenant abandons the Premises and/or if Landlord elects to terminate Tenant's right to possession only without terminating this Lease as above provided, Landlord may remove from the Premises any and all property found therein and such repossession shall not release Tenant from Tenant's obligation to pay the rental herein. After any such repossession by Landlord without termination of the Lease, Landlord may relet the Premises or any part thereof to any person, firm or corporation and for such time and upon such terms as Landlord in Landlord's sole discretion may determine. Landlord may make repairs, alterations and additions in and to the Premises and redecorate the same to the extent deemed by Landlord necessary or desirable and Tenant, upon demand in writing, shall pay the reasonable cost thereof, (excluding tenant improvements for the replacement tenant) together with Landlord reasonable expenses of reletting, including any commissions and attorneys' fees relative thereto. If the rents collected by Landlord upon any such reletting are not sufficient to pay monthly the full amount of the monthly rent and other charges reserved herein, together with the reasonable costs of such repairs, alterations (excluding tenant improvements for any replacement tenant), additions, redecorating, and expenses, Tenant shall pay to Landlord the amount of each monthly deficiency upon demand in writing.

27. DAMAGES: Tenant agrees to be liable for and to pay to Landlord (i) all rent and other charges and sums due under this Lease at the time of termination of this Lease or upon the termination of Tenant's right of possession, as the case may be, and (ii) damages equal to the present value (discounted at the annual rate of interest then being paid on U.S. Treasury bonds which mature upon the expiration of this lease) of the excess amount, if any, of the rent and all other charges and sums due under this lease for the entire term over the rental received by Landlord for the Premises for such term, which damages shall be payable at such time as said damages as discounted by agreement of Landlord and Tenant, or by judicial decision, or at such time that said rent and other charges are payable under this Lease, which liability shall survive the terminations of this Lease, the re-entry into the Premises by Landlord, and the commencement of the action to secure possession of the Premises.

28. LANDLORD'S RIGHT TO REMOVE CHATTELS: Any and all property which may be removed from the Premises by Landlord in accordance with the terms of this Lease may be handled, removed, stored or otherwise disposed of by Landlord at the risk and expense of Tenant, and Landlord in no event shall be responsible for the preservation of safekeeping thereof. Tenant shall pay to Landlord upon demand in writing, any and all reasonable expenses incurred in connection with such removal and all storage charges against such property so long as the same shall be in Landlord's possession or under Landlord's control. If any property shall remain in the Premises or in the possession of Landlord and shall not be retaken by Tenant within a period of thirty (30) days from and after the time when the Premises are either abandoned by Tenant or repossessed by Landlord under the terms of this Lease, said property shall conclusively be deemed to have been forever abandoned by Tenant.

29. CONDITION OF PREMISES: If this lease be terminated for any reason whatsoever of if Landlord should re-enter the Premises as a result of any breach of Tenant hereunder without terminating the Lease, Tenant covenants, any other covenant herein to the contrary notwithstanding (except where this Lease is terminated following eminent domain proceeding), that (a) the Premises shall then be in the condition required by all applicable provisions of this Lease, and (b) Tenant shall perform any covenant contained in this Lease for the making of any repair, improvement, alternation or betterment to the Premises or for restoring or rebuilding any part thereof. For the breach of either of the foregoing obligations Landlord shall be entitled to recover and Tenant shall pay forthwith, without notice or other action by Landlord, the then cost of performing such obligation(s), together with interest at the Default Rate.

30. LANDLORD'S NONWAIVER: No failure by Landlord to insist upon the strict performance of any agreement, term, covenant or condition hereof or to exercise any right or remedy consequent upon a breach thereof, and no acceptance of full or partial rent during the continuance of any such breach, shall constitute a waiver of any such breach or of such agreement, term, covenant, or condition. No agreement, term, covenant, or condition hereof to be performed or complied with by Tenant, and no breach thereof, shall be waived, altered or modified except by a written instrument executed by Landlord. No waiver of any breach shall affect or alter this lease, but each and every agreement, tem, covenant and condition hereof shall continue in full force and effect with respect to any other then existing or subsequent breach thereof. No surrender of the Premises shall be effected by Landlord's acceptance of rent, or by Landlord's acceptance of the keys of the Premises, or by any other means whatsoever, unless the same is evidenced by Landlord's written agreement to accept surrender of the Premises; and if Landlord does accept surrender of the Premises, Tenant's obligations to pay rents and to perform the duties and provisions of this Lease required of Tenant hereunder shall not be released or terminated but shall continue for the remainder of the term of this Lease.

31. REMEDIES CUMULATIVE: Each right and remedy provided for in this lease shall be cumulative and shall in addition to every other right or remedy provided for in this Lease or now or hereafter existing at law or in equity or by statue or otherwise, and the exercise or beginning of the exercise by Landlord of any one or more of the rights or remedies provided for in this lease or now or hereafter existing at law or in equity or by statute or otherwise shall not preclude the simultaneous or later exercise by Landlord of any or all other rights or remedies provided for in this Lease or now or hereafter existing at law or in equity or by statue or otherwise. In the event of a default or threatened default by Tenant of any of the terms, provisions, covenants, conditions, rules and regulations of this lease, Landlord shall have the right to injunction and the right to invoke any remedy permitted to Landlord in law or in equity.

32. SELF-HELP: If Tenant shall default in the performance or observance of any agreement or condition in this Lease contained on its part to be performed or observed and shall not cure such default within any applicable curer period set forth herein, Landlord may, at its option, without waiving and claims for damages for breach of agreement, at any time thereafter cure such default for the account of Tenant, and any amount paid or any contractual liability incurred by Landlord in so doing shall be deemed paid or incurred for the account of Tenant and Tenant agrees to immediately reimburse Landlord therefore and save Landlord harmless therefrom; provided that Landlord may cure any such default as aforesaid prior to the expiration of aid waiting period, without notice to Tenant, if any emergency situation exists, or after notice to Tenant, if the cure of such default prior to the expiration of said waiting period if reasonably necessary to protect the Premises or Landlord's interest therein, or to prevent injury to damage to persons or property. If Tenant fails to reimburse Landlord upon demand for any amount paid for the account of Tenant hereunder, said amount (and all accrued interest thereon) shall be added to and become due as a part of the next payment of rent due hereunder.

33. BANKRUPTCY: Should the Tenant at anytime during the term of this Lease directly or indirectly suffer or permit an involuntary or voluntary petition in any proceedings under the Federal

Bankruptcy Act to be filed against it, or should Tenant voluntarily file any proceedings under any insolvency laws, or should a receiver or trustee be appointed for the Tenant's property, or should any order of any Court of competent jurisdiction be entered continuing the Tenant in possession of the leased premises in any Federal or State proceedings, or should the Tenant's leasehold interest be levied upon and the lien of said levy remain undischarged for thirty (30) days after said levy has been made, or should the Tenant fail to promptly make the necessary returns and reports required by State and Federal Law, or should the Tenant fail to promptly pay when due all taxes of whatever kind required to be paid to the Federal or State governments or any subdivision there, then and upon the happening of either or any of the aforesaid events, the Landlord shall have the right, at its election, to consider the same a material default on the part of the Tenant of the terms and provisions hereof, and in the event such default is not cured by the Tenant within thirty (30) days after written notice by Landlord to the Tenant of the existence of such default, the Landlord shall have the option to declare this Lease terminated and the interest of the Tenant therein forfeited, or the Landlord may exercise any other options herein conferred upon it. The pendency of any proceedings under the Bankruptcy Act or of any proceedings under State Insolvency Law to which the Tenant shall be a party shall not preclude the Landlord from exercising the option herein conferred upon it. Upon termination of the lease at the Landlord's option and/or as herein otherwise provided, the parties agree that the Court having jurisdiction of the cause may require and direct the re-delivery to the Landlord of the entire leased premises, without notice to Tenant (which said Tenant hereby waives), upon motion or application of the Landlord. All revenues derived from or accruing from the leased premises subsequent to the date of the termination of said Lease shall constitute the property of the Landlord and the same is hereby declared to be a trust fund and shall not constitute as asset of the Tenant or its estate.

34. RECEIVERSHIP: The Tenant pledges and assigns unto the Landlord all of the rents, revenues, issues and profits which might otherwise accrue unto the Tenant for the use, enjoyment and operation of the leased premises. In connection with the aforementioned pledges and assigns, the Tenant covenants and agrees with the Landlord that if the Landlord, upon the default of the Lease and after giving proper notice to the Tenant as provided in this Lease, elects to file a suit in any Court having jurisdiction to enforce the Lease and protect the Landlord's rights thereunder, then the Landlord may, ancillary to such suit, apply to the appropriate Court for the appointment of a receiver of all and singular, the leased premises and the improvements and building(s) located thereon, and thereupon it is expressly covenanted and agreed that in such event, Tenant consents to the appointment of said receiver and that the Court, without notice to Tenant, may appoint a receiver with the usual powers and duties of receivers in like cases, and such appointment shall be made by such Court as a matter of strict right to the Landlord and without reference to the adequacy or inadequacy of the value of the property which is subject to the Landlord's lien, or to the solvency or insolvency of the Tenant, and without reference to the commission of waste.

35. SUBORDINATION: Tenant hereby subordinates this Lease to the lien of any deed of trust, mortgage or mortgages now or hereafter placed upon Landlord's interest in the Premises; provided, however, that Landlord shall procure from any such mortgagee an agreement, in writing, in form and substance reasonably acceptable to Tenant, which acceptance shall be deemed given if such agreement provides in substance that so long as Tenant substantially performs the obligations imposed upon Tenant hereunder within the applicable grace or cure period, its tenancy will not be disturbed, not its rights under this Lease affected by, and default under such mortgage nor shall Tenant be named as a defendant in any foreclosure proceeding, and such agreement is otherwise customary in form and substance.

36. QUIET ENJOYMENT: Landlord covenants and agrees with Tenant that upon Tenant paying the Rent and observing and performing all of the terms, covenants and conditions on Tenant's par to be observed and performed hereunder, Tenant may peaceably and quietly have, hold, occupy and enjoy the Premises without hindrance or molestation from Landlord or any persons lawfully claiming through Landlord.

37. SECURITY DEPOSIT: Tenant herewith deposits with Landlord the sum of one (1) month's rent as a guarantee of the fulfillment of the terms and conditions of this Lease. Said deposit shall remain with the Landlord upon the same terms if Tenant exercises its option to renew this Lease. Tenant shall have the security deposit refunded at the end of the lease, assuming all payments due to Landlord have been made and the property is returned to the Landlord in clean condition, ordinary wear and tear excepted.

38. HOLDING OVER: In the event that Tenant or anyone claiming under Tenant shall continue occupancy of the Premises after the expiration of the original or renewal term of the Lease without any agreement in writing between Landlord and Tenant with respect thereto, and Landlord has not given its written consent to said continued occupancy, such occupancy shall not be deemed to extend or renew the term of this lease, but such occupancy shall continue as a tenancy from month to month upon the covenants, provisions and conditions herein contained and at two hundred percent (200%) of the Rental in effect upon the expiration of the term, prorated and payable for the period of such occupancy, and Landlord shall have the right to terminate such tenancy upon five (5) days' written notice to Tenant.

39. WAIVERS: Failure of either party to complain of any act or omission on the part of the other party, no matter how long the same may continue, shall not be deemed to be a waiver by said party of any of its rights hereunder. No waiver by either party at any time, express or implied, of any breach of any provision of this Lease shall be deemed a waiver of a breach of any other provisions of this Lease or a consent to any subsequent breach of the same or any other provisions. If any action by either party shall require the consent or approval of the other party, the other party's consent to or approval of such action on any one occasion shall not be deemed a consent to or approval of said action on any subsequent occasion or a consent to or approval of any other action on the same or any subsequent occasion.

40. NOTICES: All notices and other communications authorized or required hereunder shall be in writing and shall be given by mailing the same by certified mail or registered mail, return receipt requested, postage prepaid, and any such notice or other communication shall be deemed to have been given when received by the party to whom such notice or other communication shall be addressed, or on the date noted that the addressee has refused delivery or on the date that the notice is returned to sender due to the inability of the postal authorities to deliver. Notices shall be mailed to the address hereinabove set forth or such other address as either party may hereafter designate by notice to the other.

41. COST INCURRED BY BREACH: The Tenant shall be liable to the Landlord for all costs, expenses, reasonable attorney's fees and damages which may be incurred or sustained by the

Landlord by reason of the Tenant's breach of any of the provisions of this Indenture. Any sums due the Landlord under the provisions of this Item shall constitute a lien against the interest of the Tenant in the leased premises to the same extent and on the same conditions as delinquent rent would constitute a lien on said premises. The Landlord shall be liable to the Tenant for any costs, expenses, reasonable attorney's fees and damages which may be incurred or sustained by the Tenant by reason of the Landlord's breach of any of the covenants herein contained, providing Tenant asserts a claim therefore in the appropriate Court and secures a judgment thereon.

42 FORCE MAJEURE: In the event that Landlord or Tenant shall be delayed or hindered in or prevented from the performance of any act (other than Tenant's obligation to make payments of Rent and other charges required hereunder), by reason of strikes, lockout, unavailability of materials, failure of power, restrictive governmental laws or regulations, riots, insurrections, the act, failure to act, or default of the other party, war or other reason beyond its control, then performance of such act shall be excused for the period for the delay and the period of the performance of such act shall be extended for a period equivalent to the period of such delay. Notwithstanding the foregoing, lack of funds shall not be deemed to be a cause beyond control of either party.

43. ESTOPPEL CERTIFICATES: At any time and from time to time, Landlord and Tenant each agree, within five (5) days after request in writing from the other, to execute, acknowledge and deliver to the other or to any person designated by the other a statement in writing certifying that his Lease is unmodified and is in full force and effect, or if there have been medications, that the same is in full force and effect as modified (stating the medications), that the other party is not in default in the performance of its covenants hereunder, or if there have been such defaults, specifying the same and the dates to which the rent and other charges have been paid, and such other matters as the requesting party may reasonably request.

44. INVALIDITY OF PARTICULAR PROVISION: If any term of provision of this Lease or the application hereto to any person or circumstance shall, to any extent, be invalid or unenforceable, the remainder of this Lease, or the application of such term or provision to persons or circumstances other than those as to which it is held invalid or unenforceable shall not be affected thereby, and each term and provision of this Lease shall be valid and be enforced to the fullest extent permitted by law.

45. CORPORATE TENANCY: If Tenant is a corporation, the undersigned officer of Tenant hereby warrants and certifies to Landlord that Tenant is a corporation in good standing and is authorized to do business in the State of Florida. The undersigned officer of Tenant hereby further warrants and certifies to Landlord that he or she, as such officer, is authorized and empowered to bind the corporation to the terms of this Lease by his or her signature thereto. Landlord, before it accepts and delivers this Lease, may require Tenant to supply it with a certified copy of the corporate resolution authorizing the execution of this Lease by Tenant. If Tenant is a corporation (other than one whose shares are regularly and publicly traded on a recognized stock exchange), Tenant represents that the ownership and power to vote its entire outstanding capital stock belongs to and is vested in the officer of officers executing this Lease or members of his, her or their immediate family. If there shall occur any change in the ownership and/or power to vote the majority of the outstanding capital stock of Tenant, whether such change of ownership is by sale, assignment, bequest, inheritance, operation of law or otherwise, without the prior written consent of Landlord, then Landlord shall have the option to terminate this Lease upon thirty (30) days' written notice to Tenant, furthermore, Tenant shall have an affirmative obligation to notify immediately Landlord or any such change.

46. CAPTIONS AND DEFINITIONS: The captions of the Sections of this Lease are for convenience only and are not a part of this Lease and do not in any way limit or amplify the terms and provisions of this Lease. The word “Landlord” and the pronouns referring thereto, shall mean, where the context so admits or requires, the persons, firm or corporation made herein as landlord or the mortgagee in possession for the time being of the land and building comprising of the Premises. Any pronoun shall be read in the singular or plural number and in such gender as the context may require. Except as in this Lease otherwise provided, the terms and provisions of this Lease shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns.

47. ENTIRE AGREEMENT: This instrument contains the entire and only agreement between the parties and no oral statement or representations or prior written matter not contained in this instrument shall have any force and effect. This Lease shall not be modified in any way except by a writing executed by both parties.

48. NO PARTNERSHIP: Landlord is not and shall not become by this Lease or by any rights granted or reserved herein a partner or joint venture of or with Tenant in the conduct of Tenant’s business or otherwise.

49. LIABILITY OF LANDLORD:

(a) If Landlord should sell or otherwise transfer Landlord’s interest in the Premises, Tenant agrees that landlord shall thereafter have no liability to Tenant under this Lease or any modification or amendment thereof or extensions or renewals thereof, except for such liabilities which might have accrued prior to the date of such sale or transfer of Landlord’s interest. Landlord shall be liable under this Lease only while owner of the Premises provided that any successor in interest to Landlord hereunder shall assume such obligations and liabilities as of the date Landlord’s interest in the Premises is sold, assigned, or otherwise transferred hereunder.

(b) If Landlord shall fail to perform any covenant, term or condition of this Lease upon Landlord’s part to be performed or if Landlord shall be liable to Tenant in any way arising out of this Lease, or pursuant to statute, law, ordinance or regulation, or under the common law, and, as a consequence, if Tenant shall recover a money judgment against Landlord, such judgment shall be satisfied only out of the proceeds received at a judicial sale upon execution and levy against the right, title and interest of Landlord in the Premises. If Landlord is an individual, a trustee of a trust or a company, Landlord’s obligations hereunder shall not be binding upon, nor shall there be any personal liability by, Landlord individually, the trustees of said trust, the beneficiaries of said trust, the company, or the partners of the company.

50. EARLY TERMINATION: Tenant may terminate this lease at any time after the first 12 months of this lease upon payment to Landlord of a sum equal to 12 months rent in which event both parties shall be released from any further liability or obligation under this lease.

IN WITNESS WHEREOF, the parties hereto have executed this Lease the day and year first above written.

WITNESS:

/s/
Printed Name:

/s/
Printed Name:

LANDLORD:
Hawley-Wiggins, LLC, a Florida limited liability company

BY: /s/ Phillip L. Hawley
Phillip L. Hawley, Manager

TENANT:
Oragenics, Inc., a Florida corporation

/s/
Printed Name:

BY: /s/ Brian Bohunicky

ITS: Chief Financial Officer

/s/
Printed Name:

STATE OF FLORIDA
COUNTY OF ALACHUA

The foregoing instrument was acknowledged before me this 28th day of October, 2011, by Phillip L. Hawley as Manager of Hawley-Wiggins, LLC, a Florida limited liability company, [ ] who is personally known to me or [ ] who has produced his Florida driver's license as identification and who did take an oath.

/s/ Corinne Marie Jarvis
NOTARY PUBLIC STATE OF FLORIDA
Printed Name: Corinne Marie Jarvis

STATE OF FLORIDA
COUNTY OF ALACHUA

The foregoing instrument was acknowledged before me this day of November 4, 2011, by Brian Bohunicky as Chief Financial Officer, on behalf of Oragenics, Inc., a Florida corporation, [ ] who is personally known to me or ☑ who has produced his Florida driver's license as identification and who did take an oath.

/s/ Emily McDonnell Richeson
NOTARY PUBLIC STATE OF FLORIDA
Printed Name: /s/ Emily McDonnell Richeson

EXHIBIT B

LEASEHOLD IMPROVEMENTS

Landlord agrees that, subject to delays due to causes beyond Landlord's control, it will, at its own expense, do the following work to the Premises:

As provided in plans prepared by _____ ,
Project No.: _____

Exhibit 10.28

LICENSE AGREEMENT

Between

Oragenics Inc

and

The Texas A& M University System

This agreement ("Agreement") is made between Oragenics, Inc., a corporation with principal offices in Tampa, Florida, ("ORAGENICS") and The Texas A&M University System, an agency of the State of Texas, with principal offices in College Station, Texas, ("SYSTEM"), collectively referred to as "Parties" and individually as "Party."

W I T N E S S E T H :

WHEREAS, SYSTEM and ORAGENICS are the joint owners of a certain intellectual property related to "new antibiotic variants of mutacin 1140", and

WHEREAS, SYSTEM desires that such intellectual property be commercialized for the public benefit and welfare; and

WHEREAS, ORAGENICS has represented that it has certain marketing, technical and financial capabilities, and that it will undertake a thorough and diligent program of development and commercialization of SYSTEM's intellectual property for public benefit; and

WHEREAS, SYSTEM is willing to grant to ORAGENICS, and ORAGENICS is willing to accept, a license to use SYSTEM's intellectual property, upon the terms and conditions below.

NOW THEREFORE, in consideration of the mutual covenants and premises contained in this Agreement, the receipt and sufficiency of which is acknowledged, the Parties agree as follows:

ARTICLE I — DEFINITIONS

1.01 "LICENSED TECHNOLOGY" means the Parties' rights in their jointly owned proprietary technology relating to SYSTEM Disclosure of Invention Number TAMUS 3447 entitled "Site Directed Mutagenesis of Mutacin 1140 and Its Effect on Bactericidal Activity," and for the purposes of this Agreement, MATERIALS.

1.02 "PATENT RIGHTS" means the Parties' rights in each:

(a) United States patent application filed for protection of LICENSED TECHNOLOGY;

(b) Each divisional, continuation, or continuation-in-part application of the patent applications described in (a) above to the extent the claims are directed to subject matter specifically described in such patent applications;

(c) Equivalent patent application in each country other than the United States which claims priority under the applications described in (a) or (b) above; and

(d) Patent issuing from the applications described above and each extension or reissue of such patents.

1.03 “LICENSED PRODUCT’ or “LICENSED PRODUCTS” means any product, process, or composition of matter that is within the scope of any Valid Claim of PATENT RIGHTS. Valid Claim means and includes a claim of a patent application or an unexpired patent or a patent whose expiration date has been extended by law, so long as the claim has not been held invalid and/or unenforceable in an unappealable decision of a court or other authority of competent jurisdiction.

1.04 “MATERIAL” or “MATERIALS” means the *Streptococcus mutans* JH1140 mutant strains listed in Exhibit A. For the purposes of this Agreement, MATERIALS shall also include any progeny, unmodified derivatives and modifications therefrom, specifically modifications substantially based on, or incorporating a substantial element of, the MATERIALS, or any modifications which are not new or not obviously distinct from the MATERIALS.

1.05 “EFFECTIVE DATE’ means the date this Agreement has been executed by the last Party.

1.06 “NET SALES’ means ORAGENICS’ and its sublicensees’ receipts for sales of LICENSED PRODUCTS or for services requiring the use of LICENSED PRODUCTS less the sum of the following:

(a) sales taxes, tariffs, duties and/or use taxes directly imposed with reference to particular sales;

(b) outbound transportation prepaid or allowed; and

(c) amounts allowed or credited on returns.

Commissions paid to individuals, whether independent sales agents or regularly employed by ORAGENICS, and the cost of collections may not be deducted from NET SALES.

1.07 “TERRITORY” means worldwide.

ARTICLE II — LICENSE GRANT

2.01 Grant. SYSTEM grants ORAGENICS an exclusive license and right under SYSTEM’s rights in PATENT RIGHTS and LICENSED TECHNOLOGY to make, have made, import, export, use, and sell the LICENSED PRODUCTS in the TERRITORY, and to grant sublicenses of the same scope, to the end of the term of this Agreement as prescribed in Article VIII.

2.02 Reservation. SYSTEM reserves an irrevocable, nonexclusive, royalty-free right to practice the grant made in paragraph 2.01 for research and educational purposes only, and not for commercial purposes.

ARTICLE III — CONSIDERATION

3.01 License Fec. hi consideration for the license granted in this Agreement, ORAGENICS must make an initial payment in the amount of five thousand dollars ($5,000). This payment is due no later than thirty (30) days after the EFFECTIVE DATE. Failure to make this payment within the specified period will cause this Agreement to immediately terminate.

3.02 Royalty Rate. As additional consideration for the license granted in this Agreement, ORAGENICS must remit to SYSTEM a royalty of five percent (5%) of NET SALES. ORAGENICS may not accept anything of value in lieu of money payment without the express written permission of SYSTEM.

3.03 Royalty Stacking. In the event that LICENSED PRODUCT contains technology subject to royalties payable to third parties, the royalty due in accordance with paragraph 3.02 shall be reduced by one half of the royalty due to third parties, but in no event shall royalties due to SYSTEM under this Agreement be less than two percent (2%) of NET SALES. LICENSEE shall provide evidence to SYSTEM of its royalties due to third parties in association with a LICENSED PRODUCT.

3.04 Minimum Annual Consideration. In order to maintain this exclusive license to PATENT RIGHTS and LICENSED TECHNOLOGY, ORAGENICS must pay SYSTEM minimum annual consideration according to the following schedule:

(a) Calendar Year 2014 and each year thereafter prior to the Calendar Year of the first sale of a LICENSED PRODUCT	$ 15,000
(b) Calendar Year of the first sale of a LICENSED PRODUCT and every year thereafter through the expiration of this Agreement	$100,000

In the event that ORAGENICS' payment of royalties for the Calendar Year due under paragraph 3.02 do not meet or exceed the required minimum annual consideration, ORAGENICS' royalty payment for the last quarter of the Calendar Year must include payment of the balance needed to achieve the required minimum. If this Agreement expires or is terminated before the end of a Calendar Year, the corresponding minimum annual consideration will be prorated for that year.

3.05 Patent Expense Responsibility. As additional consideration for the license granted in this Agreement, ORAGENICS will be responsible for all expenses incurred in the filing, prosecution and maintenance of PATENT RIGHTS, as further described in Article VI.

ARTICLE IV — SUBLICENSES

4.01 Sublicenses. ORAGENICS may grant sublicenses to persons, firms or corporations under such conditions as it may arrange, as consistent with this Agreement, as long as each such sublicense comports with all applicable law, rules and regulations and provided that ORAGENICS includes the following in any of its sublicenses and any other provisions that logically would flow-down to any sublicensees:

1. **Indemnification. [INSERT NAME OF SUBLICENSEE] MUST AT ALL TIMES DURING AND AFTER THE TERM OF THIS AGREEMENT INDEMNIFY, DEFEND, AND HOLD HARMLESS THE TEXAS A&M UNIVERSITY SYSTEM ("SYSTEM"), ITS REGENTS, OFFICERS, AND EMPLOYEES AGAINST ANY CLAIM, PROCEEDING, DEMAND, LIABILITY OR EXPENSE (INCLUDING LEGAL EXPENSE AND REASONABLE ATTORNEYS' FEES) WHICH RELATES TO INJURY TO PERSONS OR PROPERTY, ANY ACTION BROUGHT BY A THIRD PARTY ALLEGING INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OR AGAINST ANY OTHER CLAIM, PROCEEDING, DEMAND, EXPENSE, OR LIABILITY OF ANY KIND RESULTING FROM THE PRODUCTION, MANUFACTURE, SALE, COMMERCIAL USE, LEASE, CONSUMPTION, OR ADVERTISEMENT OF LICENSED PRODUCTS OR ARISING FROM ANY OBLIGATION OF [INSERT NAME OF SUBLICENSEE] UNDER THIS AGREEMENT.**

2. Compliance with Law. [insert sublicensee name] ,must comply with all applicable federal, state and local laws and regulations in its exercise of all rights granted under this Agreement.

4.02 Sublicensee Consideration. Sales of LICENSED PRODUCTS by each sublicensee will be subject to the unit royalty due to SYSTEM prescribed in paragraph 3.02. Further, for any sublicense executed within two years of the EFFECTIVE DATE of this Agreement, ORAGENICS must pay SYSTEM forty percent (40%) of other considerations not in the form of royalty received by ORAGENICS from each sublicensee for a grant of rights in PATENT RIGHTS or LICENSED TECHNOLOGY. For any sublicense executed after two years of the EFFECTIVE DATE of this Agreement, ORAGENICS must pay SYSTEM twenty percent (20%) of any such other considerations from each sublicensee. Notwithstanding the above, ORAGENICS may not be required to remit to SYSTEM any portion of funds it receives from any sublicensee(s) when the funds are documented in writing as payments for the following purposes: (i) research, development, or testing of LICENSED PRODUCTS, or (ii) patent expenses for protection of PATENT RIGHTS to which the sublicensee is contributing.

4.03 Reporting. ORAGENICS must notify SYSTEM of the grant of sublicense to a third party and must provide SYSTEM with copies of each sublicense and of each sublicensee's report as is pertinent to calculation of amounts due SYSTEM under this Agreement.

4.04 Non-Cash Transactions. ORAGENICS may not accept anything of value in lieu of money payment under a sublicense without the express written permission of SYSTEM, which shall not be unreasonably withheld or delayed,

ARTICLE V — ORAGENICS RESPONSIBILITIES

5.01 Commercial Development Milestones. In accomplishing the development and commercialization under this Agreement, ORAGENICS shall use commercially reasonable efforts to achieve the following milestones to the satisfaction of SYSTEM:

Milestone	*Due Date for First Occurrence*	*Milestone Achievement Payment*
Enrollment of the first patient in a Phase I clinical trial of a Product	June 1, 2015	$ 50,000
Successful completion of a Phase II clinical trial of a Product, where "successful completion" means enrollment of the first patient in a Phase III clinical trial of a Product	June 1, 2019	$100,000
Successful completion of a Phase III clinical trial of a Product, where "successful completion" means receipt of an approved New Drug Application (NDA) from the FDA or foreign equivalent for a Product	June 1, 2022	$150,000
First sale of a Product	June 1, 2025	$400,000

For the purposes of this Section 5.01, a "Product" means a therapeutic composition within the LICENSED PRODUCTS that is selected for entry into clinical trials for a specified indication. Milestone Achievement Payments, according to the above schedule, shall be payable to SYSTEM upon the attainment of the milestone with respect to each Product. LICENSEE shall provide written notification to SYSTEM within thirty (30) days of achieving each milestone.

5.02 Failure to Accomplish Milestones. Should ORAGENICS fail to achieve any milestone specified in paragraph 5.01, or should ORAGENICS fail to record NET SALES for two (2) consecutive Calendar Years once sales begin, SYSTEM, at its sole option, may waive the requirement to achieve the milestone, renegotiate the missed milestone, or terminate this Agreement under paragraph 8.03.

5.03 Legal Compliance. ORAGENICS must comply with all applicable federal, state and local laws and regulations in its exercise of all rights granted by SYSTEM under this Agreement.

5.04 No Royalties for Sales to U.S. Government. Under 35 USC Section 200-212, ORAGENICS has no duty to pay SYSTEM royalties under this Agreement on NET SALES made to the United States Government, including any United States Government agency. ORAGENICS must reduce the amount charged for a LICENSED PRODUCT sold to the United States Government by an amount equal to the royalty otherwise due SYSTEM.

5.05 U.S. Manufacture. Under 35 USC Section 200-212, LICENSED PRODUCTS must be manufactured substantially in the United States of America.

ARTICLE VI — PROTECTION OF INTELLECTUAL PROPERTY

6.01 Authorization. As to prosecution, registration, and/or protection of PATENT RIGHTS, SYSTEM hereby authorizes ORAGENICS to: 1) direct the preparation and filing of patent applications, 2) direct the prosecution of broad patent claims for the mutual benefit of ORAGENICS and SYSTEM, 3) maintain U.S. and non-U.S. issued and granted patents, and 4) be invoiced directly by ORAGENICS' outside patent counsel (as approved by SYSTEM under paragraph 6.02 herein) and/or annuity service providers for patent prosecution and associated maintenance fees and costs.

6.02 Selection of Counsel. ORAGENICS may select an outside patent counsel (Counsel) law firm staffed by experienced, reputable, and licensed intellectual property attorneys for the prosecution, registration, protection, and maintenance of PATENT RIGHTS. ORAGENICS will notify SYSTEM of its selection of Counsel.

6.03 Contract with Counsel. ORAGENICS shall execute a written agreement with Counsel establishing that: 1) the attorney/client relationship relative to the prosecution, registration, or protection of PATENT RIGHTS will be with SYSTEM and ORAGENICS jointly; 2) Counsel will not take any actions adverse to the interests of SYSTEM in relation to PATENT RIGHTS including, for example and without limitation, any future invalidity or adverse litigation actions; 3) costs for prosecution, registration, or protection of PATENT RIGHTS will be invoiced directly to ORAGENICS with a courtesy copy of the. invoice to SYSTEM; and 4) SYSTEM will not be responsible for payment of invoices relating to prosecution, registration, or protection of PATENT RIGHTS conducted under this Agreement, including, without limitation, attorneys' fees, costs, official filing fees, and foreign associates' fees and costs. ORAGENICS shall provide a copy of such written agreement to SYSTEM. Additionally, ORAGENICS shall ensure that Counsel promptly signs the standard Outside Counsel Agreement, which Counsel can obtain from SYSTEM's Office of General Counsel.

6.04 Approvals. ORAGENICS shall notify SYSTEM before any substantive actions are taken in prosecuting, continuing, or abandoning any patents or patent applications or otherwise affecting PATENT RIGHTS. and ORAGENICS will instruct Counsel to so notify SYSTEM. In addition to other substantive actions, ORAGENICS and SYSTEM must jointly approve the filing of any action or application that seeks to, or effects, changes in inventorship related to PATENT RIGHTS, and will so instruct Counsel. ORAGENICS and SYSTEM must jointly approve how to proceed with any substantive actions relating to and/or affecting PATENT RIGHTS.

6.05 Patent Maintenance. During the term of this Agreement, ORAGENICS shall be directly responsible for annual or periodic annuity payments to maintain the pendency of non-U.S. patent applications in countries that require such annual or periodic annuities. Furthermore, during the term of this Agreement, ORAGENICS agrees to continue any required annual and periodic payments for maintenance of U.S. and non-U.S. issued and granted patents that ORAGENICS and SYSTEM jointly agree to procure.

6.06 Patent Maintenance Contract. ORAGENICS shall engage Counsel or a reputable annuity service to be responsible for docketing and payment of annual or periodic annuities and maintenance fees for both U.S. and non-U.S. pending applications and U.S. and non-U.S. issued and granted patents during the term of this Agreement.

6.07 Confidential Communications. SYSTEM and ORAGENICS have a community of interest with regard to work conducted in relation to PATENT RIGHTS due to their common interest in the generation of enforceable intellectual property rights relating to LICENSED PRODUCTS. Any communications between ORAGENICS and Counsel shall not be confidential vis-à-vis SYSTEM, but shall be otherwise confidential and protected by attorney client privilege.

6.08 Correspondence. ORAGENICS shall contemporaneously copy SYSTEM on all correspondence to and from any patent office, U.S. or non-U.S., including all periodic annuities and maintenance fees correspondence, and ORAGENICS agrees to so instruct Counsel to provide copies of such correspondence to SYSTEM. ORAGENICS further agrees that ORAGENICS- failure to timely provide such correspondence will be considered a breach of this Agreement in accordance midi Paragraph 8.03 below.

6.09 Information. To aid ORAGENICS in the prosecution, registration, protection, and maintenance of PATENT RIGHTS, SYSTEM at its expense will provide information, execute and deliver documents, and perform other acts as ORAGENICS reasonably requests from time to time.

6.10 Abandonment. Should ORAGENICS decide to abandon withdraw, or otherwise cease prosecution or maintenance of any U.S. or non-U.S. patent application or issued or granted patent for any reason (including but not limited to declining to make an annuity or maintenance payment), ORAGENICS shall so notify SYSTEM in writing at least sixty (60) days prior to taking (or not taking) any action which would result in abandonment, withdrawal, or lapse of such patent or application. SYSTEM shall then have the right to continue patent prosecution or maintenance of each such patent or application at its own expense and any such patent application and granted or issued patent there from will be excluded from LICENSED PATENT RIGHTS in this License Agreement.

6.11 Assignee. All patent applications and patents related to this Agreement shall have "The Texas A&M University System" and Oragenics, Inc." named as an assignee.

6.12 Previous Obligations. All previously approved. authorized, and accrued obligations and instructions under this Agreement, including ORAGENICS' reimbursement of patent expenses to SYSTEM, shall remain enforceable. All other matters survive per Paragraph 8.04 below.

6.13 Obligation to File or Maintain. Should ORAGENICS decide not to file or maintain patent protection, SYSTEM may, at its own expense, without reimbursement from ORAGENICS, file, prosecute, or maintain the patent protection and ORAGENICS hereby agrees that any such patent will be excluded from the rights granted herein.

ARTICLE VII — PAYMENTS AND REPORTS

7.01 When Payments are Due. Unless otherwise specified, ORAGENICS must make payments to The Texas A&M University System, in College Station. Texas, not later than sixty (60) days after the last day of the calendar quarter in which they accrue.

7.02 Royalty Reports. ORAGENICS must provide a sales report to SYSTEM each quarter, providing information sufficient to allow SYSTEM to calculate amounts due SYSTEM for the reporting period. No quarterly reports are due until sales of LICENSED PRODUCTS begin. After product sales begin, quarterly reports shall be provided even if no royalties accrued during the quarter.

7.03 Currency. Payment due to SYSTEM must be paid in U.S. dollars. Royalty payments requiring conversion must use the exchange rate as reported in The Wall Street Journal on the last business day of the royalty reporting period.

7.04 Inspection of Books and Records. At its own expense, SYSTEM may no more than once annually inspect ORAGENICS' books and records as needed to determine royalties payable. ORAGENICS must maintain those books and records for at least three (3) years following the dates of the underlying transactions. Any inspections will be in confidence and conducted during ordinary business hours, and SYSTEM will provide ORAGENICS advance notice no less than two (2) weeks before making an inspection. SYSTEM may employ a Certified Public Accountant for this purpose. If SYSTEM's audit identifies a shortage of five percent (5%) or more of amounts due to SYSTEM, then ORAGENICS must pay the costs of SYSTEM's audit. ORAGENICS must pay all amounts due *as* a consequence of an audit to SYSTEM promptly, with interest.

7.05 Interest Charges. SYSTEM may, in its sole discretion, charge daily interest on overdue payments commencing on the 31st day after the payment is due, compounded monthly, at the lower of either 1.5% per month or the highest legal interest rate. The payment of interest will not foreclose SYSTEM from exercising any other rights it may have due to the lateness of any payment.

7.06 Commercialization Report. Within sixty (60) days following the close of each Calendar Year, ORAGENICS shall deliver to SYSTEM a written report as to ORAGENICS' efforts and accomplishments during the preceding year in commercializing LICENSED PRODUCTS, as well as its commercialization plans for the coming year.

ARTICLE VIII — TERM AND TERMINATION

8.01 Expiration. This Agreement, unless sooner terminated as provided below, will remain in effect until (a) failure to obtain at least one issued patent for protection of LICENSED TECHNOLOGY, (b) expiration of the last to expire patent under PATENT RIGHTS, or (c) final and unappealable determination by a court of competent jurisdiction that PATENT RIGHTS are invalid.

8.02 Termination by ORAGENICS. ORAGENICS may terminate this Agreement by providing written notice to SYSTEM at least ninety (90) days before the termination is to take effect.

8.03 Termination by System. If ORAGENICS materially breaches this Agreement, SYSTEM may give ORAGENICS written notice of the breach. ORAGENICS will have a period of sixty (60) days from receipt of the notice to cure the breach. If ORAGENICS does not cure the breach within this period, SYSTEM may terminate this Agreement without further notice.

8.04 Matters Surviving Termination. All accrued obligations and claims, including payment of patent expenses, license fee obligations, royalty obligations, minimum annual consideration obligations, interest charge obligations, and all other financial obligations, and claims or causes of action for breach of this Agreement, will survive termination of this Agreement. Obligations of confidentiality will survive termination of this Agreement. This section controls in the case of a conflict with any other section of this Agreement.

ARTICLE IX — INDEMNIFICATION AND REPRESENTATION

9.01 Indemnification. **ORAGENICS MUST AT ALL TIMES DURING AND AFTER THE TERM OF THIS AGREEMENT INDEMNIFY, DEFEND, AND HOLD HARM LESS SYSTEM, ITS REGENTS, OFFICERS AND EMPLOYEES AGAINST ANY CLAIM, PROCEEDING, DEMAND, LIABILITY OR EXPENSE (INCLUDING LEGAL EXPENSE AND REASONABLE ATTORNEYS' FEES) WHICH RELATES TO INJURY TO PERSONS OR PROPERTY, ANY ACTION BROUGHT BY A THIRD PARTY ALLEGING INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OR AGAINST ANY OTHER CLAIM, PROCEEDING, DEMAND, EXPENSE, OR LIABILITY OF ANY KIND RESULTING FROM THE PRODUCTION, MANUFACTURE, SALE, COMMERCIAL USE, LEASE, CONSUMPTION, OR ADVERTISEMENT OF LICENSED PRODUCTS OR ARISING FROM ANY OBLIGATION OF ORAGENICS OR SUBLICENSEE(S) UNDER THIS AGREEMENT.**

9.02 Representation. SYSTEM represents that it jointly owns with ORAGENICS PATENT RIGHTS and LICENSED TECHNOLOGY and has the full right and power to grant the license in paragraph 2.01, **and** that there are no outstanding agreements, assignments, or encumbrances inconsistent with the provisions of this Agreement. **SYSTEM MAKES NO OTHER REPRESENTATIONS AND EXTENDS NO OTHER WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LI M I TED TO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, NOR DOES SYSTEM ASSUME ANY OBLIGATIONS REGARDING INFRINGEMENT OF PATENT RIGHTS OR OTHER RIGHTS OF THIRD PARTIES DUE TO ORAGENICS' ACTIVITIES UNDER THIS AGREEMENT.**

ARTICLE X — NOTICES

10.01 Notices. Payments, notices, or other communications required by this Agreement will be sufficiently made or given if mailed by certified First Class United States mail, postage pre-paid, or by commercial carrier (e.g., FedEx, UPS, etc.) when the carrier maintains receipt or record of delivery, addressed to the address stated below, or to the last address specified in writing by the intended recipient.

If to SYSTEM:

Associate Vice Chancellor
Office of Technology Commercialization
3369 TAMU
College Station, Texas, USA 77843-3369
Phone: 979-847-8682
FAX: 979-845-1402

If to ORAGENICS:

CEO, Oragenics,
3000 Bayport Dr. Suite 685
Tampa, FL 33607
Phone: 813-286-7900
FAX: 813-286-7904

ARTICLE XI — MISCELLANEOUS PROVISIONS

11.01 Notice of Infringement. Each Party must promptly notify the other in writing of any alleged infringement of PATENT RIGHTS. Within thirty (30) days after receipt of such notice, SYSTEM and ORAGENICS will formulate a strategy for resolving the alleged infringement. SYSTEM's involvement, participation, and representation in any enforcement litigation is contingent upon SYSTEM receiving the consent of the Attorney General of the State of Texas, and ORAGENICS' obligation to enforce PATENT RIGHTS is contingent upon SYSTEM being a party to any suit to the extent required by law.

11.02 Export Controls. SYSTEM is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities, and its obligations under this Agreement are contingent on compliance with applicable laws and regulations. The transfer of certain technical data and commodities may require a license from the cognizant agency of the United States Government or written assurances by ORAGENICS that ORAGENICS will not export data or commodities to certain countries without advance approval of such agency. SYSTEM neither represents that a license will not be required nor that, if required, it will be issued.

11.03 Confidential Information. Sales reports submitted by ORAGENICS under ARTICLE VII will be considered Confidential Information under this Agreement and not be disclosed by SYSTEM to any third party except as may be required by law, including but not limited to a valid court order or the Texas Public Information Act (Tex. Gov't Code Ch. 552). If the Parties contemplate exchanging other information of a confidential nature, they should enter into a separate confidentiality agreement.

11.04 Non-Use of Names. ORAGENICS may not use the names or any adaptation of the names of The Texas A&M University System, nor of any of its employees or members, in any advertising, promotional, or sales literature without the advance written consent of SYSTEM in each case, except that ORAGENICS may state that it is licensed by SYSTEM under PATENT RIGHTS.

11.05 Trademarks. ORAGENICS may select, own and use its own trademark on LICENSED PRODUCTS. However, SYSTEM does not grant ORAGENICS any license or other right under any trade name, trademark, or service mark owned or licensed by SYSTEM, Conversely, SYSTEM has no rights to trade names, trademarks, or service marks owned by ORAGENICS.

11.06 Assignment of this Agreement. This Agreement, with the rights and privileges it creates, is assignable only with the written consent of both Parties, which shall not be unreasonably withheld or, delayed.

11.07 Force Majeure. Other than an obligation for the payment of money, SYSTEM, upon receipt of documentation from ORAGENICS which it deems appropriate, must excuse any breach of this Agreement which is proximately caused by war, strike, act of God, or other similar circumstance normally deemed outside the control of well-managed businesses.

11.08 Entire Agreement. This Agreement contains the entire understanding of the Parties regarding PATENT RIGHTS and LICENSED TECHNOLOGY, and supersedes all other written and oral agreements between the Parties regarding PATENT RIGHTS and LICENSED TECHNOLOGY. It may be modified only by a written amendment signed by the Parties.

11.09 Governing Law. The substantive laws of the State of Texas (and not its conflict of law principles), USA, govern all matters arising out of or relating to this Agreement and all of the transactions it contemplates. Venue for any suit brought against SYSTEM in Texas state court must be in Brazos County, Texas under Tex. Educ. Code § 85.18, and venue for any suit brought against SYSTEM in federal court must be in the Houston Division of the Southern District of Texas. Venue for any suit brought against ORAGENICS must be in Hillsborough County, Florida, and venue for any suit brought against ORAGENICS in federal court must be in the Tampa Division of the Middle District of Florida.

11.10 Headings. Headings are solely for convenience of reference and are not part of, and may not be used to construe, this Agreement.

11.11 No Waiver; Severability. If any provision of this Agreement is invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions will not in any way be affected or impaired. A waiver of any breach of this Agreement does not waive any other breach of the same or other provision of this Agreement. A waiver is not effective unless made in writing.

11.12 Privileges and Immunities. SYSTEM is an agency of the State of Texas and nothing in this Agreement waives or relinquishes the right of SYSTEM to claim any exemptions, privileges, or immunities as may be provided by law.

11.13 Counterparts. This agreement may be executed in any number of counterparts, including facsimile or scanned PDF documents. Each such counterpart, facsimile, or scanned PDF document shall be deemed an original instrument, and all of which, together, shall constitute one and the same executed Agreement.

The Parties have caused this Agreement to become effective as of the date last executed below.

ORAGENICS,

/s/ John Bonfiglio

CEO, Oragenics, Inc.
Date: December 6, 2011

THE TEXAS A&M UNIVERSITY SYSTEM

/s/ Brett Cornwell

Brett Cornwell
Associate Vice Chancellor for Commercialization
Date: December 20, 2011

Exhibit A

MATERIALS

1. ***Streptococcus mutans* JH1140 *lanA* Trp4Ala**
2. ***Streptococcus mutans* JH1140 *lanA* DhaSAla**
3. ***Streptococcus mutans* JH1140 *lanA* Argl 3Asp**
4. ***Streptococcus mutans* JH1140 *lanA* Trp4insAla**
5. ***Streptococcus mutans* JH1140 *lanA* A Trp4**
6. ***Streptococcus mutans* JH1140 *lanA* Ala_s7insAla**

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 April 13, 2012, with respect to the 2011 and 2010 financial statements of Oragenics, Inc. We consent to the incorporation by reference in the Form S-8 Registration Statements (Nos. 333-110646, 333-150716 and 333-163083) of Oragenics, Inc. pertaining to the Oragenics, Inc. Amended and Restated 2002 Stock Incentive Plan.

/s/ Mayer Hoffman McCann P.C.

Certified Public Accountants

Clearwater, Florida

April 13, 2012

Exhibit 31.1

CERTIFICATION

I, John N. Bonfiglio, 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: April 16, 2012

/s/ John N. Bonfiglio
Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Michael Sullivan, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: April 16, 2012

/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, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John N. Bonfiglio, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

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

Dated this 16th day of April, 2012.

/s/ John N. Bonfiglio
John N. Bonfiglio,
President and Chief Executive Officer

Exhibit 32.2

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

In connection with the Annual Report of Oragenics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2010 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 16th day of April, 2012.

/s/ Michael Sullivan
Michael Sullivan
Chief Financial Officer