

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, 2009

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

For the transition period from to

Commission file number 001-32188

ORAGENICS, INC.

(Exact name of registrant as specified in its charter)

Florida

(State or Other Jurisdiction of  
Incorporation or Organization)

59-3410522

(IRS Employer  
Identification No.)

13700 Progress Blvd., Alachua, Florida  
(Address of Principal Executive Offices)

32615  
(Zip Code)

(386) 418-4018

(Issuer's Telephone Number, Including Area Code)

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

Title of each class  
None

Name of each exchange on which registered

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, 2009 was approximately \$8,303,178 based upon a last sales price of \$0.25 as reported by the OTCBB.

As of March 17, 2010, there were 108,203,148 shares of the registrant's Common Stock outstanding.

Documents Incorporated by Reference: Portions of the Proxy Statement for the registrant's 2010 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K.

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## FORWARD LOOKING STATEMENTS AND CERTAIN CONSIDERATIONS

This report, along with other documents that are publicly disseminated by us, contains or might contain forward-looking statements within the meaning of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements included in this report and in any subsequent filings made by us with the 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 continue to raise capital,
- We have incurred significant operating losses since our inception and cannot assure you that we will generate revenue or profit,
- As a result of our lack of financial liquidity and negative shareholders’ equity, our auditors have indicated there is uncertainty of our ability to continue as a “going concern,”
- If we fail to raise significant additional capital we may need to significantly curtail operations, marketing and development and it could cause us to be forced to cease operations,
- If we raise capital it may be on terms that result in substantial dilution to our existing shareholders,
- We may be unable to achieve sustainable commercial viability of our consumer products and acceptance of our proposed products,
- Orders we receive for our consumer products may be subject to terms and conditions that could result in their cancellation or the return of products to us,
- We may become dependent on a few large retail customers for sales of our consumer products,
- If we are unable to raise sufficient capital our license for our SMaRT™ Replacement Therapy and M 1140 with the University of Florida Research Foundation could be terminated,
- We are subject to extensive and costly regulation by the FDA, applicable international regulators and other regulatory bodies, which must approve our product candidates in development and could restrict or delay the sales and marketing of our products and products in development,
- 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 the current worldwide credit crisis and its impact on consumers and equity 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 new reporting requirements, which will increase our costs and require additional management resources.

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

## PART I

### ITEM 1. BUSINESS.

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

#### Overview

We are a multifaceted biopharmaceutical company focused on the discovery, development and commercialization of a variety of products and technologies. Our offices are in Tampa, Florida and Alachua, Florida. Our research and development facilities are located in Alachua, Florida, near the University of Florida where we have experienced scientific and management teams in place to lead the Company into what we anticipate will be an exciting new phase of operations. We have historically operated largely within the confines of the United States. We have also positioned ourselves for development of a global foundation, with international partners and customers.

#### Corporate History

Oragenics was founded in 1996 by Dr. Jeffrey Hillman and Dr. Robert Zahradnik to commercialize the fruits of 25 years of research. After earning a PhD in Molecular Genetics at Harvard, Dr. Hillman began his basic research into the concept of Replacement Therapy for preventing dental caries, or cavities, at the Forsyth Institute in Boston. He was recruited to continue his research at the University of Florida College of Dentistry in 1992. There, he continued to pursue the development of a genetically engineered strain of *Streptococcus mutans* that could prevent cavities by replacing the body's natural caries-causing strains of *S. mutans*. His work in replacement therapy also led to other discoveries such as MU 1140 and ProBiora3<sup>™</sup>.

#### Corporate Strategy

We have transitioned from a company with a focus purely on discovery and development to a company focused primarily on commercialization. Our overall strategy is to maximize shareholder value by commercializing and developing products internally and by seeking out alliances and strategic partnerships with major, global pharmaceutical, diagnostics and consumer products companies. To maximize shareholder value, we may internally develop or commercialize some of our technologies before entertaining investments or ventures from strategic investors or partners. As technologies proceed through the regulatory process, they become significantly more valuable. The difference in value can be an order of magnitude higher. As such, in certain cases, the return on investment on clinical trials that we fund can be exceptional. We intend to take each technology on a case-by-case basis to determine the most appropriate path to maximize shareholder value and ROI. We also intend on continuing the culture of innovation that fostered the creation of many of our technologies.

#### Our Technologies

We have a number of technologies, products and platforms. For ease in understanding, we have broken them down into four distinct groups. Each technology can be characterized as an over-the-counter consumer product or technology that requires the completion of all relevant FDA clinical trials and FDA approval before it can be marketed.

- (1) Consumer Healthcare
  - a. Oral probiotics that contain our ProBiora3<sup>™</sup> technology (food additive);
  - b. Products for weight loss that revolve around our LPT3-04<sup>™</sup> weight loss agent (food/nutritional supplement)
- (2) Antibiotics
  - a. DPOLT<sup>™</sup> lantibiotic synthesis platform (for generation of drug products);
  - b. MU 1140, *mutacin* (drug)
- (3) Biomarker Discovery
  - a. PIVIAT<sup>™</sup> (diagnostics, therapeutics, vaccines and drugs) and
  - b. PCMAT<sup>™</sup> (diagnostics, therapeutics, vaccines and drugs)

(4) Biologics

- a. SMaRT Replacement Therapy™ (biological drug)

**CONSUMER HEALTHCARE:**

Our Consumer Healthcare Division markets products that we have determined do not require pre-approval by the Food and Drug Administration and can be sold through retail channels. There are two product categories; (1) Oral Probiotics, and (2) Weight Loss.

**Oral Probiotic Product Category:**

Our oral probiotics revolve around the ProBiora3™ technology. ProBiora3™ employs three naturally occurring strains of beneficial bacteria which promote oral health. Probiotics are live microorganisms that confer a health benefit to their host when administered in adequate amounts. The beneficial bacteria in a probiotic formulation help to maintain a healthy balance with bacteria in the body. Examples of common probiotic applications are yogurt containing live cultures and *acidophilus* capsules to improve digestion, plus products for improved immune system response and vaginal and urinary tract health.

***Oral Biology***

According to Asa et al. (Journal of Clinical Microbiology 2005 Nov; 43(11) 5721-32), the oral cavity provides an ecological niche for over 700 bacterial species, some of which are responsible for periodontal disease (gum disease) and dental caries (tooth decay). Of all of the bacteria normally residing in a person's mouth, only about half a dozen are the primary cause of periodontal disease and dental caries.

***Regulatory Status of Oral Probiotics***

Probiotic products that make cosmetic or structure-function claims are generally able to enter the market without the need for extensive regulatory filings and clinical testing. This avenue, called GRAS ("Generally Recognized as Safe"), is available for products that are generally recognized as safe do not make any claim that they treat, prevent, or cure a disease, which would be considered to be drug claims. We intend to market our probiotic product in reliance on GRAS without making disease prevention claims.

***Market Opportunities***

**Oral Care:** The oral care market is exceptionally large and is expected to grow larger. It has been estimated by Packaged Facts that the US oral care market was \$9.1 billion in 2008 and that this market will break the \$10.9 billion mark by 2014. We believe, ProBiora3™ is the only comprehensive oral probiotic technology currently available in the oral care market.

**Companion Pets:** According to the APPA ("American Pet Products Association") Pet Owners Survey, in 2009/2010, approximately 62% of US households owned a pet, with 38.2 and 45.6 million households owning cats and dogs, respectively. The APPA also estimates that total pet industry expenditures in 2009 in the US were \$45.5 billion, representing an increase of 5.4% from 2008. Of this, \$10.4 billion was spent on Supplies/OTC Medicine, representing a 5.8% increase over 2008.

**Probiotics in general:** The Probiotics markets are expected to grow at a rapid pace during the next several years. According to MarketsandMarket, a research firm, the global probiotics market is expected to reach \$32.4 billion by 2014, which equates to a CAGR ("compound annual growth rate") of 12.6% from 2006 through 2014. Probiotics products are relatively common in Asia and Europe. The probiotics market in the U.S. is emerging, and products are available that address gastrointestinal problems and other uses, especially as nutritional supplements, food supplements or dietary aide products. Our oral probiotics products containing ProBiora3 are widely recognized as the first probiotic product designed for comprehensive oral care to hit the market. This has provided us, with what we believe to be, a significant first mover advantage.

## ***Marketing ProBiora3™***

To market ProBiora3™, we have developed a bifurcated strategy. We have branded the technology, ProBiora3™, as an active ingredient for licensing and private labeling. We also market products containing ProBiora3™ under our own house brand names. Our house brand products will contain different ratios, or blends, of the three natural strains contained in ProBiora3™ and potentially different delivery mechanisms such that each product will be tailored to the needs of specific markets. These products are:

- **EvoraPlus™**: a product with equal weight of all three strains that is optimally designed for the general consumer market
- **EvoraKids™**: a product that has a greater concentration of the strain designed to address tooth health, which is more of an issue for children.
- **Teddy's Pride™**: a product that has a mixture that is overloaded with two strains which focus on cleaner teeth and fresher breath, problems endemic with cats and dogs.

All three products have been launched and are available through various distribution channels.

*Large Retailers - The Drugstore & Big Box Retail Channels:* The process for product adoption by large retailers typically has five essential phases; (1) the incorporation of a product into a retailer's "planagram", (2) the assignment of a "vendor ID" to the vendor and the establishment of connectivity, typically using electronic data interchange, (3) the transmission and receipt of an initial order, (4) the fulfillment and delivery of the initial order, and (5) the subsequent re-order by the retailer to replenish inventory. In early November 2009, we received written confirmation that EvoraPlus™ would be included in the planagram of one of the nation's largest drugstore chains. In connection with our efforts with this drugstore chain, we established a vendor ID and have since received an initial order from this customer. We expect to continue to approach prospective retail customers regarding our consumer healthcare products and we are optimistic about our prospects.

*Grocery Store Channel:* We have received orders from several large regional grocery store chains. We are optimistic about the potential opportunities for our products in this channel, there can be no assurances, however, that our products will be successfully received by the marketplace through this channel. We are also in discussions with several grocery store chains including some of the largest grocery chains in the United States.

*International Interest:* We have experienced an increase in interest and demand for our consumer products internationally. To address such interests, we have retained a Director of International Sales and Marketing with substantial international marketing experience and we remain optimistic about potential future developments from this channel.

In addition to the distribution of our consumer healthcare products, we have participated in a trade show and have received broad based media coverage.

*Trade Show:* In mid-November, we exhibited our products at the Supply-Side West trade show, which is one of the largest raw material / ingredient shows in the world. We experienced a substantial amount of interest from a number of company representatives in attendance at the show and we are optimistic about the potential for future business arising from such initial interest.

*Media Exposure:* In July, a segment on EvoraPlus appeared on Fox News throughout the United States. This segment was followed by a subsequent segment that aired on November 4, 2009 on Fox News. We believe this media coverage was beneficial for us in our efforts to gain market traction and acceptance of our consumer healthcare products.

We remain optimistic about our marketing efforts. We also expect to increase the consumer awareness of our consumer products through advertising initiatives we have underway.

### ***EvoraPlus™ EvoraKids™ and Teddy's Pride™ - Description & Manufacturing***

EvoraPlus™ is a mint flavored probiotic tablet packaged in a 60 unit box with four 15-dose blister packs. EvoraKids™ comes in the same format as EvoraPlus™ except we have exchanged the flavoring to one that is preferable to children. The intended use for EvoraPlus™ and EvoraKids™ is for the consumer to take one tablet twice per day after brushing. As such, one box equals approximately one-month's supply of the product. These products are designed for repetitive use in order to achieve the intended benefits. We believe this feature provides the potential for recurring revenue as consumers who continue to seek the benefits of the products will need to continue to make purchases.

Teddy's Pride™ comes in powder form, which is odorless and tasteless. The powder is sprinkled on a pet's food once per day. It is sold in a pail containing a pre-measured measuring spoon that provides the pet the recommended dosage per application. Each pail provides a 60-day supply of Teddy's Pride™.

We have completely outsourced the manufacturing process for our probiotics products. We have qualified separate contract manufacturers for production of our active, ProBiora<sup>3</sup> probiotics blend, for powder bending and tablet manufacture, and for the finished packaging of our probiotics products. Each of our contract manufacturers is GMP certified with the ability to scale production as needed. Our arrangement with each of the manufacturers is that we place orders for components or finished product to be produced for a fixed fee which we are expected to pay on completion of the manufacturing process. Packaged probiotics products are shipped to us or to a destination specified by us, which would be a central distribution center in the case of either one of our larger drugstore chains or a private label distributor. We currently maintain an inventory of our products for direct online 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 do not have a long-term supply agreement or commitment with any of our manufacturers. Each manufacturer has the ability to terminate its services to us at any time. We have qualified and used at least two contract manufacturers for each step in our manufacturing process. Any manufacturer has the ability to terminate its services to us at any time. Our arrangements with the manufacturers are not exclusive and we are able to have our components/products contract manufactured at other facilities, which we have already qualified in the event of loss of any single relationship or if order volumes spike significantly.

### ***Competition to the ProBiora<sup>3</sup>™ Technology***

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*, a bacterial species isolated from the gastrointestinal tract, can reduce the levels of *Streptococcus mutans* in the mouth and may aid in the prevention of tooth decay. *Lactobacillus 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 *lactobacillus reuteri*, which is on the market today as GUM® PerioBalance® and is targeted to maintain oral health. Another probiotic bacteria for oral care is commercially available in the US from the supplier, Frutarum, (known as BLIS K12 probiotic); it is promoted for bad breath and contains the bacterium, *Streptococcus salivarius* K12. This bacterium principally colonizes the cheek and tongue surfaces in the oral cavity, and as such is promoted only for its oral care activity as an aid for halitosis. As compared to all of these competitors, ProBiora<sup>3</sup>™, with its unique blend of three proprietary probiotic strains, potentially has greater beneficial actions for maintaining oral health.

### **Weight Loss Product Category:**

The Company's weight loss products are based on the discovery of LPT3-04™. LPT3-04™ is a naturally occurring compound, which is normally consumed in the human diet in small amounts. Our scientists discovered that consumption of significantly larger amounts results 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 completely safe in humans.

### ***The Weight Loss & Diet Control Market***

According to Marketdata, Inc., the US Weight Loss & Diet Control market was approximately \$59 billion in 2008. Obesity is at epidemic proportions and is a global problem.

### ***Weight Loss Marketing Strategy***

Our strategy for our weight loss technology is to develop a house brand to market to consumers through channels similar to probiotics. We plan on developing several products under the house brand that vary by delivery mechanism. We expect to also develop a product for the pet market as well. We expect to essentially use two of the three channels that were developed for our oral probiotic; (1) DTC and (2) Mass Retail. We may also market directly to Medical Professionals and Veterinary Offices.

At present, we are re-formulating the delivery mechanism for LPT3-04. We expect to conduct clinical trials for efficacy sometime in 2010. Once these trials have been completed, if successful, we will launch a product containing the technology.

## ANTIBIOTICS:

### **DPOLT™**

The cornerstone of our antibiotics division is our Synthetic Chemistry Platform, DPOLT™ (Differentially Protected Orthogonal Lantionine Technology), which affords us the ability to synthesize a unique class of antibiotics known as lantibiotics. DPOLT™ is a patented, novel organic chemistry synthesis platform that will enable large scale, cost effective production of clinical grade MU 1140 and potentially 50 other known lantibiotics. Over the past 80 years, efforts to devise methods to investigate the usefulness of this class of antibiotics have met with uniform failure. We believe DPOLT™ can lead to 6-10 new antibiotics with novel mechanisms of action. This represents a substantial pipeline of antibiotics to replace ones that are currently failing due to the development of bacterial resistance.

### **MU 1140**

Through his work with *S. mutans* at the Harvard affiliated Forsyth Institute and later at the University of Florida, Dr. Hillman discovered MU 1140, or *mutacin*, a powerful lantibiotic that is produced in the oral cavity by the natural parent of the SMaRT™ strain. MU 1140 is an antibiotic that belongs to the novel class of molecules called lantibiotics. It is active against Gram positive bacteria responsible for a variety of clinically important diseases such as MRSA (methicillin-resistant *Staphylococcus aureus*) and VRE (vancomycin-resistant *Enterococcus faecalis*). In preliminary studies it has also been shown to be active against both growing and non-replicating *Mycobacterium tuberculosis* cells. Preclinical testing has demonstrated low toxicity, efficacy in animal models of infection, and good pharmacological properties. Sensitive bacteria show minimal ability to develop resistance to MU 1140. In general, preclinical studies indicate that it has the potential to replace current antibiotic drugs of last resort that are increasingly failing.

### **Market Opportunity**

According to the Center for Disease Control ("CDC"), Nosocomial infections are estimated to occur in 5% of all acute-care hospitalizations; the incidence rate is 5 infections per 1,000 patient-days. Based on the 35 million patients admitted to 7,000 acute-care institutions in the United States, the incidence of hospital-associated infections ("HAIs") is more than 2 million cases per year.<sup>2</sup> HAIs result in an additional 70,000 deaths (range 17,500-70,000) and an added expenditure in excess of \$4.5 billion. Nosocomial infections are estimated to more than double the mortality and morbidity risks of any admitted patient. This is the equivalent of 350,000 years of life lost in the United States. The critical care market for antibiotics is about \$7 billion in U.S.A. Cubicin®, a newer gram positive lipopeptide antibiotic, had 2009 revenues of \$562 million in the US. The need for novel antibiotics is increasing as a result of the growing resistance of target pathogens. The Center for Disease Control estimates that bacteria resistant to known antibiotics cause 44% of hospital infections; individual hospitals have resistant rates as high as 70% for many important gram positive infections. Vancomycin, introduced in 1956, serves as the last line of defense against certain life-threatening infections, but certain bacteria have developed strains which resist even vancomycin. The annual direct cost to treat HAIs is also quite high. The CDC estimates that the annual cost to be \$35.7 to \$45.0 billion dollars annually (adjusted to 2007 dollars).

Our antibiotic, MU 1140, is a new broad spectrum antibiotic that has demonstrated activity against a wide variety of disease-causing bacteria and a novel mechanism of action. Moreover, we believe there is no evidence for development of pathogen resistance to MU 1140. In light of the fact that pathogen resistance has become a major health problem associated with antibiotics in use today, we believe MU 1140 offers the potential to fulfill a significant and increasing medical need for non-resistant antibiotics.

### **Preclinical Studies**

Our scientists and others have conducted laboratory studies on MU 1140 to determine its activity as an antibacterial agent. To test MU 1140's ability to kill bacteria, standard microbiological testing methods were employed. MU 1140 was purified and incorporated into growth medium at different concentrations. The medium was then inoculated with the bacterium under study, and its ability to grow in the presence of MU 1140 was observed. The minimal inhibitory concentration (MIC) of MU 1140 to inhibit growth of the test bacterium was recorded. We believe the results of our laboratory studies demonstrate that MU 1140 is effective at killing a broad spectrum of bacteria, including *Streptococcus pneumoniae*, causing the predominant type of pneumonia and bacterial endocarditis. The antibiotic has also been shown to be effective against vancomycin-resistant *Staphylococcus aureus* and *Enterococcus faecalis*.

MU 1140 was found to kill all gram-positive bacteria tested at concentrations comparable to therapeutically effective antibiotics. A particularly interesting feature of MU 1140 is that none of the sensitive species of bacteria tested was able to acquire genetically stable resistance to purified MU 1140. During 2006 and 2007, we completed a significant preclinical study and demonstrated that MU 1140 is effective in an animal infection model of septicemia against *Staphylococcus aureus*. In 2007, further pharmacodynamic studies were done demonstrating the antimicrobial activity, its novel mechanism of action, synergy with an aminoglycoside, and utility of MU 1140, especially against drug resistant organisms, such as MRSA (methicillin-resistant *Staphylococcus aureus*), VRE, (vancomycin-resistant *Enterococcus faecalis*), and *Streptococcus pneumoniae*, all common and serious sources of infections in humans. Pilot pharmacokinetics studies were done. Since 2007, research work has been focused on scaling up the synthetic molecule through our Synthetic Chemistry Platform, DPOLT™ (Differentially Protected Orthogonal Lantionine Technology).

### ***Intellectual Property***

We have exclusively licensed the intellectual property for our MU 1140 technology from the University of Florida Research Foundation, Inc. See the discussion regarding our license in the Intellectual Property section under our Replacement Therapy technology.

### ***Progress***

In the fourth quarter of 2008, we announced the successful synthesis of an antibiotic using our proprietary DPOLT™ technology. The molecule belongs to a class of antibiotics called Lantibiotics that were first discovered over 80 years ago. Although there are now over 50 different Lantibiotics known, this is the first report of a cost-effective method for making one in sufficient amounts and with sufficient purity to enable comprehensive testing and commercial viability. We have retained Almac Sciences in October 2008, a leading contract manufacturer and a division of the Almac Group, to refine and scale-up GMP production of the synthetic MU1140™ analogue to achieve sufficient quantities for it to be fully tested for regulatory approval. In conjunction with Almac, we continued throughout 2009 to improve and refine the processes we have developed to shorten the process to scale MU 1140 and decrease overall production costs. We currently estimate that, once commenced, the regulatory process will take at least four years of clinical testing and the application and approval of an NDA by the FDA before this drug could be commercially available. Other synthetic Lantibiotics are expected to follow as they are developed and tested.

### ***Competition***

MU 1140 would compete directly with antibiotic drugs such as vancomycin and newer drugs, 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.

We are aware of a mutacin peptide similar to MU 1140 patented in the U.S. by the University of Laval in Quebec. Successful development of that technology would constitute major competition for MU 1140. Management believes that the Laval peptide, if developed, would infringe on the MU 1140 patent.

Many of our competitors are taking approaches to drug development differing from our approach, including traditional screening of natural products; e.g., 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 MU 1140 technology will depend on our ability and the ability of our sub-licensees to compete effectively in all of these areas, against other companies with existing and pipeline antibiotics to be commercialized in the future. There can be no assurance that competitors will not succeed in developing products that are more effective than MU 1140 or would render MU 1140 obsolete and non-competitive.

Producers of antibiotic products include many large, international pharmaceutical companies, who have much greater financial and technical resources than us. We intend to compete in the antibiotic market by obtaining a strategic partner with an established product development record and sales force. There can be no assurance that we will be able to obtain any such partner. If not, we will need to develop our own product and channels of distribution for products based on the MU 1140 technology. There can be no assurance that we will be able to do so.

## **BIOMARKER DISCOVERY:**

Our Biomarker Discovery division is driven by our two proprietary platforms for the identification of genetic targets that can be used in diagnostic tests as well as in vaccines and therapeutics. The two platforms are PIVIAT™ (Proteomic-based In-Vivo Induced Antigen Technology) and PCMAT™ (Proteomic-based Change Mediated Antigen Technology). What we believe makes our platforms unique is that we focus on the infection or disease *in vivo*, or in the body, rather than *in vitro*, or in the test tube. We believe that infections and diseases behave differently in different environments and produce different proteins, or gene targets. One of the first major initiatives has proven this to be true; our study on colorectal cancer.

### ***Developing a Diagnostic Test Using Gene Targets***

The process to develop a diagnostic test using gene targets has the following basic steps:

- (1) **Identification of Gene Targets.** We use our proprietary platforms to identify gene targets for specific disease states.
- (2) **Validation.** Once targets have been identified, they then need to be validated. This can be done internally or by a third-party. Once targets have been validated they can be sold or licensed to a third party diagnostics, therapeutics or vaccine company.
- (3) **Incorporation into a Diagnostic Test, Therapeutic or Vaccine.** Validated targets can then be incorporated into a diagnostic test, therapeutic or vaccine.

Once a test is developed, it would then need to go through the appropriate regulatory process in order to be registered and marketed. In the US, this will typically require the filing of a 510K application with the FDA, to-date we have not commenced any filings with the FDA regarding diagnostic tests using our gene targets.

Our revenues for out-licensing markers would typically be a combination of upfront fees, milestone payments based on regulatory filings and approvals, and royalties on the sale of diagnostic tests, therapeutics or vaccines to end users. Fees will vary depending on the timing of a licensing arrangement. Obviously, gene targets that have been discovered and validated will command a higher premium. Our objective is to carry our gene targets as far down the process as possible. At present, we are developing techniques to validate targets as quickly and efficiently as possible. Eventually, we would like to have all three steps performed internally.

#### ***PIVIAT™ Brief Description***

PIVIAT™ is a platform technology that enables rapid identification of novel targets for use in the diagnosis and treatment of human infectious diseases. The method is faster, more cost effective, and more sensitive than other methods currently in use to identify such targets. As an example, a recent tuberculosis project has yielded 44 novel targets for *Mycobacterium tuberculosis* that are currently being analyzed for their use in vaccine and diagnostic strategies.

#### ***PCMAT™ Brief Description***

PCMAT™ is a platform technology that was derived from and greatly extends the potential applicability of PIVIAT™. This technology rapidly identifies proteins (and their genes) that are expressed when a cell undergoes any sort of change. PCMAT™ has been used to identify proteins of both plants and pathogens that are expressed during infection. Such genes are excellent targets for manipulation to increase the resistance of the plant to infection. It has also been used to identify novel proteins of human bowel cells that are expressed when the cell undergoes transformation to a cancerous cell. Such proteins are excellent targets for new diagnostics and therapeutic strategies. PCMAT™ has the potential to study an extraordinary range of medical and agricultural applications.

#### ***The In Vitro Diagnostics (“IVD”) Market***

In 2007, according to Research and Markets, the global In Vitro Diagnostics market was in excess of \$38 billion with a forecasted compound annual growth rate of 6.7%. The fastest growing segment of the In Vitro Diagnostics market is molecular diagnostics, which has a compound annual growth rate of 15.4%.

#### ***Progress***

We continue to make advances with our biomarker discovery platforms. One major advance, which we internally characterize as the “fluidics approach”, has shown substantial promise. The fluidics approach focuses primarily on the discovery and analysis of shed proteins. Through this adaptation to our platforms, we believe we will be able to discover a small set of high-value protein targets for a variety of disease states in a fraction of the time and at a fraction of the cost compared to our competitors. We are in the final stages of completing a proof of concept for the fluidics approach. If the fluidics approach is proven, then we anticipate we will initiate studies on a number of disease states during the year.

## BIOLOGICS:

### **SMaRT Replacement Therapy™**

SMaRT Replacement Therapy™ is a single, painless, one time, 5 minute topical treatment that has the potential to offer lifelong protection against dental caries (tooth decay). Dental caries is a worldwide epidemic that affects the majority of populations in industrialized and developing countries. According to the World Health Organization, tooth decay is the most prevalent chronic infectious disease, affecting more than 5 billion people. Much of the tooth decay in low-income countries remains untreated until the teeth are extracted. Replacement therapy is suitable for use by the general population. The ideal application would be to treat children when bacterial colonization of their new tooth surfaces is occurring. Applied topically to the teeth with a swab, the therapy can be administered by dentists to patients during routine office visits.

Replacement therapy represents a novel approach to preventing bacterial infections by capitalizing on interactions between different strains or species of bacteria inhabiting the same ecosystem. This approach involves permanently implanting a harmless strain of bacteria in the host's microflora. Once established, the harmless strain prevents the colonization and outgrowth of potential pathogens, including harmful bacteria that cause tooth decay.

Tooth decay is characterized by the dissolution of enamel and dentin, eventually resulting in the destruction of the entire tooth. The immediate cause of tooth decay is lactic acid produced by microorganisms on the tooth surface. Studies suggest that of the 400 to 700 oral micro-organisms, *Streptococcus mutans* (*S. mutans*), a common bacterium found in virtually all humans, is the principal causative agent in the development of tooth decay. Residing within dental plaque, *S. mutans* derives its energy from carbohydrate metabolism as it converts dietary sugar to lactic acid which, in turn, erodes the tooth enamel.

Our replacement therapy technology is based on genetically altering the bacterium, *S. mutans*, and employs this genetically modified strain of *S. mutans* that does not produce lactic acid. When applied to the teeth, this non-lactic acid-producing organism can displace and permanently replace the indigenous lactic acid-producing strains of *S. mutans*, thereby potentially providing lifelong protection against most forms of tooth decay.

#### ***Regulatory Status***

We have conducted a FDA Phase I clinical trial and we have been approved for a FDA Phase I(b) clinical trial. We anticipate initiating this second Phase I safety trial in the coming months. We also believe that SMaRT Replacement Therapy will be an appealing technology for developing countries.

#### ***Manufacturing, Marketing and Distribution***

The manufacturing methods for producing our genetically modified strain of *Streptococcus mutans* are standard fermentation techniques. These techniques involve culturing bacteria in large vessels and harvesting them when mature by centrifugation or filtration. The cells are then suspended in a pharmaceutical medium appropriate for application in the human mouth. These manufacturing methods are commonplace and readily available within the pharmaceutical industry. Upon successful completion of Phase I clinical trials, we intend to consider sublicensing our replacement therapy technology to one or more strategic partners that would be responsible for advanced clinical development and commercialization including product manufacturing, marketing, and distribution.

#### ***Market Opportunity***

Despite the introduction of fluorides in public water systems, fluoridated toothpastes, fluoride treatments in the dental office and dental sealants, tooth decay still affects the majority of children and adults. There are a number of factors that are likely to increase the incidence and frequency of tooth decay which include:

- increasing consumption of dietary sugar;
- increasing consumption of bottled water, which generally does not contain fluoride; and
- increasing age of the population.

During the last 20 years, sugar consumption has increased. Higher dietary intake of sugar predisposes individuals to higher rates of tooth decay. Moreover, according to the Beverage Marketing Corporation, in 2005, U.S. consumers drank more bottled water than any other alcoholic or non-alcoholic beverage, with the exception of carbonated soft drinks. Since bottled water generally does not contain fluoride, the protective effects of fluoridated public water systems are lost. With the aging of the population, the incidence and frequency of tooth decay is likely to further increase as most of the baby boomers upon reaching retirement age will have a relatively intact dentition unlike previous generations. Therefore, more teeth will be at risk for tooth decay.

Replacement therapy represents a novel approach to preventing tooth decay. The technology confers potentially lifelong protection against tooth decay with one treatment, is anticipated to be used by the general population and involves minimal patient education and compliance.

### ***Competition***

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 are developing and testing caries vaccines aimed at eradicating *S. mutans*. An alternative approach involves topical application of adhesion-blocking synthetic peptides that prevent *S. mutans* from attaching to the tooth surface. Products that result in the elimination of *S. mutans* from the natural ecosystem would 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.

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. All of these companies are much larger and have far greater technical and financial resources than us.

### **Our In-Licensed Technology Agreements**

#### ***Replacement Therapy***

We have exclusively licensed the intellectual property for our replacement therapy technology from the University of Florida Research Foundation, Inc., a nonprofit Florida corporation (the "Florida Research Foundation"). 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 United States Patent Office 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 *Streptococcus 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 599,940 shares of our common stock to the Florida Research Foundation as partial consideration for the initial license.

We received notification from Celunol (formerly B.C. International Corporation) on July 29, 2002 that a gene utilized in our licensed, patented strain of *Streptococcus mutans* infringes a patent which it holds under a license from the Florida Research Foundation. On September 17, 2006, Celunol notified us regarding the possibility of a sublicense. As of this date, no further communication has been received from Celunol. Their notification did not state that they intended to pursue legal remedies. Our management does not believe the gene in question infringes that patent. On February 12, 2007 Celunol and the Diversa Corporation announced that they had signed a definitive merger agreement and subsequently formed the Verenium Corporation.

#### ***MU 1140.***

We have exclusively licensed the intellectual property for our MU 1140 lantibiotic technology from the Florida Research Foundation. The original license agreement was dated June 22, 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. 5,932,469 entitled "Antimicrobial Polypeptide 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, the Florida Research Foundation has reserved the right to use and sell products and services for research purposes only. The amended license agreements also provide the Florida Research Foundation 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 Florida Research Foundation. In addition, if we sublicense any rights granted by the amended license agreements, we are obligated to pay the Florida Research Foundation twenty percent (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 Florida Research Foundation 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 replacement therapy and Mutacin 1140 minimum royalty payments, we must pay the Florida Research Foundation 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 replacement therapy and Mutacin 1140 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 Florida Research Foundation may terminate our license agreement.

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

We have agreed to indemnify and hold the Florida Research Foundation 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 the products, for which we obtained liability insurance that expired March, 2010. Our liability insurance has been renewed up through March 2011 however there is no assurance that we can obtain continued coverage on reasonable terms.

The amended license agreements further provide that the United States 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 United States Government is entitled, as a right, under the provisions of US law 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 Florida Research Foundation 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 Florida Research Foundation'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.

#### **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 & Drug Administration (the "FDA");
- the Federal Trade Commission (the "FTC");
- the Drug Enforcement Administration (the "DEA");
- the Consumer Product Safety Commission (the "CPSC");
- the United States Postal Service ("USPS");
- the Environmental Protection Agency ("EPA"); and
- the Occupational Safety and Health Administration ("OSHA").

These activities are also 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 (the "FDCA") regulates the safety, manufacturing, labeling and distribution of OTC drugs, medical devices, dietary supplements, functional toiletries, and skin care products. In addition, the FTC has primary jurisdiction to regulate the advertising of OTC drugs, medical devices, dietary supplements, functional toiletries and skin care products and the USPS regulates advertising claims with respect to such products sold by mail order. The National Advertising Division ("NAD") of the Council of Better Business Bureaus oversees an industry-sponsored self-regulatory system that permits competitors to resolve disputes over advertising claims. The NAD has no enforcement authority of its own, but may refer matters that the NAD views as violating FTC guides or rules to the FTC for further action. While we use our best efforts to adhere to the regulatory and licensing requirements, as well as any other requirements affecting our products, compliance with these often requires subjective legislative interpretation. Consequently, we cannot assure that our compliance efforts will be deemed sufficient by regulatory agencies and commissions enforcing these requirements. Violation of these regulations may result in civil and criminal penalties, which could materially and adversely affect our operations. Recent events have suggested that the regulatory requirements governing our industry may expand in the near future.

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 U.S.

### ***Generally Recognized As Safe("GRAS") Status***

Under the FDCA any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by the FDA, unless 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 additive. 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.

### ***Dietary Supplements***

The Dietary Supplement Health and Education Act of 1994 ("DSHEA") was enacted on October 25, 1994. DSHEA amends the FDCA by defining dietary supplements, which include vitamins, minerals, amino acids, nutritional supplements, herbs and botanicals, as a new category of food separate from conventional food. DSHEA provides a regulatory framework to ensure safe, quality dietary supplements and to foster the dissemination of accurate information about such products. Under DSHEA, the FDA is generally prohibited from regulating dietary supplements as food additives or as drugs unless product claims, such as claims that a product may diagnose, mitigate, cure or prevent an illness, disease or malady, permit the FDA to attach drug status to a product. In such case, the FDA could require pre-market approval to sell the product. Manufacturers are not required to obtain prior FDA approval before producing or selling a dietary supplement unless the ingredient is considered "new" or was not on the market as of October 15, 1994.

Dietary supplement products may include truthful, non-misleading and substantiated statements of nutritional support. Examples of such claims are statements describing general well-being resulting from consumption of a dietary ingredient or the role of a nutrient or dietary ingredient in affecting or maintaining a structure or function of the body. These claims are also known as "structure/function" claims. FDA requires companies which include structure/function claims on their labeling to notify the agency of the claim within 30 days of first marketing the dietary supplement with the identified claims. FDA does not typically respond to these notifications, but could issue a "courtesy letter" should the agency question some aspect of the submission. A dietary supplement that includes a structure/function claim on its labeling is also required to include a disclaimer stating that the FDA has not evaluated the claim. FDA distinguishes between structure/function claims which do not require FDA pre-approval and disease-related health claims which require FDA prior approval or the issuance of an authorizing regulation. There can be no assurance that the FDA will not determine that a particular statement of nutritional support that we want to use is an "unauthorized health or disease claim" or an unauthorized version of a "health claim." Such a determination might prevent us from using the claim.

A product marketed as a dietary supplement and subsequently approved for use as a drug or biologic may continue to be sold and regulated as a dietary supplement unless the FDA specifically finds that it is unsafe for use as a dietary supplement. A substance that has not been marketed as a dietary supplement prior to its approval as a drug or biologic, or prior to initiation of substantial clinical investigations for such uses, may be sold as a dietary supplement only pursuant to an FDA regulation authorizing its use as a dietary supplement.

The FDA may take enforcement action against a dietary supplement if the FDA 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 may also take enforcement action for unlawful promotion of a dietary supplement.

The FDA has finalized some of its regulations to implement DSHEA including those relating to nutritional labeling requirements and nutritional support claims. The FDA also has under development additional regulations and guidelines to implement DSHEA. Newly adopted and future regulations may require expanded or different labeling for our dietary supplements. We cannot determine what effect these regulations, when fully implemented, will have on our business in the future. These regulations could require the reformulation or discontinuance of certain products, additional recordkeeping, warnings, notification procedures and expanded documentation of the properties of certain products and scientific substantiation regarding ingredients, product claims and safety. Failure to comply with applicable FDA requirements can result in sanctions being imposed on us or the manufacture of our products including, but not limited to, warning letters, product recalls and seizures, injunctions or criminal prosecution.

The FDA has promulgated regulations relating to the manufacturing process for drugs, which are known as current Good Manufacturing Practices, (GMP's). In June 2007, the FDA published the final rule on GMP's for dietary supplements, with an effective date of June 25, 2008. As authorized by DSHEA, the FDA adopted GMPs specifically for Dietary Supplements. These new GMP regulations are more detailed than the GMPs that previously applied to dietary supplements and require, among other things, dietary supplements to be prepared, packaged and held in compliance with specific rules, and require quality control provisions similar to those in the GMP regulations for drugs. We source all of our dietary supplement products from outside suppliers. We believe the manufacturing and distribution practices we utilize will comply with the new rules. As part of its regulatory authority, the FDA may periodically conduct audits of the physical facilities, machinery, processes and procedures that we, or our suppliers, use to manufacture products. The FDA may perform these audits at any time without advanced notice. As a result of these audits, the FDA may order us, or our suppliers, to make certain changes in manufacturing facilities and processes. We may be required to make additional expenditures to comply with these orders or the new GMP requirements, or possibly discontinue selling certain products until we, or our suppliers, comply with these orders and requirements. As a result, our business could be adversely affected.

Although the regulation of dietary supplements in some respects is less restrictive than the regulation of drugs, there can be no assurance that dietary supplements will continue to be subject to less restrictive regulation. In December 2006, the Dietary Supplement and Nonprescription Drug Consumer Protection Act (the "AER Act") amended the FDCA to require that manufacturers, packers, and distributors of dietary supplements report serious adverse events to FDA. The AER Act became effective on December 22, 2007. We expect to be in compliance with the AER Act.

Our advertising of dietary supplement products is also subject to regulation by the Federal Trade Commission 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 Federal Trade Commission'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 Federal Trade Commission requirement we are required to have adequate substantiation for all material advertising claims made for our products.

In recent years the Federal Trade Commission has initiated numerous investigations of dietary supplement and weight loss products and companies. The Federal Trade Commission is reexamining its regulation of advertising for dietary supplements and has announced that it will issue a guidance document to assist supplement marketers in understanding and complying with the substantiation requirement. Upon release of this guidance document we will be required to evaluate our compliance with the guideline and may be required to change our advertising and promotional practices. We may be the subject of investigation in the future. The Federal Trade Commission may impose limitations on our advertising of products. Any such limitations could materially adversely affect our ability to successfully market our products. The Federal Trade Commission 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. Federal Trade Commission 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. A violation of such orders could have a material adverse effect on our business, financial condition and results of operations.

Governmental regulations in foreign countries where our plans to commence or expand sales may prevent or delay entry into the market or prevent or delay the introduction, or require the reformulation, of certain of our products. Compliance with such foreign governmental regulations is generally the responsibility of our distributors for those countries. These distributors are independent contractors over whom we have limited control.

We may have certain products manufactured pursuant to contracts with customers who distribute the products under their own or other trademarks. Such private label customers are subject to government regulations in connection with their purchase, marketing, distribution and sale of such products. We are subject to government regulations in connection with our manufacturing, packaging and labeling of such products. Our private label customers are independent companies and their labeling, marketing and distribution of their products is beyond our control. The failure of these customers to comply with applicable laws or regulations could have a materially adverse effect on our business, financial condition, results of operations and cash flows.

We may be subject to additional laws or regulations by the Food and Drug Administration or other federal, state or foreign regulatory authorities, the repeal of laws or regulations which we consider favorable, such as the Dietary Supplement Health and Education Act of 1994, or more stringent interpretations of current laws or regulations, from time to time in the future. We are unable to predict the nature of such future laws, regulations, interpretations or applications, nor can we predict what effect additional governmental regulations or administrative orders, when and if promulgated, would have on our business in the future. The Food and Drug Administration or other governmental regulatory bodies could, however, 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.

The FDA regulates the formulation, manufacturing, packaging, labeling and distribution of OTC drug products under a "monograph" system that specifies active drug ingredients that are generally recognized as safe and effective for particular uses. If an OTC drug is not in compliance with the applicable FDA monograph, the product generally cannot be sold without first obtaining the FDA approval of a new drug application, a long and expensive procedure. There can be no assurance that, if more stringent statutes are enacted for dietary supplements, or if more stringent regulations are promulgated, we will be able to comply with such statutes or regulations without incurring substantial expense.

The FDA has broad authority to enforce the provisions of the FDCA applicable to dietary supplements and OTC drugs, including powers to issue a public "warning letter" to a company, to publicize information about illegal products, to request a voluntary recall of illegal products from the market, and to request the Department of Justice to initiate a seizure action, an injunction action, or a criminal prosecution in the US courts.

#### ***FDA Regulation — Approval of Biological Products and New Drug Products***

Under the FDCA all "new drugs" and "biological products", including over the counter "OTC" products, are subject to pre-market approval by the FDA under the new drug application ("NDA") process. The FDC Act defines a "new drug" as a drug that is not generally recognized among scientifically qualified experts as safe and effective for use under the conditions stated in its labeling. A drug might also be considered new if it has not been used, outside of clinical investigations, to a material extent or for a material time under conditions described for a product. A drug that is generally regarded as safe and effective is not a "new drug" and therefore does not require pre-market approval.

Biological products, like other drugs, are used for the treatment, prevention or cure of disease in humans. 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. The *Public Health Service (PHS) Act* defines a biological product as a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, applicable to the prevention, treatment, or cure of a disease or condition of human beings." FDA regulations and policies have established that 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 *PHS Act* also meet the definition of *drugs* under the *Federal Food, Drug and Cosmetic Act (FDCA)*. Biological products are a subset of drugs; therefore both are regulated under provisions of the FDCA. However, only biological products are licensed under the PHS Act. The overall development process 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 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 for its intended use;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product is manufactured, processes, packaged or held to assess compliance cGMP; and
- the submission to, and review and approval by, the FDA of a biologics license application "BLA", or new drug application ("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 to assess the potential safety and efficacy of the product candidate. The FDA requires that preclinical tests be conducted in compliance with good laboratory practice 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. A 30-day waiting period after the filing of each IND application is required by the FDA prior to the commencement of clinical testing in humans. In addition, the FDA may, at any time during this 30-day waiting period or any time thereafter, impose a clinical hold on proposed or ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization.

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 I clinical trials, the initial introduction of the biological product candidate into human subjects or patients, the product candidate is tested to assess safety, dosage tolerance, absorption, metabolism, distribution and excretion, including any side effects associated with increasing doses.

Phase II 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 II evaluations, Phase III 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 IV, or post-marketing, trials may be mandated by regulatory authorities or may be conducted voluntarily. Phase IV trials are typically initiated to monitor the safety and efficacy of a biological product in its approved population and indication but 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 IV 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 IV trials may result in the withdrawal or restriction of a drug.

If the required Phase I, II and III clinical testing is completed successfully, the results of the required clinical trials, 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 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, 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 unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements.

If the FDA evaluations of the BLA or NDA and the manufacturing facilities are favorable, the FDA may issue either an approval letter or an approvable letter. The approvable letter usually contains a number of conditions that must be met to secure final FDA approval of the BLA or NDA. When, and if, those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. If the FDA's evaluation of the BLA, NDA or manufacturing facility is not favorable, the FDA may refuse to approve the BLA or NDA or issue a non-approvable letter that often requires additional testing or information.

The required testing, data collection, analysis and compilation of an IND and a new biological or drug application 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 establish a Phase II or III clinical trial and achieve enrollment sufficient to commence such trials and ultimately proceed through to approval. Therefore, we cannot estimate with any certainty the length or the costs of the approval process. We can offer no assurance that we will ever receive FDA approval of products derived from our licensed, patented technologies.

#### ***FDA Regulation — Approval of Medical Devices***

The FDCA defines a medical device, which would be subject to premarketing and postmarketing regulatory controls as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

Medical devices are also subject to extensive regulation by the FDA. To be commercially distributed in the United States, medical devices must receive either 510(k) clearance or pre-market approval, or PMA, from the FDA prior to marketing. Devices deemed to pose relatively low risk are placed in either Class I or II, which requires the manufacturer to submit a pre-market notification requesting permission for commercial distribution, or 510(k) clearance. 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 which requires PMA.

To obtain 510(k) clearance, a manufacturer must submit a pre-market notification demonstrating that the proposed device is substantially equivalent in intended use and in safety and efficacy to a previously 510(k) cleared device, a device that has received PMA or a device that was in commercial distribution before May 28, 1976. 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 efficacy, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require PMA. The FDA requires each manufacturer to make this determination, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA is obtained.

A product not eligible for 510(k) clearance must follow the PMA pathway, which requires proof of the safety and efficacy of the device to the FDA's satisfaction. The PMA pathway is much more costly, lengthy and uncertain than the 510(k) approval pathway. A PMA application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, 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. The review time is often significantly extended as a result of the FDA asking for more information or clarification of information already provided.

If the FDA's evaluation of the PMA application is favorable, and the applicant satisfies any specific conditions (e.g., changes in labeling) and provides any specific additional information (e.g., submission of final labeling), the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the manufacturer. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and efficacy of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in an enforcement action, which could have material adverse consequences, including the loss or withdrawal of the approval.

Even after approval of a pre-market application, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process.

#### ***FDA Regulation — Post-Approval Requirements***

Even if regulatory clearances or approvals for our product candidates are obtained, our products and the facilities manufacturing our products will be subject to continued review and periodic inspections by the FDA. For example, as a condition of approval of a new drug application, 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 new BLA, PMA or 510(k) clearance product 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.

In addition, manufacturing facilities are subject to periodic inspections by the FDA to confirm the facilities comply with cGMP requirements. In complying with cGMP, 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. Manufacturers must report to the FDA any deviations from cGMP or any unexpected or unforeseeable event that may affect the safety, quality, or potency of a product. The regulations also require investigation and correction of any deviations from cGMP and impose documentation requirements.

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.

#### ***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.

In the European Economic Area, composed of the 25 European Union Member States, plus Norway, Iceland and Lichtenstein, marketing authorization applications for medicinal products may be submitted under a centralized or national procedure. Detailed preclinical and clinical data must accompany all marketing authorization applications that are submitted in the European Union. The centralized procedure provides for the grant of a single marketing authorization, referred to as a community authorization, that is valid for the entire European Economic Area. Under the national or decentralized procedure, a medicinal product may only be placed on the market when a marketing authorization, referred to as a national authorization, has been issued by the competent authority of a European Economic Area country for its own territory. If marketing authorization is granted, the holder of such authorization may submit further applications to the competent authorities of the remaining member states via either the decentralized or mutual recognition procedure. The decentralized procedure enables applicants to submit an identical application to the competent authorities of all member states where approval is sought at the same time as the first application. We expect to position our products so that we will be eligible to seek commercial approval of our products under either the centralized or national procedure.

Under the mutual recognition procedure, products are authorized initially in one member state, and other member states where approval is sought are subsequently requested to recognize the original authorization based upon an assessment report prepared by the original authorizing competent authority. The other member states then have 90 days to recognize the decision of the original authorizing member state. If the member states fail to reach an agreement because one of them believes that there are grounds for supposing that the authorization of the medicinal product may present a potential serious risk to public health, the disagreement may be submitted to the Committee for Medicinal Products for Human Use of the European Medicines Agency for arbitration. The decision of this committee is binding on all concerned member states and the marketing authorization holder. Other member states not directly concerned at the time of the decision are also bound as soon as they receive a marketing application for the same product. The arbitration procedure may take an additional year before a final decision is reached and may require the delivery of additional data.

The European Economic Area requires that manufacturers of medical devices obtain the right to affix the CE Mark to their products before selling them in member countries. The CE Mark is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain the right to affix the CE Mark to a medical device, the medical device in question must meet the essential requirements defined under the Medical Device Directive (93/42/ EEC) relating to safety and performance, and the manufacturer of the device must undergo verification of regulatory compliance by a third party standards certification provider, known as a notified body. Provided that we enter into a long term manufacturing contract with an entity that satisfies the requirements of the International Standards Organization, we anticipate that we will file an application to obtain the right to affix the CE Mark as needed.

In addition to regulatory clearance, the conduct of clinical trials in the European Union is governed by the European Clinical Trials Directive (2001/20/ EC), which was implemented in May 2004. This directive governs how regulatory bodies in member states may control clinical trials. No clinical trial may be started without authorization by the national competent authority and favorable ethics approval.

Manufacturing facilities are subject to the requirements of the International Standards Organization. In complying with these requirements, manufacturers must expend money, time and effort in the area of production and quality control to ensure full compliance.

Despite efforts to harmonize the registration process in the European Union, the different member states continue to have different national healthcare policies and different pricing and reimbursement systems. The diversity of these systems may prevent a simultaneous pan-European launch, even if centralized marketing authorization has been obtained.

In some cases, we may plan to submit applications with different endpoints or other elements outside the United States due to differing practices and requirements in particular jurisdictions. However, in cases where different endpoints will be used outside the United States, we expect that such submissions will be discussed with the FDA to ensure that the FDA is comfortable with the nature of human trials being conducted in any part of the world. 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 in Mexico or Europe.

## **Competition**

**Industry.** 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, retail, 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 do. 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.

**Personnel.** Our ability to compete successfully will also depend on our continued ability to attract and retain skilled and experienced scientific, clinical development and executive personnel, to identify and develop our product candidates and to exploit these products and compounds commercially before others are able to develop competitive products. Competition among biotechnology and biopharmaceutical companies for qualified employees is intense, and there can be no assurance we will be able to attract and retain qualified individuals. If we fail to do so, this would have a material, adverse effect on the results of our operations. We do not maintain any life insurance on the lives of any of our officers and directors. We are highly dependent on the services of our directors and officers, particularly on those of Jeffrey Hillman. If one or all of our officers or directors die or otherwise become incapacitated, our operations could be interrupted or terminated.

We believe the principal competitive factors affecting our markets include, but are not limited to:

- the safety and efficacy of our product candidates;
- the freedom to develop and commercialize our products, technology platforms and replacement therapy, including appropriate patent and proprietary rights protection;
- the timing and scope of regulatory approvals;
- the cost and availability of our products;
- the availability and scope of third party reimbursement programs; and
- the availability of alternative treatments.

We are still in the process of determining, among other things:

- if replacement therapy is safe and effective;
- the market acceptance of EvoraPlus and our weight loss product;
- the timing and scope of regulatory approvals; and
- the availability and scope of third party reimbursement programs.

Accordingly, we have a limited ability to predict how competitive our products, technology platforms and replacement therapy will be in the market place.

### **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 Replacement Therapy and Mutacin 1140 technologies from the University of Florida Research Foundation, Inc., a nonprofit, Florida corporation. The related patents to which our exclusive license applies are U.S. patent 5,607,672, "Replacement Therapy for Dental Caries," and U.S. patent 5,932,469, "Antimicrobial Polypeptide and Methods of Use" (including derivative patents: 6,391,285, 6,475,771, 6,964,760 and 7,067,125). 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. As of March 21, 2010, we hold two issued U.S. patents and we have 7 non-provisional U.S. patent applications directed toward our products and technologies. 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 two patent applications on our probiotic technology on (U.S. patent application serial number 10/567592, filed August 10, 2004; U.S. Pat. Appl. Serial Number 12/482,881, filed June 11, 2009). We also filed a patent application entitled “Methods for Size and Weight Reduction” (U.S. patent application serial number 11/265, 414).
- **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 of polynucleotides expressed during the process of infection: *In Vivo* Induced Antigen Technology-U.S. Patent 7,033,748, and U.S. Patent Application Serial Nos. 09/980,845; 12/327,056; Method of Detection of *Mycobacterium Tuberculosis*, U.S. Patent Application Serial No. 12/293,497 filed 3/13/07; Compositions for Detection and Treatment of Colorectal Cancer, PCT/US09/050938, filed 7/17/09.
- **Antibiotics.** In our Antibiotics division we have filed a patent application directed at the intellectual property surrounding the DPOLT™ solid/liquid phase peptide synthesis platform technology, as well as associated areas of antibiotics technology, in the U.S. (Pat. No. 7,521,529; U.S. Pat. Appl. 12/413,551) and internationally (August 2006). In addition, we have the exclusive license for our MU 1140 antibiotic technology from the University of Florida Research Foundation. See “License Agreements” above.
- **Biologics.** We have licensed Replacement Therapy technology, the use of recombinant *Streptococcus* strains to combat dental caries, from the University of Florida Research Foundation. See License Agreements above.

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 Health Care Reform legislation contains a section that provides a 12 year market exclusivity for new biologics. We believe that our SMaRT Replacement Therapy™ technology would fall under this section of the reform legislation and as such would be granted a 12 year period of protection from biosimilar competition.

**Trademarks.** Our trademarks are of material importance to our business. We have developed many brand names and trademarks for our products. Accordingly, our future success may depend in part upon the goodwill associated with our brand names. We currently use the following unregistered trademarks: SMaRT Replacement Therapy™, MU 1140™, Probiora3™, IVIAT™ and CMAT™, LPT3 04™ and DPOLT™. Oragenics is among our non-registered trademarks. We currently have pending with the U.S. Patent & Trademark Office, applications for registration of our principal brands, including the marks for EVORAKIDS, EVORAPRO, PROBIORA, and TEDDY’S PRIDE. We also hold U.S. trademark registrations for EVORAPLUS® and PROBIORA3®. Finally, we hold a European Community trademark registration for PROBIORA3®.

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.

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

#### **Research and Development Costs**

We have spent \$1,833,746, \$1,955,488 and \$1,569,551 on research and development of our technologies in 2009, 2008 and 2007, respectively.

#### **Employees**

As of December 31, 2009, we had 14 full-time and no part-time employees. We have 3 employees in research and development, 5 employees in general and administrative and 6 employees in sales, marketing and business development. We enjoy good employee relations. None of our employees are members of any labor union, and we are not a party to any collective bargaining agreement.

#### **Available Information**

Our website is [www.oragenics.com](http://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.**

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

#### **Risks Related to Our Business**

***We have a limited operating history with significant losses and expect to continue to experience losses for the foreseeable future and our independent auditors have expressed doubt about our ability to continue as a going concern.***

We have yet to establish any history of profitable operations. Our profitability will require the successful commercialization of one or more of the technologies we either license or own. Since our organization, we have incurred operating losses and negative cash flow from operating activities as a result of minimal sales coupled with our significant clinical development, research and development, general and administrative, sales and marketing and business development expenses. Furthermore, our cash burn rate and expenses have recently increased significantly due to our aggressive commercialization, marketing and international initiatives. We expect to incur losses for at least the next several years as we expand our sales and marketing capabilities, make use of the sales and marketing capabilities of third parties and continue our clinical trials and research and development activities. Losses have totaled approximately:

\$5,519,348 for the year ended December 31, 2009

\$6,021,742 for the year ended December 31, 2008

\$2,311,712 for the year ended December 31, 2007

These losses, among other things, have had and will continue to have an adverse effect on our working capital, total assets and stockholders' (deficit) equity. In light of our recurring losses, accumulated deficit and cash flow difficulties, the report of our independent registered public accounting firm on our financial statements for the fiscal year ended December 31, 2009 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.

We have experienced losses from operations during the last three years and have an accumulated deficit of \$25,511,883 as of December 31, 2009. We have an operating cash flow deficit of \$5,799,481 for the year ended December 31, 2009 and we sustained operating cash flow deficits of \$3,835,190 and \$1,913,760 in 2008 and 2007, respectively. At December 31, 2009 and December 31, 2008, we had working capital of approximately \$2,564,147 and \$(500,672), respectively.

The Company's principal source of liquidity at December 31, 2009 was \$2,751,592 in cash and cash equivalents and restricted cash. The Company currently does not have sufficient capital to operate beyond June 2010.

***We continue to require additional financing to operate beyond the second half of the year.***

We do not have sufficient capital to sustain our operations beyond June 2010 and we will require additional financing as soon as possible. If we are not able to raise additional capital, among other things:

- We will need to scale back or cease our marketing and development efforts;
- We will be forced to cease operations;
- We will be unable to pursue further development of our technologies;
- We will be forced to sell off our technologies prior to maximizing their potential value;
- We will be unable to aggressively market our products;
- We will be unable to pursue patenting some of our technologies and development of our technologies and products;
- We will have to lay-off personnel;
- We could be unable to continue to make public filings; and
- Our licenses for our SMaRT™ Replacement Therapy technology and MU 1140 technology could be terminated.

There can be no assurance that we will be able to raise additional capital and any of these events would significantly harm our business.

***Our business may be adversely affected by the current economic recession.***

The domestic and international economies are experiencing a significant recession. This recession has been magnified by the tightening of the credit markets. The domestic and international markets may remain depressed for an undeterminable period of time. A prolonged recession could have a material adverse effect on the Company's revenues, profits and its ability to obtain additional financing if sales revenue is insufficient to sustain our operations as needed. In such event, we could be forced to limit our marketing and development efforts and significantly curtail or suspend our operations, including laying-off employees, recording asset impairment write-downs and other measures. We must generate significant revenues to achieve and maintain profitability.

***The Koski Family Limited Partnership ("KFLP") together with members of the Koski Family have a controlling interest in our outstanding shares of common stock.***

The KFLP together with its partners own approximately 53.4% of our outstanding shares of common stock. Our directors, officers and principal security holders (greater than 5%), taken as a group, together with their affiliates, beneficially own, in the aggregate, approximately 74% of our outstanding shares of \$.001 par value common stock. Certain principal security holders are our directors or executive officers. As a result of such ownership, these security holders may be able to exert significant influence, or even control, matters requiring approval by our security holders, including the election of directors. In addition, certain provisions of Florida law could have the effect of making it more difficult or more expensive for a third party to acquire, or of discouraging a third party from attempting to acquire, control of us.

***Sales of our consumer healthcare products may be adversely affected by fluctuations in buying decisions of mass merchandiser, drug and food trade buyers and the trend toward retail trade consolidation.***

We sell our consumer healthcare products to mass merchandisers and food and drug retailers in the United States. Consequently, our revenues could be affected by fluctuations in the buying patterns of these customers. These fluctuations may result from wholesale buying decisions, economic conditions and other factors. In addition, with the growing trend towards retail consolidation, we are increasingly dependent upon a few leading retailers, whose bargaining strength can continue to grow due to their size. Such retailers have demanded, and may continue to demand, increased service and order accommodations as well as price and incremental promotional investment concessions. As a result, we may face pressure on our prices and experience increased expenses from promotions to meet these demands, which would reduce our margins. We also may be negatively affected by changes in the policies of our retail trade customers such as inventory destocking, limitations on access to shelf space and other conditions.

***Government regulation of the processing, formulation, packaging, labeling and advertising of our consumer healthcare products can impact our ability to market such products.***

Under the Dietary Supplement Health and Education Act of 1994, companies that manufacture and distribute dietary supplements are limited in the statements that they are permitted to make about nutritional support on the product label without FDA approval. In addition, a manufacturer of a dietary supplement must have substantiation for any such statement made and must not claim to diagnose, mitigate, treat, cure or prevent a specific disease or class of disease. The product label must also contain a prominent disclaimer. These restrictions may restrict our flexibility in marketing our consumer healthcare products.

The FDA has proposed GMPs (Good Manufacturing Practices) specifically for dietary supplements. These new GMPs, when finalized, will be more detailed than the GMPs that currently apply to dietary supplements and may, among other things, require dietary supplements to be prepared, packaged and held in compliance with certain rules (including quality control provisions) similar to the GMPs applicable to drugs. There can be no assurance that, if the FDA adopts GMPs for dietary supplements, we and/or our suppliers will be able to comply with the new rules without incurring substantial expenses that might have a material adverse effect on our financial position or results of operations. As a formulator, distributor and marketer of dietary supplements, we are subject to the risk that one or more of the ingredients in our product may become subject to regulatory action in the future.

The processing, formulizing, packaging, labeling and advertising of our consumer healthcare products, however, are subject to regulation by one or more federal agencies including the FDA, the Federal Trade Commission, the Consumer Products Safety Commission, the Department of Agriculture and the Environmental Protection Agency. Our activities also are subject to regulation by various agencies of the states and localities in which our products are sold. Among other things, such regulation puts a burden on our ability to bring products to market. Any changes in the current regulatory environment could impose requirements that would make bringing new products to market more expensive or restrict the ways we can market our products. In addition, the adoption of new regulations or changes in the interpretation of existing regulation may result in significant compliance costs or discontinuation of product sales and may adversely affect our revenue. The FDA may implement additional regulations with which we would have to comply, which would increase expenses.

No governmental agency or other third party makes a determination as to whether our products qualify as dietary supplements or not. We make this determination based on the ingredients contained in the products and the claims we make for the products and if our determination is denied by any regulatory authority we could face significant penalties that may require us to shut down our operations

***If we incur product recalls or liability claims regarding our consumer healthcare products, it could increase our costs and adversely affect our reputation, revenues and operating income.***

Our consumer healthcare products are designed for human consumption and we may face product recalls, withdrawals or declining sales, as well as liability claims if the use of our products is alleged to have resulted in injury. Our products consist of ingredients that are classified as foods or dietary supplements and, in most cases, are not necessarily subject to pre-market regulatory approval in the United States. Some of our products contain innovative ingredients that may not have long histories of human consumption. Previously unknown adverse reactions resulting from human consumption of these ingredients could occur. We may be subject to various product recalls and liability claims, including, among others, that our products include inadequate instructions for use or inadequate warnings concerning possible side effects and interactions with other substances. A product recall and 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, results of operations, financial condition and cash flows.

***We must spend at least \$1 million annually on development of our MU 1140™ and SMaRT™ Replacement Therapy technologies and \$100,000 annually as minimum royalties under our license agreements with the University of Florida Research Foundation, Inc. We must also comply with certain other conditions of our licenses. If we do not, our licenses to these and other technologies may be terminated, and we may have to cease operations.***

We hold our MU 1140™ and SMaRT™ Replacement Therapy technologies under licenses from the University of Florida Research Foundation, Inc. Under the terms of the licenses, we must spend at least \$1 million per year on development of those technologies before the first commercial sale of products derived from those technologies. In addition, we must pay \$25,000 per quarter as minimum royalties to the University of Florida Research Foundation, Inc. under our license agreements. The University of Florida Research Foundation, Inc. may terminate our licenses in respect of our MU 1140™ and our SMaRT™ Replacement Therapy technology and technology if we breach our obligations to timely pay monies to it, submit development reports to it or commit any other breach of the covenants contained in the license agreements. There is no assurance that we will be able to comply with these conditions. If our license is terminated, our investment in development of our SMaRT™ Replacement Therapy™ and MU 1140™ technologies will become valueless and we may have to cease operations.

Until commercial sales of any products developed from these licensed technologies take place, we will not be earning revenues from the sale of products derived from them and will, therefore, have to raise the money we must spend on development of our technologies by other means, such as commercialization and sale of our consumer products, or the sale of our common stock. There is no assurance we will achieve a sufficient level of sales to provide such funding or be able to raise the financing necessary to meet our obligations under our licenses. If we cannot, we may lose our licenses to these technologies and have to cease operations.

***We are currently depend primarilyt upon a single third party manufacturer for our ProBiora 3™ product.***

Since we currently have no manufacturing facilities, we are dependent upon establishing relationships with independent manufacturers to supply our product needs. We currently rely primarily on one key contract manufacturer as our single source supplier for ProBiora3™ product. If our contract manufacturer is unable or unwilling to produce the product we would not be able to have it manufactured until a alternative manufacturer is qualified, which could impair our ability to commercialize the *Evora™line of* product and harm our business. We may not be able to find alternative manufacturers on favorable terms to provide us with these services or at all. In addition, competitors who do own their own manufacturing 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 manufacture of our products is a highly exacting and complex process, and if our manufacturers or suppliers encounters problems manufacturing products, our business could suffer.***

The manufacture of our products is a highly exacting and complex process, due in part to strict regulatory requirements. Problems may arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, natural disasters, and environmental factors. In addition, certain suppliers are currently used for certain products and materials. If problems arise during the production of a batch of product, that batch of product may have to be discarded. This could, among other things, lead to increased costs, lost revenue, damage to customer relations, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred. To the extent our manufacturers or suppliers experiences significant manufacturing problems, this could have a material adverse effect on our revenues and profitability.

***If we are unable to maintain regulatory clearance or obtain approval for our technologies, we will be unable to generate revenues and may have to cease operations.***

Only our SMaRT™ Replacement Therapy technology has been granted clearance to begin Phase 1 human clinical trials by the FDA. Clinical trials on our SMaRT™ Replacement Therapy are expected to take several years to fully complete. Our other drug technologies have not been cleared for testing in humans. Our drug technologies have not been cleared for marketing by the FDA or foreign regulatory authorities and they will not be able to be commercially distributed in the United States or any international markets until such clearances are obtained. Before regulatory approvals can be obtained, our drug technologies will be subject to extensive preclinical and clinical testing. These processes are lengthy and expensive. We cannot assure that such trials will demonstrate the safety or effectiveness of our drug technologies. There is a possibility that our technologies may be found to be unsafe or ineffective or otherwise fail to satisfy regulatory requirements. If we are unable to resolve the FDA's concerns, we will not be able to proceed further to obtain regulatory approval for that technology. If we fail to maintain regulatory clearance for our SMaRT™ Replacement Therapy or fail to obtain FDA clearance for our other drug technologies, we may have to cease further development.

***Many of our product candidates are in the early development stage, and may not be effective at a level sufficient to support a profitable business venture. If they are not, we will be unable to create marketable products, and we may have to cease operations.***

Many of our product candidates are in the early development stage. Although we have current data which indicates the promise of the concept of our technologies (including, SMaRT™ Replacement Therapy, MU 1140™, PIVIAT™, PCMAT™, DPOLT™ and LPT3-04), we can offer you no assurance that the technologies will be effective at a level sufficient to support a profitable business venture. If they are not, we will be unable to create marketable products, we will not generate revenues from our operations, and we may have to cease operations. The science on which our technologies are based may also fail due to flaws or inaccuracies on which the data are based, or because the data are totally or partially incorrect, or not predictive of future results. If our science proves to be flawed, incorrect or otherwise fails, we will not be able to create a marketable product or generate revenues and we may have to cease operations.

***Our contracts may be delayed, terminated or reduced in scope with little or no notice, which could adversely impact our profitability.***

Many of our contracts with our clients may be terminated or reduced in scope with little or no notice. Cancellations may occur for a variety of reasons, including the failure of our product to satisfy safety and/or efficacy requirements, unexpected results of our product or our decision to reduce research and development activities. In addition, if we are unable to provide the sufficient number of staff required for a project, the contract may be delayed, terminated, or reduced in scope.

***The success of our research and development activities is uncertain. If they do not succeed, we will be unable to generate revenues from our operations and we will have to cease doing business.***

We intend to continue with research and development of our technologies for the purpose of licensing these technologies to third parties for obtaining regulatory approval to manufacture and market them. Research and development activities, by their nature, preclude definitive statements as to the time required and costs involved in reaching certain objectives. Actual costs may exceed the amounts we have budgeted and actual time may exceed our expectations. If research and development requires more funding than we anticipate, then we may have to reduce technological development efforts or seek additional financing. There can be no assurance that we will be able to secure any necessary additional financing or that such financing would be available on favorable terms. Additional financings could result in substantial dilution to existing shareholders. We anticipate, subject to available funding, that we will remain engaged in research and development for a considerable period of time, and there can be no assurance that we will be able to generate adequate funding or revenue from operations to do so.

***Each of the technologies we are commercializing and developing for eventual commercialization will 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 the products developed from our technologies will face will come from companies that are large, well established and have greater financial, marketing, sales and technological resources than we have. Commercial success of our technologies will depend on our ability and the ability of our sub licensees to compete effectively in marketing and product development areas such as, 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 the products developed from our technologies or that would render our products obsolete and non-competitive.

***We rely on the significant experience and specialized expertise of our senior management and must retain and attract qualified scientists and other highly skilled personnel in a highly competitive job environment to maintain and grow our business.***

Our performance is substantially dependent on the continued services and on the performance of our senior management and our limited number of research scientists, who have experience and specialized expertise in our business. Our performance also depends on our ability to retain and motivate our other key employees. The loss of the services of our Chief Executive Officer, David Hirsch, our Chief Scientific Officer, Dr. Jeffrey D. Hillman, and our Chief Financial Officer, Brian Bohunicky and any of our researchers could harm our ability to develop and commercialize our technologies. We have no "key man" life insurance policies. We have employment agreements with Dr. Hillman and Mr. Hirsch. Dr. Hillman's agreement automatically renews for one-year terms unless 90 days written notice is given by either party. Mr. Hirsch's agreement automatically renews for one-year terms unless 30 days written notice is given by either party.

Our future success also depends on our ability to identify, attract, hire, train, retain and motivate highly skilled technical, managerial and research personnel. If we fail to attract, integrate and retain the necessary personnel, our ability to maintain and build our business could suffer significantly.

***It is possible that our SMaRT™ Replacement Therapy technology will be less effective in humans than it has been shown to be in animals. It is possible our MU 1140™ technology will be shown to be ineffective or harmful in humans. If any of these technologies are shown to be ineffective or harmful in humans, we will be unable to generate revenues from them, and we may have to cease operations.***

To date the testing of our SMaRT™ Replacement Therapy technology 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 technology is shown to be ineffective in preventing tooth decay in humans, we will be unable to commercialize and generate revenues from this technology. To date the testing of the antibiotic substance, Mutacin has been undertaken solely in the laboratory and in animals. We have not yet conducted human studies of Mutacin. It is possible that when these studies are conducted, they will show that MU1140 is ineffective or harmful. If Mutacin is shown to be ineffective or harmful, we will be unable to commercialize it and generate revenues from sales of Mutacin. If we are unable to generate revenues from our technologies, we may have to cease operations.

***It is possible we will be unable to find a method to produce Mutacin 1140 in large-scale commercial quantities. If we cannot, we will be unable to generate revenues from product sales, and we may have to cease operations.***

Our antibiotic technology, Mutacin 1140, is a substance produced by our genetically altered strain of *S. mutans*. To date, it has been produced only in laboratory cultures. In March 2005 we successfully developed a methodology for manufacturing Mutacin 1140 in quantities sufficient to undertake the preclinical studies necessary to prepare an Investigational New Drug (IND) application to the FDA. We believe we will be able to optimize this methodology or the DPOLT synthetic chemistry methodology to allow large-scale commercial production of the antibiotic. However, these methodologies may not be feasible for cost effective, large-scale manufacture of the MU1140 antibiotic. If we are not able to optimize either of these methodologies, we will be unable to generate revenues from this technology and we may have to cease operations.

***If clinical trials for our product candidates are unsuccessful or delayed, we will be unable to meet our anticipated development and commercialization timelines, which could cause our stock price to decline and we may have to cease operations.***

Before obtaining regulatory approvals for the commercial sale of any drug products, we must demonstrate through preclinical testing and clinical trials that our products are safe and effective for use in humans. Conducting clinical trials is a lengthy, time-consuming and expensive process.

Completion of clinical trials may take several years. Commencement and rate of completion of clinical trials may be delayed by many factors, including:

- lack of efficacy during the clinical trials;
- unforeseen safety issues;
- slower than expected patient recruitment; and
- government or regulatory delays.

Results from preclinical testing and early clinical trials are often not predictive of results obtained in later clinical trials. A number of new products have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from preclinical and clinical activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including perceived defects in the design of the clinical trials and changes in regulatory policy during the period of product development. Any delays in, or termination of, our clinical trials will materially and adversely affect our development and commercialization timelines, which would adversely affect our business and cause our stock price to decline and may cause us to cease operations.

***We intend to consider relying on third parties to pay the majority of costs relating to regulatory approvals necessary to manufacture and sell products using our technologies. If we are unable to obtain agreements with third parties to fund such costs, we will have to fund the costs ourselves. We may be unable to do so, and if we are not, we may have to cease operations.***

We intend to consider sublicensing our technologies to strategic partners prior to commercialization. If we do so, our sub-licensees will pay the costs of any remaining clinical trials, and manufacturing and marketing of our technologies. If we are unable to sublicense our technologies, we will have to pay for the costs of Phase II and III trials and new drug applications to the FDA ourselves. We would also have to set up our own manufacturing facilities and find our own distribution channels. This would greatly increase our future capital requirements and we cannot be assured we would be able to obtain the necessary financing. If we cannot obtain financing, we may have to cease operations.

***If our expected collaborative partnerships do not materialize or fail to perform as expected, we will be unable to develop our products as anticipated.***

We expect to enter into collaborative arrangements with third parties to develop certain products by sublicensing our technologies to strategic partners. We cannot assure you that we will be able to enter into these collaborations or that, if entered, they will produce successful products. If we fail to maintain our existing collaborative arrangements or fail to enter into additional collaborative arrangements, the number of products from which we could receive future revenues would decline.

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 can 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 products would be materially and adversely affected.

***We are subject to risks of doing business internationally.***

We have formed a subsidiary in Mexico and may encounter certain risks of doing business internationally including:

- differences in protection of our intellectual property rights;
- unexpected changes in, or impositions of, legislative or regulatory requirements that may limit our ability to conduct research or sell our products and repatriate funds to the United States;
- political and economic instability;
- fluctuations in foreign exchange rates;
- difficulty in staffing, developing and managing foreign operations as a result of distances, languages and cultural differences;
- difficulties in enforcement of contractual obligations;
- national and regional labor strikes or labor requirements;
- increased costs in maintaining international research, manufacturing, marketing operations;
- potential trade restrictions and exchange controls;
- political instability; and
- the burden of complying with foreign laws.

Our exposure to these risks could cause us to be unable to attain the anticipated benefits and our business could be adversely impacted.

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

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 technologies. 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. We received notification from Celunol (formerly B.C. International Corporation) on July 29, 2002 that a gene utilized in our licensed, patented strain of *S. mutans* infringes a patent which it holds under a license. On September 17, 2006, Celunol notified Oragenics regarding the possibility of sublicenses to date. As of this date, no further communication has been received from Celunol. Their notification did not state that they intended to pursue legal remedies. Our management does not believe the gene in question infringes that patent. We have sent them correspondence setting out our position. If necessary, we would need to be prepared to assert our rights vigorously with respect to such matter, which we may not be able to do without sufficient funding. If litigation should ensue and we are unsuccessful in that litigation, we could be enjoined for a period of time from marketing products which infringe any valid patent rights held or licensed by Celunol and/or we could owe substantial damages. On February 12, 2007 Celunol and the Diversa Corporation announced that they had signed a definitive merger agreement.

***We are subject to substantial government regulation, which could materially adversely affect our business.***

The production and marketing of products which may be developed from our technologies and our ongoing research and development, preclinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities. For example, while we plan to market Probiora3™ and LPT3-04™ products in the United States under self proclaimed GRAS (Generally Recognized As Safe) status; most of the technologies we are developing must undergo rigorous preclinical and clinical testing and an extensive regulatory approval process before they can be marketed in the United States or internationally. If the FDA or any other governmental regulatory body does not agree with our contention that certain of our products are exempt from testing and approval, we could be required to undergo the regulatory authority approval process. This process makes it longer, harder and more costly to bring products which may be developed from our technologies to market, and we cannot guarantee that any of such products will be approved. 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, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

Delays in or rejection of FDA or other government entity approval of our technologies 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, slower than expected rate of patient recruitment for clinical trials, inability to follow patients after treatment in clinical trials, inconsistencies between early clinical trial results and results obtained in later clinical trials, varying interpretations of data generated by clinical trials, or changes in regulatory policy during the period of product development. More stringent regulatory oversight 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 technologies for broader or different applications or to market updated products that represent extensions of our basic technologies. In addition, we may not receive FDA approval to export our products based on our licensed, patented technologies in the future, and countries to which products are to be exported may not approve them for import.

Any manufacturing facilities would also be subject to continual review and inspection. For example, the FDA has stated publicly that compliance with manufacturing regulations will be scrutinized more strictly. A governmental authority may challenge our compliance with applicable federal, state and foreign regulations. In addition, any discovery of previously unknown problems with one of our products or facilities may result in restrictions on the product or the facility, including withdrawal of the product from the market or other enforcement actions.

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

U.S. and foreign governmental regulations mandating price controls and limitations on patient access to our products could impact our business, and our future results could be adversely affected by changes in such regulations. In the U.S., pharmaceutical products are subject to increasing pricing pressures. Such pressures have increased as the result of the 2003 Medicare Modernization Act due to the enhanced purchasing power of the private sector plans that negotiate on behalf of Medicare beneficiaries. In addition, if the 2003 Medicare Modernization Act were amended to impose direct governmental price controls and access restrictions, it could have a significant adverse impact on our future revenues and business. In addition, MCOs, as well as Medicaid and other government agencies, continue to seek price discounts. Some states have implemented and other states are considering price controls or patient-access constraints under the Medicaid program and some states are considering price-control regimes that would apply to broader segments of their populations that are not Medicaid eligible. Other matters also could be the subject of U.S. federal or state legislative or regulatory action that could adversely affect our business, including changes in patent laws, the importation of prescription drugs from outside the U.S. at prices that are regulated by the governments of various foreign countries, restrictions on U.S. direct-to-consumer advertising or limitations on interactions with healthcare professionals and the use of comparative effectiveness methodologies that could be implemented in a manner that focuses primarily on the cost differences and minimizes the therapeutic differences among pharmaceutical products.

***We can offer you no assurance the government and the public will accept our licensed patented technologies. If they do not, we will be unable to generate sufficient revenues from our technologies, which may cause us to cease operations.***

The commercial success of our MU 1140 and SMaRT Replacement Therapy, ProBiora3, LPT3-04 and other technologies will depend in part on government and public acceptance of their production, distribution and use. Biotechnology has enjoyed and continues to enjoy substantial support from the scientific community, regulatory agencies and many governmental officials in the United States and around the world. Future scientific developments, media coverage and political events may diminish such support. Public attitudes may be influenced by claims that health products based on biotechnology 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 technologies developed through biotechnology such as ours could be delayed or impaired in certain geographical areas because of such factors. Products based on our technologies may compete with a number of traditional dental therapies and drugs manufactured and marketed by major pharmaceutical companies and other biotechnology companies. Market acceptance of products based on our technologies 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 technologies. If they do not, we may be unable to generate sufficient revenues from our technologies, which may cause us to have to cease operations.

***We may be exposed to product liability claims as products based on our technologies are marketed and sold. Because our liability insurance coverage will have limitations, if a judgment is rendered against us in excess of the amount of our coverage, we may have to cease operations.***

Because we are testing new technologies, and will be involved either directly or indirectly in the manufacturing and distribution of the technologies, we are exposed to the financial risk of liability claims in the event that the use of the technologies results in personal injury or death. There can be no assurance that we will not experience losses due to product liability claims in the future, or that adequate insurance will be available in sufficient amounts, at an acceptable cost, or at all. A product liability claim, product recall or other claim, or claims for uninsured liabilities or in excess of insured liabilities, may have a material adverse effect on our business, financial condition and results of operations. Although we currently carry general liability insurance, such insurance may not be sufficient to cover any potential liability. We could be sued for a large sum of money and held liable in excess of our liability coverage. If we cannot pay the judgment, we may have to cease operations.

***There is uncertainty relating to favorable third-party reimbursement. If we are not able to obtain third party reimbursement for products based on our technologies, it could limit our revenue.***

Our success in obtaining payment for a new product from third parties such as insurers and government programs depends greatly on the 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 we are unable to obtain favorable third party reimbursement and patients are unwilling or unable to pay for our products out-of-pocket, it could limit our revenue and harm our business.

***If users of our proposed products are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our proposed products may be limited and we may not achieve revenues.***

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 U.S., given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, 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.

Our ability to commercialize our proposed 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 HMOs. Third-party payers are increasingly challenging the prices charged for medical drugs and services. Also, the trend toward managed health care in the U.S. and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and drugs, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our products.

***Products are sold subject to a right of return to our customers.***

Our consumer healthcare products may be sold to mass retail customers with a right of return. This practice is not unusual or uncommon for retail customers in our business. For example, a right of return may be granted when the shelf life has reached its expiration or the product has remained unsold for a period of time. We are just beginning our roll out of our consumer healthcare products on a larger scale to mass retailers and we have limited data to determine the expected returns in future periods in situations when we may grant rights of return.

***We have limited resources which exposes us to potential risks resulting from internal control requirements under Section 404 of the Sarbanes-Oxley Act of 2002.***

While we have evaluated our internal controls in order to allow management to report on our internal controls, as required by Section 404 of the Sarbanes-Oxley Act of 2002, our independent registered public accounting firm has not issued its attestation report on our internal controls due to temporary rules of the SEC. There can be no assurances that when our independent registered public accounting firm performs its attestation work that it will concur with management's assessment. Any failure to obtain the attestation report from our independent registered public accounting firm on the identification of material weaknesses by them could result in unexpected delays in further implementing the requirements relating to internal controls; remediation actions or the impact that these activities will have on our operations. We also expect to incur additional expenses and diversion of management's time as a result of performing the system and process evaluation, testing and any remediation required when our auditors perform their attestation work in order to comply with the auditor attestation requirements.

We are a small company with limited resources that will make it difficult for us to comply with the auditor attestation requirements of Section 404 in a timely fashion. If we are not able to comply with the requirements set forth in Section 404, we might be subject to sanctions or investigation by regulatory authorities. Any such action could adversely affect our business and financial results.

***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 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. For example, "material weaknesses" were identified in our quarter ended June 30, 2009 which means that there was "a significant deficiency, or a combination of significant deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected." During this period, we were under significant operational stress due to a lack of liquidity and much of our staff was terminated. During this period and until we can complete our remediation efforts including the re-staffing and training of our accounting personnel, we have a higher risk of deficiencies in our financial reporting. 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.

***Current levels of securities and financial market volatility are unprecedented.***

The capital and credit markets have been experiencing volatility and disruption for more than 12 months. In recent months, the volatility and disruption has reached unprecedented levels. In some cases, the markets have produced downward pressure on stock prices and credit availability for certain issuers which effects may or may not be directly related to those issuers' underlying financial strength. If current levels of market disruption and volatility continue or worsen, there can be no assurance that we will not experience an adverse effect, which may be material, on our ability to access capital and on our business, financial condition and results of operations.

***Recent legislative and regulatory initiatives to address difficult market and economic conditions may not stabilize the U.S. financial system or economy or benefit us.***

On February 17, 2009, President Obama signed the American Recovery and Reinvestment Act, to stimulate the economy. Prior to that on October 3, 2008, former President Bush signed into law the Emergency Economic Stabilization Act of 2008 in response to the financial crises affecting the banking system and financial markets. The U.S. Department of the Treasury and banking regulators have implemented a number of programs under pursuant to such legislation to address capital and liquidity issues in the banking system and to stimulate economic recovery. There can be no assurance, however, as to the actual impact that these programs and legislation or any other governmental program will have on the financial markets, including the extreme levels of volatility and limited credit availability currently being experienced, or on the economy. The failure of any such program or the U.S. government to maintain stability in the financial markets and a continuation or worsening of current financial market conditions and the national and regional economy could materially and adversely affect our business, financial condition, results of operations, access to credit and the trading price of our common stock.

**Risks Related to our Common Stock**

***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 historically has been volatile and our stock's trading volume has been low.***

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;
- the results of testing, technological innovations, or new commercial products by us or our competitors;
- governmental regulations, rules, and orders;
- general conditions in the healthcare, dentistry, or biotechnology industries;
- comments 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;
- adverse announcements by our competitors; 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. Since our initial public offering in June 2003 and through December 31, 2009 our stock price has fluctuated from \$5.00 to \$0.05 per share. To the extent our stock price fluctuates and/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.

***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 17, 2010, there were 108,203,148 shares of our common stock outstanding, with another 6,127,778 shares of common stock issuable upon exercise of warrants to investors, 7,881,800 shares issuable upon exercise of options outstanding and an additional 4,618,200 shares available for option grants under our stock option plans. The issuance of shares of our common stock under our Stock Option and Incentive Plan is covered by S-8 registration statements we filed with the SEC and upon exercise of the options, such shares may be resold into the market. We have also issued shares in connection with private placements that are available for resale as well as shares issuable upon exercise of warrants also issued with respect to such private placements. Most recently, we issued 17,016,250 shares of our common stock in a private placement commenced in late December 2009. 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 stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act of 1933, which we refer to in this memorandum as the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, after satisfying a six month holding period: (i) affiliated stockholders (or stockholders 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 stockholders may sell without such limitations, 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. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale memorandum may have a material adverse effect on the market price of our securities.

*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.

**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 is currently being used for sales and marketing and some administrative matters. It is expected that the Tampa office will ultimately become our principal executive office in the near future. The office space is approximately 3,150 square feet and the annual lease cost is \$63,317 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 facility located at 13700 Progress Boulevard, Alachua, Florida 32615. This lease was renewed for a two year period beginning December 2009 and expires November 2011. 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 twelve months lease costs for 2009 was approximately \$97,187, of which eleven months were net of insurance, taxes and utilities that are paid by us and the new lease cost beginning December 2009 includes these amounts. Lease payments are capped during the term. We expect the location in Alachua, Florida to be used primarily as our research and laboratory space in the near future as we seek to migrate move of the administrative and accounting functions to Tampa.. There were no leasehold improvements in 2009, 2008 or 2007. The Company terminated two lease agreements in August and October 2009 for office spaces which were located in Alachua and St. Petersburg, Florida, respectively.

**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. RESERVED.**

## PART II

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

Our common stock began trading on the NYSE Alternext US (formerly known as the American Stock Exchange) under the symbol ONI on May 20, 2004. Our common stock was de-listed from the NYSE Alternext US Exchange on December 19, 2008. Following de-listing our common stock has been quoted on the over-the counter (OTC) Bulletin Board under the ticker symbol "ORNI." On December 18, 2008, our common stock was listed on the Alternext Paris exchange under the symbol "ALONI." The following sets forth the high and low sales prices for the common stock on the NYSE Alternext US for the period in which we were listed and the high and low bid quotations reflected on the OTC Bulletin Board for the periods applicable in the last two fiscal years.

Period	2009		2008	
	High	Low	High	Low
First quarter	\$ 0.45	\$ 0.22	\$ 0.58	\$ 0.40
Second quarter	\$ 0.41	\$ 0.05	\$ 0.76	\$ 0.43
Third quarter	\$ 0.51	\$ 0.22	\$ 0.85	\$ 0.47
Fourth quarter	\$ 0.32	\$ 0.20	\$ 0.81	\$ 0.20

On March 17, 2010, the closing bid price of the common stock, as reported by the OTC Bulletin Board, was \$0.60. As of March 17, 2010, there were approximately 95 registered holders of our common stock according to Continental Stock Transfer. 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 multi-faceted biopharmaceutical company focused on the discovery, development and commercialization of a variety of products and technologies. Our offices are located in Tampa, Florida and Alachua, Florida. The office in Alachua, Florida is near the University of Florida where we have our experienced scientific team in place in which to lead us into an exciting new phase of operations. In 2009, we transitioned from a company with a historic focus exclusively on research and development to a company with increased focus on immediate and long term commercialization and monetization. We possess a number of proprietary products and technologies some of which we have begun to commercialize. We believe that each of our products and platform technologies addresses potentially large market opportunities.

We generate revenue through the sale of our consumer healthcare products and sponsored research agreements and government grants. We are optimistic about the ongoing level of interest we are experiencing with our lead branded consumer healthcare products at this time. As our ProBiora3 and EvoraPlus manufacturing, marketing and selling initiatives progress, we expect to continue to experience a higher level of overall expenses associated with such efforts as well as with the continued development of our technologies. We expect the current increases in our expenses to continue into the near future as we fully implement the initiatives we have underway.

Our goal is to achieve positive operational cash flow as quickly as possible by allocating most of our resources on the commercialization or monetization of technologies that can provide revenues in the near term. This initially means that our priority will be to focus the bulk of our resources on the Consumer Healthcare Division. We will also seek opportunities in Biomarker Discovery that either provide up-front money or fee-for-service arrangements. Concurrently, we expect to seek additional capital to fund our operations and, is sufficient to accelerate the development of our technologies. While we are pursuing these priorities, we expect to simultaneously make incremental progress in Antibiotics, Biomarker Discovery and Biologics, as capital resources permit, until they reach an inflexion point and can be monetized. The pace of any incremental progress we may achieve, however, will be based on the amount of our limited available capital resources we are able to allocate to each individual technology. If we are able to obtain sufficient additional capital, the pace of progress would be expected to increase. Once we begin to monetize our current technologies, we will also be able to commit greater capital to further research and development alternative technologies that are in alignment with our vision and strategic goals.

### Financial Strategy

Since our inception, we have funded a significant portion of our operations from the public and private sales of our securities. Furthermore, we have not earned significant revenue from operations during the last two years. Until recently most of our revenue has been from sponsored research agreements and various governmental grants. We will require additional capital to fund our business operations and we continue to seek additional capital to effectuate our business plans. The further development, testing and commercialization of our technologies, individually and in the aggregate, are expected to be costly to undertake and complete and will require additional capital over and above what we currently have available to us. Our current available capital limits our ability to fully develop our technologies. We expect to allocate our limited capital resources to the development of our technologies while we continue to explore additional capital raising opportunities. There can be no assurances that such additional capital will be available to us or on favorable terms or at all. The time periods for the expected continued development of our technologies have been extended from those previously indicated by us from time to time due primarily to our insufficient capital position. The time periods for expected developments could also change in the future depending on the progress of our ability to negotiate a partnering arrangement, as well as our efforts to raise additional capital and generate revenue.

Although we have started to earn revenue from the sales of our Consumer Healthcare products and technologies, revenue to date has been modest. Our objective is that the revenue from Consumer Healthcare products will be able to fully and sufficiently support the continued operations of the Consumer Healthcare Products Division. We anticipate additional purchase orders and/or revenue from the sale of EvoraPlus™, our oral probiotic for adults, and from Teddy's Pride™, our oral probiotic for the companion pet market. We also anticipate that, we will have opportunities to partner with or license some of our technologies to larger global companies. We hope to be able to negotiate upfront payments in connection with these potential partnerships and/or licenses.

## Operational Strategy

We have a number of products and platforms. These products and platforms are structured and viewed by us as four distinct Divisions:

- (1) Consumer Healthcare, which consists of ProBiora3™, the EvoraPlus™, Teddy's Pride™ and EvoraKids™ as well as the LPT3-04™ weight loss agent;
- (2) Biomarker Discovery (formerly referred to by us as "Diagnostics"), which consists of the PIVIAT™ and PCMAT™ platforms;
- (3) Antibiotics, which consists of our lead antibiotic, MU 1140, and the DPOLT™ antibiotic synthesis platform; and
- (4) Biologics (formerly referred to by us as "Replacement Therapy"), which consists of our SMaRT™ Bacterial Replacement Therapy technology.

Because we have limited capital and human resources, we cannot pursue commercialization and further development of each and every technology that we own simultaneously. As such, we have decided to pursue a strategic course that focuses the majority of our resources towards those technologies that present the best opportunity to generate revenue for the Company in the short-term. The allocation of resources is determined by us on a case-by-case basis and is subject to periodic review. Currently, we are rolling out products in our Consumer Healthcare Division and most of our resources are being deployed in support of that endeavor. However, we expect to continue to commit any remaining available resources to our other three divisions. As the Consumer Healthcare Division matures and begins to generate meaningful revenue and is able to become self-sustaining, we anticipate being able to allocate greater resources to the other divisions. We have a contractual obligation to pay a minimum royalty of \$25,000 per quarter and spend or cause to be spent an aggregate of \$1,000,000 per annum toward research, development and regulatory prosecution, in order to maintain our license with the University of Florida Research Foundation, Inc. for our SMaRT Replacement Therapy™ and MU 1140™ technologies. We believe we have met the \$1,000,000 per annum threshold for research, development and regulatory prosecution in 2009. If we are unable to make the minimum royalty payments in the future, our license could be terminated which will substantially diminish the value of our company.

## Highlights and Recent Developments

Company highlights and recent developments are set forth below in the following categories; Operational, Financial, Corporate and Management.

### Operational:

We believe we have made important strides operationally in the second half of 2009 and in 2010. Most notably, we recently gained significant traction in the domestic mass retail distribution channel for our consumer healthcare products as evidenced by the following announcements:

- **Walgreens:** On February 8<sup>th</sup>, 2010, we announced that Walgreens, the country's largest drug store chain, will offer EvoraPlus™ chain-wide beginning March 19, 2010 and that EvoraPlus™ would now be available both at all of Walgreens more than 7,000 locations as well as its popular online destination.
- **A&P Supermarkets and Pathmark :** On December 15<sup>th</sup>, 2009, we announced the mass retail launch of EvoraPlus and Teddy's Pride in A&P Supermarkets and Pathmark, which together account for nearly 1,000 locations across the country.
- **Hannaford and Sweet Bay Supermarkets:** On December 15<sup>th</sup>, 2009, we also announced that EvoraPlus will be carried in early January by Hannaford Supermarkets' pharmacies covering Maine, Massachusetts, New Hampshire, New York and Vermont and Sweet Bay Supermarkets covering Florida.
- **Chiropractors Buying Group:** On January 26<sup>th</sup>, 2010, we announced that we have signed a distribution agreement with Chiropractors Buying Group (CBG) to represent our probiotic oral care mint EvoraPlus to chiropractic offices nationwide.

- **EvoraKids Launch:** On January 25<sup>th</sup>, 2010, we announced the launch of EvoraKids, which has been specifically formulated for children 3-10 years old to help maintain healthy teeth, their biggest oral care problem. EvoraKids features a tasty Wild Very Cherry Berry flavored chew.
- **Wolverton Garden and Pet Supplies:** On January 7<sup>th</sup>, 2010, we announced that we had named Wolverton Garden and Pet Supplies as a regional distributor for Teddy's Pride™, the first-ever all-natural probiotics breath freshener and teeth whitener created especially for dogs and cats. Established in 1940 in Lansing, Michigan, Wolverton Garden and Pet Supplies today ranks among the industry's largest and most distinguished pet supply distributors with more than 14,000 items from over 300 suppliers for all categories of pets. Wolverton's customer base comprises kennels, veterinarian clinics, independent pet stores, and large chain and mass accounts.
- **Garden of Life.** On February 4, 2009, we announced that Garden of Life has been awarded rights to use our oral-care probiotic ingredient, ProBiora3. This agreement gives Garden of Life exclusive rights to use ProBiora3 in the natural products market. ProBiora3 is a patent-pending probiotic formula containing a blend of three bacteria that work below the gum line to address oral health at its root cause.

In addition to the above announcements, the Company's oral-care product lines have been the subject of numerous feature stories and positive reviews in magazines, newspapers and websites nationwide, along with television segments. Some of this media coverage is listed below:

- **FOX Television:** The Company and its core products have been featured several times on FOX television newscasts nationally.
- **National Medical Report with Hugh Downs:** The Company has been featured on the National Medical Report hosted by Hugh Downs.
- **The Balancing Act:** Oragenics and its product line were featured on The Balancing Act, an award-winning talk and magazine show reaching 96 million homes that airs weekday mornings on Lifetime Channel on January 18<sup>th</sup>, February 8<sup>th</sup> and March 8<sup>th</sup>.
- **Newspapers and Blogs:** More than 800 newspapers have discussed EvoraPlus in their editorial section and hundreds of health-oriented websites and grassroots 'blogs' have prominently featured both EvoraPlus and Teddy's Pride with unanimous positive reviews and 'recommendations to purchase'.

We believe these events provide a solid foundation from which to build and expand upon the marketing and distribution of our consumer healthcare products in future periods.

#### **Financial:**

During 2009, we completed two private placement transactions. In June 2009, we consummated a private placement with the Koski Family Limited Partnership ("KFLP") which resulted in the KFLP acquiring a controlling interest in our Company (the "June 2009 Private Placement"). With the proceeds from the June 2009 Private Placement, we were able to continue to initiate our transition efforts toward commercialization of our consumer healthcare products as well as continue the development of our other technologies. In addition, and in furtherance of its commitment to us, the KFLP also participated in the initial closing of a private placement along with other accredited investors in December 2009 (the "December 2009 Private Placement"). The December 2009 Private Placement provided us with additional necessary capital and resulted in the exchange of equity for secured debt that was outstanding to the KFLP in connection with the earlier June 2009 Private Placement. For further information on the details of the June 2009 Private Placement and the December 2009 Private Placement see "*Management's Discussion and Analysis of Final Condition and Results and Operations —Liquidity and Capital Resources.*"

#### **Corporate and Management:**

At our Annual meeting of shareholders, held on October 28, 2009, the shareholders approved a Second Amendment to our Amended and Restated 2002 Stock Option and Incentive Plan (the "Plan") to increase the available shares from 5,000,000 to 12,500,000 shares with all other terms of the Plan remaining the same. In addition the shareholders also approved an amendment to our Articles of Incorporation to increase our authorized common shares from 100 million (100,000,000) shares to 300 million (300,000,000). All other provisions of the Articles of Incorporation remained in full force and effect. The Amended Articles of Incorporation have been filed with the Secretary of State of Florida. With these changes to our articles we were able to proceed with the December 2009 Private Placement and will have the availability of additional authorized shares to be able to continue to seek additional capital on a go forward basis.

In addition, on January 20<sup>th</sup>, 2010, we announced that we had engaged government relations firm GSP Consulting ("GSP") to represent the Company for the purpose of securing government funding for a number of its technologies. GSP will focus on partnering with government and NGO healthcare organizations to increase the speed to market for Antibiotics, Biomarker Discovery and our Biologic, SMaRT Replacement Therapy.

During the course of 2009, we also experienced changes in our directors and senior management. As a result of the June 2009 Private Placement, Christine Koski, Robert Koski and David Hirsch were appointed to our Board of Directors with Christine Koski elected as Chairperson. Three of our then existing directors resigned upon the consummation of the transaction. Our acting President and Chief Executive Officer, David Hirsch, was also appointed President and Chief Executive Officer and Brian Bohunicky was appointed as our Chief Financial Officer.

## **Business Objectives and Milestones**

In each of our divisions we have designated business objectives as follows:

### **Consumer Healthcare**

Our Consumer Healthcare unit has been tasked with the commercialization of our oral probiotics, which revolve around the ProBiora3 technology, and the further development and commercialization of our weight loss agent, LPT3-04.

**Oral Probiotics:** We have established two primary goals regarding the development of our oral probiotics business: (1) for the consumer healthcare division to become operationally cash flow positive by the end of 2010, and (2) to maximize the combined sale of our consumer healthcare products in the markets served.

**Weight Loss:** We are currently in the process of re-formulating the delivery mechanism of LPT3-04 such that it provides an enhanced consumer experience. Once this is finished, we will conduct a clinical trial to fully establish efficacy. After the clinical trial has been completed and efficacy is established, we will then begin marketing our first product in the weight loss category. Our goal is to begin to market a product containing LPT3-04 in the first quarter of 2011.

### **Antibiotics**

We are currently scaling production of Synthetic MU 1140 with Almac Sciences, a top-tier European peptide manufacturer. Once this process has been completed, we then plan on conducting pre-clinical testing. If pre-clinical testing is positively concluded, we will file an IND with the FDA, which will include a protocol for Phase I clinical safety trials. Our goal is to complete the scale up and complete pre-clinical testing by the end of 2010 and begin Phase I clinical safety trials in the first half of 2011. We have also started efforts to seek partnerships or licensing arrangements with large pharmaceutical companies for both MU 1140 and the DPOLT Platform; however, we anticipate that we will be unable to procure such arrangements until we have completed either a pivotal pre-clinical animal trial or Phase I clinical trials for MU 1140, our lead antibiotic.

### **Biomarker Discovery**

The goal of our Diagnostics unit is to utilize the PIVIAT™ and PCMAT™ platforms to identify and secure intellectual property rights to gene targets associated with the natural onset and progression of infections, cancers and other diseases in humans, animals, and agricultural products. We believe these platforms provide a number of profitable business models from which to realize value. We believe that our new fluidics based approach will provide us substantial advantages once it has been fully proven. If this occurs, our goal will be to complete three to five studies on high-value disease states by the end of 2010.

### **Biologics**

Our Biologics Division is centered on SMaRT Replacement Therapy™, our product for dental caries (tooth decay). SMaRT Replacement Therapy™ can potentially provide substantial back-end savings to countries since the long-term costs associated with dental caries are substantial. We have been approved by the FDA for a Phase I(b) clinical trial. As such, we are also investigating the possibility of beginning the Phase I(b) clinical trial in the United States in the immediate future. Popular Mechanics cited our patented SMaRT Replacement Therapy tooth decay-fighting bacterial strain #1 among its "20 New Biotech Breakthroughs That Will Change Medicine" published in the monthly magazine's March 2009 issue.

### **Critical Accounting 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 of America. The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America 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. Our financial statements do not include any significant estimates that would have a material impact on our results of operations or financial condition.

## New Accounting Pronouncements

See *Notes to Financial Statements* – Item #1. Organization and Significant Accounting Policies: New Accounting Pronouncements.

## Results of Operations:

	Years ended December 31			Three months ended December 31	
	2009	2008	2007	2009	2008
Revenue	\$ 641,285	233,539	133,088	275,443	8,539
Cost of sales	221,198	14,864	-	120,354	14,864
Operating expenses:					
Research and development	1,833,746	1,955,488	1,569,551	426,230	480,763
Selling, general and administrative	4,917,844	4,312,246	902,655	1,033,860	2,502,833
Total operating expenses	<u>6,751,590</u>	<u>6,267,734</u>	<u>2,472,206</u>	<u>1,460,090</u>	<u>2,983,596</u>
Loss from operations	(6,331,503)	(6,049,059)	(2,339,118)	(1,305,001)	(2,989,921)
Other income (expense):					
Interest income	922	32,511	29,385	126	3,044
Interest expense	(44,292)	(10,054)	-	(18,377)	(10,000)
Gain (loss) on sale of property and equipment	22,743	4,860	(1,979)	11,469	-
Gain on extinguishment of payables	832,959	-	-	79,017	-
Local business tax	(177)	-	-	-	-
Total other income, net	<u>812,155</u>	<u>27,317</u>	<u>27,406</u>	<u>72,235</u>	<u>(6,956)</u>
Loss before income taxes	(5,519,348)	(6,021,742)	(2,311,712)	(1,232,766)	(2,996,877)
Net Loss	<u>\$ (5,519,348)</u>	<u>(6,021,742)</u>	<u>(2,311,712)</u>	<u>(1,232,766)</u>	<u>(2,996,877)</u>

### For the Quarters Ended December 31, 2009 and 2008

We had \$275,443 in revenue during the three months ended December 31, 2009 compared with the \$8,539 of revenues in the same period in 2008. The revenue was generated from \$176,045 of EvoraPlus product sales, \$39,216 of Teddy's Pride product sales and \$60,182 of grant revenue recorded during the quarter. There were no new grants received during the three months ending December 31, 2009.

Cost of sales of \$120,354 or 43.7% were recorded in the three months ended December 31, 2009 compared with \$14,864 or 174% in the same period in 2008. Cost of sales associated with EvoraPlus sales were \$49,112 or 27.9% and Teddy's Pride were \$19,324 or 49.3%. Cost of sales was higher for Teddy's Pride due the lower pricing of products sold into the re-label sales channel. Cost of sales also includes shipping and warehouse processing expenses of \$41,150 and scrap expense of \$10,768.

Our fourth quarter operating expenses consist of Research and Development (R&D) expenses and Selling, General and Administrative (SG&A) expenses. R & D expenses consist primarily of salaries/benefits, patent fees, and research expenses. SG&A expenses consist primarily of salaries/benefits, marketing costs, and legal fees. Operating expenses decreased 51.1% to \$1,460,090 in the three months ended December 31, 2009 from \$2,983,596 in the same period in 2008. R&D expenses decreased 11.3% to \$426,230 in the three months ended December 31, 2009 from \$480,763 in the same period in 2008. The R&D decrease is represented by lower salaries and fringe benefit costs of \$24,490 as a result of the reduction in staff, drop in depreciation expense of \$20,084 due to fully depreciated lab equipment and a decrease in lab supplies expenses of \$59,590. There were several increases in R&D during the same period which included stock options expense of \$26,638 and real estate/tangible property taxes of \$23,187. SG&A expenses decreased 58.7% to \$1,033,860 in the three months ended December 31, 2009 from \$2,502,833 in same period in 2008. Of this decrease \$1,008,505 is attributable to a reduction in legal fees and the remaining decrease of \$460,468 is attributable to decreases in filing and registration fees of \$329,345, consulting services by \$159,051, officer/staff salaries and benefits of \$92,975, and travel related expenses of \$63,703 offset by increases in SG&A expenses during the same period which include stock option expense of \$87,278, selling and marketing expenses due to advertising expense of \$73,269 and the addition of staff of \$24,564 in salaries and fringe benefits. Last year's SG&A expenses included fees associated with services to expand our global business in Mexico and France and fees associated with the change in our common stock listing from the NYSE Alternext US LLC to the OTC Bulletin Board.

Other income of \$72,235 for the three months ended December 31, 2009 included the gain on extinguishment of payable of \$79,017 due to the reduction in expenses owed to several creditors following the June 29, 2009 financing transaction and an \$11,469 gain on the sales of equipment no longer being used. It also included interest expense for the three months ended December 31, 2009 totaling \$18,377 which primarily represents accrued interest expense on the long term note with the KFLP (entered into as part of the June 2009 Private Placement transaction and repaid in exchange for our common stock contemporaneously with the December 2009 Private Placement) offset by a small amount of interest income in the three months ended December 31, 2009 compared to the same period in 2008. The lower interest income is primarily due to the low money market interest rates available during the fourth quarter of 2009 compared to the comparable period in the prior year. These lower interest rates are expected to continue for the foreseeable future.

Our net loss decreased 58.9% to \$1,232,766 during the three months ended December 31, 2009 from \$2,996,877 loss in the same period in 2008. The improvement in net loss is represented by increase in revenue and margin and the overall decrease in G&A expenses.

#### ***For the Years Ended December 31, 2009 and 2008***

We had \$641,285 in revenue in the year ended December 31, 2009 as compared to \$233,539 in 2008. Revenue increased due to product sales of EvoraPlus by \$327,585 and Teddy's Pride by \$39,216. Grant revenues also increase by \$49,484 due to the recognition of grant revenue grant associated with the University of Florida to identify disease-specific proteins expressed during citrus greening.

Cost of sales of \$221,198 were recorded in the year ending December 31, 2009 compared to \$14,864 in cost of sales for the same period in 2008. Cost of sales associated with EvoraPlus sales were \$109,273 or 33.3% and Teddy's Pride were \$19,324 or 49.3%. Cost of sales was higher for Teddy's Pride due the lower pricing of products sold into the re-label sales channel. Cost of sales also includes shipping and warehouse processing expenses of \$67,864 and scrap expense of \$24,737.

Our operating expenses increased 7.7% to \$6,751,590 for the year ended December 31, 2009 from \$6,267,734 in 2008. R&D expenses decreased 6.2% to \$1,833,746 in 2009 from \$1,955,488 in 2008. The decrease in R&D expense is primarily represented by the reduction in stock options expense by \$153,191. SG&A expenses increased 14% to \$4,917,844 in 2009 from \$4,312,246 in 2008. SG&A changes include increases in selling and marketing salaries and benefits and advertising expenses totaling \$983,349, consulting expenses of \$280,604, officer/staff salaries and benefits of \$117,174, travel related expenses of \$48,768, stock options expense of \$31,709 and Board fees of \$26,347. Decreases in SG&A expenses were reflected in legal fees by \$440,463 and filing/registration fees of \$360,263, relocation expenses of \$44,300 and bank financing fees of \$22,572.

Other income of \$812,155 increased by \$784,838 for the year ended December 31, 2009. Other income included the gain on extinguishment of payable of \$832,959 due to the reduction in expenses owed to several creditors following the June 29, 2009 financing transaction. Interest expense for the year ended December 31, 2009 totaling \$44,292 represents the interest expense for the short term note with an accredited investor and the long term note with the KFLP which was part of the June 2009 Private Placement transaction. Interest income decreased by \$31,589 for the year ended December 31, 2009 compared to the same period in 2008. This decrease is primarily due to the nominal money market interest rates available during 2009.

Our total net loss decreased 8.3% to \$5,519,348 in the year ended December 31, 2009 from \$6,021,742 in 2008. The improvement in the net loss was principally caused by the increase in revenue and margin and reduction in both R&D and G&A expenses net of the extinguishment of payables.

#### ***For the Years Ended December 31, 2008 and 2007***

We had \$233,539 in revenue in the year ended December 31, 2008 as compared to \$133,088 in 2007. This is a result of a Small Business Innovation Research (SBIR) grant for DPOLT, a National Science Foundation (NSF) grant for our Mutacin technology and the initial sales of ProBiora and EvoraPlus products. Our operating expenses increased 154% to \$6,267,734 for the year ended December 31, 2008 from \$2,472,206 in 2007. R&D expenses increased 24.6% to \$1,955,488 in 2008 from \$1,569,551 in 2007. The growth in R&D expense is represented by R&D salaries \$53,916, options expense \$176,393, and consulting services/clinical trials for Probiotics and Lilliput technologies \$140,365. SG&A expenses increased 378% to \$4,312,246 in 2008 from \$902,655 in 2007. The most significant increase was in legal fees by \$1,208,259 incurred during the fourth quarter. As mentioned above, the fees are directly related to services to expand our global business in Mexico and France, and also including fees to the change our common stock listing from the NYSE Alternext US LLC to the OTC Bulletin Board. Other major SG&A increases include consulting services for \$523,279 to promote the company and investor relations, filing and registration fees \$358,342, officer/staff salaries and benefits \$421,870, options expense \$175,747, selling and marketing expenses of \$129,553, travel related expenses \$145,602, and accounting fees/services \$177,038.

Interest income increased 10.6% to \$32,511 in the year ended December 31, 2008 from \$29,385 in the year ended December 31, 2007.

Our total net loss increased 161% to \$6,021,742 in the year ended December 31, 2008 from \$2,311,712 in 2007. The increase in the net loss was principally caused by the increase in SG&A expenses for legal fees, consulting services, filing and registration fees and salaries/benefits.

### **Liquidity and Capital Resources**

Since our inception, we have funded our operations through the sale of equity securities in private placement and our initial public offering, the sale of equity securities and warrants in private placements, debt financing and grants. During the year ending 2009, we have received \$200,000 of restricted funds as part of the \$500,000 NSF Phase II grant to advance development of its small peptide antibiotic synthesis program using our proprietary DPOLT<sup>™</sup>. This federal grant will support studies focused on the synthesis and testing of our lead antibiotic, MU 1140. During the 3rd quarter, we received \$124,570 from the University of Florida under the prime grant with the Florida Citrus Production Advisory Council.

Our operating activities used cash of \$5,799,481 for the year ended December 31, 2009 and \$3,835,190 for the year ended December 31, 2008. We had positive working capital of \$2,564,147 as of December 31, 2009 compared to a working capital deficit of \$500,672 as of December 31, 2008. Cash used by operations in the year ended December 31, 2009 resulted primarily from the operating loss of \$5,519,348.

Our investing activities provided an increase in cash by \$30,927 for the year ended December 31, 2009 as a result of the sale of used lab equipment for \$40,000. Acquisitions in 2010 included computers and office furniture of \$9,073. We anticipate investing in a new integrated enterprise wide business system during 2010.

Our financing activities provided \$4,904,213 in cash for the year ending December 31, 2009 compared to \$4,538,687 in cash for the year ended December 31, 2008. This increase was primarily attributable to the sale of our common stock to accredited investors in two private placement transactions during the year. Additional details of our financing activities are provided below:

**Warrant Exercises – Q1 2008** – On August 7, 2007, we closed on \$1,171,591 in equity based financing. We issued a total of 4,600,000 shares of restricted common stock and warrants to acquire 4,600,000 shares of common stock in a private placement to accredited investors. The shares were sold to accredited investors at \$0.25 per share, except that per AMEX requirements, our former CEO, Dr. Ronald Evens acquired his shares at \$0.44 per share, which was the closing share price on August 7, 2007. Each warrant to purchase shares of common stock is exercisable at the price of \$0.58 per share. The unexercised warrants expired on August 8, 2008 (the “August 2007 Warrants”). On January 31, 2008 we amended the August 2007 Warrants, to reduce the exercise price to \$0.44, which was the fair market value on the date of the amendment for a designated period of time (from January 28, 2008 to February 29, 2008). In February 2008, amended Warrants, of 4,536,364 were issued upon exercise at the amended exercise price resulting in additional working capital proceeds to us of \$1,996,000. The remaining unexercised August 2007 warrants expired unexercised on August 8, 2008.

**Private Placement, June 2008** – On June 12, 2008, our Securities Purchase Agreement with accredited investors became binding and we closed on \$2,600,000 in equity based financing with net proceeds of \$2,515,000. We issued a total of 5,777,778 shares of restricted common stock in the private placement. The shares were sold to accredited investors at \$0.45 per share. Each participating investor also received warrants to purchase shares of common stock at the price of \$1.30 per share. One warrant was issued for each share of common stock issued for a total of 5,777,778 shares that may be acquired upon exercise of the warrants. The warrants are exercisable and expire May 30, 2013. We intend to use the proceeds from the exercise of the warrants, if any, for working capital and general corporate purposes.

### **Other Financings.**

On October 20, 2008, the Company obtained from Signature Bank of New York, a revolving line of credit in the amount of up to \$1,000,000, for the purpose of providing working capital to the Company. We did not draw on this line and on January 21, 2009, this line of credit was terminated by us. The Company entered into a short term note payable in June 2008 with an interest rate of 5.75% to finance D&O and employment related practices liability insurance. At December 31, 2008 the balance due was \$27,687. There were no loans during the year 2007. In March 2009, the Company entered into a short term note payable for \$53,087 with an interest rate of 5.75% to finance product liability insurance. This note matures on January 10, 2010. At December 31, 2009 the balance was zero because the note was subsequently repaid on its maturity date.

On April 15, 2009 we entered into a loan agreement with an accredited investor for a short term note in the amount of \$100,000. On August 21, 2009 we paid the short term note and outstanding accrued interest in full. The note included an interest rate of 15% per annum and its maturity date was April 15, 2011. In connection with this borrowing we also issued warrants to acquire 100,000 shares of our common stock at an exercise price of \$.50 per share and such warrants are exercisable for five years.

On August 6, 2009 the Company entered into a short term note payable for \$70,025 with an interest rate of 5.75% to finance directors and officers liability insurance. This note matures on May 24, 2010. At December 31, 2009 the balance due was \$35,012.

On May 4, 2009 and June 10, 2009, we borrowed \$32,556 and \$13,100, respectively, from Dr. Jeffery Hillman, our founder, Chief Science Officer and director. These borrowings were to be repaid upon demand by Dr. Hillman, were unsecured and did not bear interest. The proceeds from these borrowings were used to purchase inventory for our Consumer Healthcare products division. On June 29, 2009 the aggregate amount of these obligations of \$45,656 were repaid by us in full through the issuance of 456,564 shares of our common stock at a price of \$.10 per share, which was the closing price of our common stock on June 29, 2009.

#### **Grants.**

On February 15, 2008, we were awarded a two year NSF SBIR Phase II grant to advance development of our small peptide antibiotic synthesis program using the Company's proprietary DPOLT<sup>tm</sup>. This federal grant supports studies focused on the synthesis and testing of our lead antibiotic, MU 1140. While the grant will total \$500,000, to date we have received \$425,000 of these restricted funds during the last two years.

On September 1, 2009 we received a grant funding from the University of Florida under the prime grant with the Florida Citrus Production Advisory Council in the amount of \$124,570. The purpose of the University of Florida grant is to identify disease-specific proteins expressed during citrus greening using our proprietary PCMAT technology.

#### **June 2009 Private Placement.**

On June 29, 2009, we successfully entered into and consummated a private placement of equity and debt financing pursuant to a securities purchase agreement (the "Purchase Agreement") with an accredited investor. Pursuant to the terms of the Purchase Agreement the Company issued 50,000,000 shares of its Common Stock to the Koski Family Limited Partnership ("KFLP") and issued warrants to the KFLP to acquire 1,000,000 shares of Company common stock at an exercise price of \$0.10 per share in exchange for \$4,000,000, the payment of which consisted of the following: \$1,500,000 in cash at closing and \$2,500,000 pursuant to a non-interest bearing promissory note providing for five consecutive monthly installment payments of \$500,000 commencing July 31, 2009 and the KFLP provided a secured loan of \$1,000,000 to the Company. The loan is secured by substantially all of the Company's assets (excluding receivables) and bears interest at the rate of Prime plus 4.0% which is payable quarterly. The principal of the loan is due in five years. The warrants expire in five years and are immediately exercisable. We also agreed to provide the KFLP with certain registration rights in connection with any underwritten or other offering by us over the next five years. Specifically, we shall include 15% of the total number of shares publicly offered from the shares to be sold by us to the KFLP. As a result of the transaction the board of directors believes there was a change of control of the Company with the KFLP acquiring a controlling interest of approximately 56.6 % of our outstanding voting common stock.

In addition to the above, as a further condition to the consummation of the transaction contemplated by the Purchase Agreement we were required to obtain satisfactory arrangements with three main creditors for reductions in the amounts payable by the Company to them. As of June 30, 2009, these reductions amounted to \$707,674 in aggregate and were conditioned upon prompt payment of the remaining balances owed to such creditors after taking into account the agreed upon reductions. As of December 31, 2009, the amount of reductions arranged with our creditors totaled \$832,959. These agreed upon reductions in payables have been fully reflected in our financial statements for the period and reported under Other Income.

In connection with, and as a closing condition to the Purchase Agreement, the purchasers, (including George Hawes our largest shareholder prior to this transaction), under that certain securities purchase agreement dated June 12, 2008, (the "Hawes Agreement") entered into waiver and release agreements with us on June 25, 2009. In addition, such individuals waived and relinquished any special rights they possessed pursuant to agreements with the Company, including, but not limited to, (i) rights of first refusal (ii) antidilution regarding future equity sales and (iii) covenants regarding secured lending contained in the Hawes Agreement. In connection with such waivers and releases, warrants to acquire 3,220,000 shares of our common stock at an exercise price of \$1.30 per share that were previously issued under the Hawes Agreement pursuant to the Private Placement in June 2008 were subject to the right of exchange for new replacement warrants to acquire the same number of shares under the same terms except for a change in the exercise price from \$1.30 to \$0.75. In addition, to the extent of any future underwritten registered offerings of our common stock, or the filing of any resale registration statement, in each case occurring within five years from the date of the waiver and release, the purchasers shall have the right to include an aggregate of up to 5% of the shares being registered in such offering or registration statement, subject to the discretion, in any underwritten primary offerings, of the underwriter on the inclusion of shares in the offering to be sold by selling shareholders.

## December 2009 Private Placement.

On December 30<sup>th</sup>, 2009, we completed the initial closing of a private placement of equity pursuant to a Common Stock Purchase Agreement (the "Securities Purchase Agreement") with accredited investors. The Company issued 10,016,250 shares of its Common Stock at a price of \$0.25 per share to the investors for \$2,504,062, the payment of which consisted of the following: \$2,450,000 in cash at closing and \$54,062.50 pursuant to the cancellation of the same dollar amount of outstanding deferred compensation obligation owed by the Company to Dr. Jeffrey Hillman, our Chief Scientific Officer and director. Approximately half of the total investment, or \$1,250,000, was made by the KFLP. In conjunction with, and as a condition to closing of the financing, the KFLP was issued 4,000,000 shares of the Company's Common Stock at \$0.25 per share, which was the same price per share paid by the investors, in exchange for the cancellation of its \$1.0 million secured note. The loan originally had been secured by substantially all of the Company's assets (excluding receivables) and required interest payments at the rate of Prime plus 4.0% which were payable quarterly.

Approximately \$1.0 million of the total proceeds from the financing are to be allocated to further the Company's development of its DPOLT synthetic chemistry platform, essential to the production of the Company's lead antibiotic, MU 1140, subject to the goals set forth by the two year NSF SBIR Phase II Grant received by the Company on February 15th, 2008. Such allocation enables the Company to be eligible to receive up to \$500K in matching funds from the NSF; however, there can be no assurances that this matching grant will in fact be awarded.

Contemporaneously with the financing transaction contemplated by the Securities Purchase Agreement, the KFLP also elected to exercise previously issued warrants (issued on June 30, 2009 as part of the June 2009 Private Placement) to purchase 1,000,000 shares of Company Common Stock. The warrants were exercised through the payment by the KFLP of the warrant exercise price of \$0.10 per share. Additionally, Christine L. Koski and Robert C. Koski, as Directors of the Company, each exercised previously issued options to purchase 100,000 shares of the Company's Common Stock at the option exercise price of \$0.10 per share. These options were automatically granted to both Christine and Robert Koski when they became non-employee directors of the Company on June 30, 2009.

On January 13, 2010, we completed the \$3,004,062 private placement contemplated by the Securities Purchase Agreement and December 2009 Private Placement and issued another 2,000,000 shares of common stock at a price of \$0.25 per share to the accredited investors for \$500,000. Of this amount the KFLP again participated in one half of the remainder of the aggregate investment by acquiring 1,000,000 shares for \$250,000.

As of the year ending December 31, 2009, included in our accounts payable for the period were amounts that we owed to former independent directors for prior meeting fees. The deferred aggregate amount owed to our former directors as of December 31, 2009 was \$34,000. The deferred amounts are expected to be settled by us in future periods. The deferrals of payments to our officer and former directors did not reduce our expenses, but served to preserve our limited cash resources at this time to the extent necessary to maintain our operations.

Our business is based on commercializing entirely new and unique technologies, and our current business plan contains a variety of assumptions and expectations that are subject to uncertainty, including assumptions and expectations about manufacturing capabilities, clinical testing cost and pricing, continuing technological improvements, strategic licensing relationships and other relevant matters. These assumptions take into account recent financings, as well as expected but currently undetermined additional financings. We have experienced losses from operations during the last three fiscal years and have an accumulated deficit of \$25,511,883 as of December 31, 2009. Cash used in operations during 2009, 2008 and 2007 was \$5,799,481, \$3,835,190 and \$1,913,760, respectively. At December 31, 2009, our principal source of liquidity was \$2,751,592 of cash and cash equivalents and restricted cash. These operating results occurred while developing and attempting to commercialize e products from entirely new and unique technologies. Our business plan requires significant spending related primarily to marketing of our Consumer Healthcare products, clinical testing expenditures, as well as conducting basic research. These factors place a significant strain on our limited financial resources and adversely affect our ability to continue as a going concern. Our ultimate success will likely depend on our ability to generate meaningful and sustained revenues from our Consumer Healthcare products and our ability to continue to raise capital for our operations.

Our capital requirements for the remainder of 2010 will depend on numerous factors, including the initial success of our commercialization efforts and of our research and development, the resources we devote to develop and support our technologies and the success of pursuing strategic licensing and funded product development relationships with external partners. Subject to our ability to generate revenue and cash flow from our Consumer Healthcare products division and our ability to raise additional capital including through possible joint ventures and/or partnerships, we expect to need 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 being a public company. We will require substantial funds to conduct research and development and preclinical and Phase I clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase II and III clinical testing and manufacture and marketing of any products that are approved for commercial sale. We must generate additional capital resources to enable us to continue as a going concern. Our plans include seeking financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to assure continuation of our operations and research and development programs as well as seeking equity financing.

Our future success depends on our ability to continue to raise capital and ultimately generate revenue and attain profitability. We 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 us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, these securities are likely to have rights, preferences, or privileges senior to those of our common stock, and our current stockholders may experience substantial dilution.

While we continue to focus on our products and technologies, we may not have sufficient capital resources to market our products and complete the development of our technologies. We had a working capital at year end December 31, 2009 of \$2,564,147. While we believe our cash and cash equivalents and restricted cash of \$2,751,592 as of December 31, 2009 (together with \$500,000 in funds we received in early January 2010 on the completion of our December 2009 private placement) are sufficient to enable us to continue to operate through June of 2010, we do not have sufficient capital to operate beyond that time. During this time, if additional capital is not raised, we would need to significantly adjust our current plan of operations until we are able to acquire additional funding. In addition, we expect to continue to explore strategic alternatives that may be available to us and our technologies.

#### **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements.

#### **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-19 at the end of this report and the supplementary data is not available.

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

None.

#### **ITEM 9AT. 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 Chief Executive Officer and Chief Financial Officer. The purpose of disclosure controls and procedures is to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Principal Financial Officer, to allow timely decisions regarding required disclosures.

As previously disclosed under Item 4T, *Controls and Procedures*, in our Quarterly Report on Form 10-Q for the quarters ended June 30 and September 30, 2009, management indicated progress had been made during the quarter to remediate material weaknesses in the internal control over financial reporting. Based on those material weaknesses, our Chief Executive Officer and Principal Financial Officer have concluded that, as of the year ended December 31, 2009, 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, 2009 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.

For the period referenced above, the matters involving internal controls and procedures that our management identified and considered to be material weaknesses were: (1) lack of a functioning audit committee due to a lack of a majority of independent members and a lack of outside directors on our board of directors, resulting in ineffective oversight in the establishment and monitoring of required internal controls and procedures; (2) inadequate staffing and supervision that could lead to the untimely identification and resolution of accounting and disclosure matters and failure to perform timely and effective reviews, (3) limited documentation of our system of internal control, (4) insufficient personnel to employ segregation of duties; (5) lack of formal written policies and procedures for accounting and financial reporting with respect to the requirements and application of U.S. GAAP and SEC disclosure requirements and related documentation; (6) deficiencies in our material technology systems and (7) ineffective controls over period end financial disclosure and reporting processes. In addition, our corporate governance activities and processes are not always formally documented or adequately communicated. Specifically, decisions made by the board to be carried out by management should be documented and communicated on a timely basis to reduce the likelihood of any misunderstandings regarding key decisions affecting our operations and management. These deficiencies and weaknesses were largely attributable to the significant lack of available financial resources and corresponding personnel reductions experienced by us during the quarter ended September 30, 2009.

### **Management' Remediation Initiatives**

Although management has not fully remediated the material weaknesses mentioned above, management believes progress has been made during the year ended December 31, 2009. We continued 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 the quarter the consulting firm completed an initial entity level control evaluation (ELC), control documentation and gap analysis for financial close and reporting. Following such evaluation, management implemented a remediation plan during the quarter and addressed the documentation of our internal controls, creation of policies and procedures, control over period end financial disclosures and update of corporate governance activities and documentation. Management also expects to review various facets of our information processing system, such as cash disbursements, sales and billing, cash receipts and other procedures. We continue to evaluate and address these weaknesses to ensure adherence to our policies, completeness of reporting, segregation of incompatible duties and compliance with generally accepted accounting principles; and we intend to continue to monitor and evaluate these and other factors affecting our internal controls as our available liquidity permits. 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**

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 CEO and CFO, 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.

## CEO and CFO Certifications

Appearing after the Signatures section of this report there are Certifications of the CEO and the CFO. 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 Orogenics, 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 CEO and CFO, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2009. 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, 2009, 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.

At our Annual Meeting of Shareholders held on October 28, 2009 our shareholders voted on three proposals as follows:

### Proposal I Election of Directors

Our shareholders elected each of the following four nominees as directors, each to hold office until their successors are duly elected and qualified. The vote for each director was as follows:

<b>Nominee</b>	<b>For</b>	<b>Withheld</b>
Christine L. Koski	67,004,441	692,057
Robert C. Koski	67,004,421	692,077
Dr. Jeffrey D. Hillman	66,123,421	1,573,077
David B. Hirsch	66,123,421	1,573,077

**Proposal II to approve an amendment to the Corporation's Amended and Restated Articles of Incorporation to increase the Corporation's total number of authorized shares of common stock from 100,000,000 shares, par value \$0.001 per share, to 300,000,000 shares, par value \$0.001 per share.**

<b>For</b>	<b>Against</b>	<b>Abstain</b>
65,785,299	1,908,799	2,400

**Proposal III Approval of the Company's Second Amendment to its Amended and Restated 2002 Stock Option and Incentive Plan to increase the number of shares available from 5,000,000 to 12,500,000.**

<b>For</b>	<b>Against</b>	<b>Abstain</b>
58,849,241	1,266,695	7,580,562

### PART III

#### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Information with respect to our directors and executive officers, the Audit Committee of the Board of Directors, the Nomination Committee of the Board of Directors (known as the Corporate Governance Committee), and the Audit Committee financial expert, will be contained in our 2010 Proxy Statement. The 2010 Proxy Statement is expected to be filed on or before April 30, 2009. Such information is incorporated herein by reference.

#### 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.rogenics.com](http://www.rogenics.com). Any possible future amendments to or waivers from the Company Operating Principles will be posted on our website.

#### Section 16(a) Beneficial Ownership Reporting Compliance

Information regarding compliance with Section 16(a) of the Exchange Act is set forth under the heading "Section 16(a) Beneficial Ownership Reporting Compliance" will be in our 2010 Proxy Statement and is incorporated herein by reference.

#### ITEM 11. EXECUTIVE COMPENSATION.

The information required by this Item 11 with respect to management remuneration and transactions is incorporated herein by reference to our Proxy Statement under the heading "Executive Compensation."

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

The information required by this Item 12 with respect to the security ownership of certain beneficial owners and management is incorporated herein by reference to our Proxy Statement under the heading "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

### Equity Compensation Plan Information

We maintain an equity-based compensation plan—the Amended and Restated 2002 Stock Option and Incentive Plan (as amended, the "Incentive Plan"). A description of our equity based compensation plan can be found in Note 8 of the Notes to Financial Statements. The 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 Incentive Plan, the weighted-average exercise price of outstanding options, and the number of shares remaining available for future award grants under the Incentive Plan as of December 31, 2009 (in thousands, except exercise price):

Plan Category	Equity Compensation Plan Information		
	(a)	(b)	(c)
	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	7,719,300	\$ 0.35	4,780,700
Equity compensation plans not approved by security holders(1)	-	-	-
<b>Total</b>	<b>7,719,300</b>	<b>\$ 0.35</b>	<b>4,780,700</b>

(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 6,127,778 shares of common stock outstanding at an a weighted average exercise price of \$0.96 per share

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

The information required by this Item 13 with respect to transactions between us and certain related entities is incorporated herein by reference to our Proxy Statement under the heading "Certain Relationships."

## ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information required by this Item 14 is incorporated herein by reference to our Proxy Statement under the heading "Principal Accountant Fees and Services."

## 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 listed in the Index to Financial Statements and are filed as part of this report.

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.

2. Exhibits required by Item 601 of Regulation S-K are submitted as a separate section herein immediately following the "Exhibit Index".

(b) Other Exhibits

No exhibits in addition to those previously filed or listed in item 15(a) (2) and filed herein.

(c) Not Applicable

**SIGNATURES**

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

Dated: March 31, 2010

ORAGENICS, INC.  
(Registrant)

By: /s/ David B. Hirsch  
David B. Hirsch, President, Chief Executive  
Officer and Principal Executive Officer  
(DULY AUTHORIZED OFFICER)

**POWER OF ATTORNEY**

Each of the undersigned officers and directors of Oragenics, Inc., hereby constitutes and appoints David B. Hirsch, and Brian J. Bohunicky, each their true and lawful attorneys-in-fact and agents, for them and in their name, place and stead, in any and all capacities, to sign their names 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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/ David B. Hirsch</u> David B. Hirsch	President, Chief Executive Officer (Principal Executive Officer) and Director	March 31, 2010
<u>/s/ Jeffrey D. Hillman</u> Jeffrey D. Hillman	Chief Scientific Officer and Director	March 31, 2010
<u>/s/ Brian J. Bohunicky</u> Brian J. Bohunicky	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 31, 2010
<u>/s/ Christine Koski</u> Christine Koski	Chairperson of the Board and Director	March 31, 2010
<u>/s/ Robert Koski</u> Robert Koski	Director	March 31, 2010

Oragenics, Inc.

Financial Statements

Years ended December 31, 2009, 2008 and 2007

**Index**

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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, 2009 and 2008, and the related statements of operations, shareholders' equity (deficit), and cash flows for the years ended December 31, 2009, 2008 and 2007. 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 audit 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, 2009 and 2008, and the results of its operations and its cash flows for the years ended December 31, 2009, 2008 and 2007 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.

March 29, 2010

/s/ Kirkland Russ Murphy & Tapp, PA

Clearwater, Florida

Certified Public Accountants

Oragenics, Inc.  
Balance Sheets  
December 31, 2009 and 2008

	<u>2009</u>	<u>2008</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 301,592	1,165,933
Restricted cash	2,450,000	-
Accounts receivables, net	162,813	6,286
Inventory	132,112	11,814
Prepaid expenses and other current assets	<u>80,839</u>	<u>86,666</u>
Total current assets	3,127,356	1,270,699
Property and equipment, net	<u>75,480</u>	<u>323,424</u>
Total assets	<u>\$ 3,202,836</u>	<u>1,594,123</u>
<b>Liabilities and Shareholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 478,111	1,743,684
Short term note payable	35,012	27,687
Deferred grant revenue	<u>50,086</u>	<u>-</u>
Total current liabilities	563,209	1,771,371
Shareholders' equity (deficit):		
Preferred stock, no par value; 20,000,000 shares authorized; none issued and outstanding	-	-
Common stock, \$0.001 par value; 300,000,000 and 100,000,000 shares authorized at December 31, 2009 and 2008, respectively; 106,083,149 and 38,316,585 shares issued and outstanding at December 31, 2009 and December 31, 2008, respectively.	106,083	38,316
Additional paid-in capital	28,045,427	19,776,971
Accumulated deficit	<u>(25,511,883)</u>	<u>(19,992,535)</u>
Total shareholders' equity (deficit)	<u>2,639,627</u>	<u>(177,248)</u>
Total liabilities and shareholders' equity (deficit)	<u>\$ 3,202,836</u>	<u>1,594,123</u>

*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, 2009, 2008 and 2007

	<b>Year Ended December 31</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
Revenue	\$ 641,285	233,539	133,088
Cost of sales	221,198	14,864	-
Operating expenses:			
Research and development	1,833,746	1,955,488	1,569,551
Selling, general and administration	4,917,844	4,312,246	902,655
Total operating expenses	<u>6,751,590</u>	<u>6,267,734</u>	<u>2,472,206</u>
Loss from operations	(6,331,503)	(6,049,059)	(2,339,118)
Other income (expense):			
Interest income	922	32,511	29,385
Interest expense	(44,292)	(10,054)	-
Gain (loss) on sale of property and equipment	22,743	4,860	(1,979)
Gain on extinguishment of payables	832,959	-	-
Local business tax	(177)	-	-
Total other income, net	<u>812,155</u>	<u>27,317</u>	<u>27,406</u>
Loss before income taxes	<u>(5,519,348)</u>	<u>(6,021,742)</u>	<u>(2,311,712)</u>
Net loss	<u>\$ (5,519,348)</u>	<u>(6,021,742)</u>	<u>(2,311,712)</u>
Basic and diluted net loss per share	<u>\$ (0.09)</u>	<u>(0.17)</u>	<u>(0.09)</u>
Shares used to compute basic and diluted net loss per share	<u>64,883,774</u>	<u>35,069,261</u>	<u>25,092,183</u>

*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, 2009, 2008 and 2007

	<u>Common Stock</u>		<u>Additional Paid In Capital</u>	<u>Accumulated Deficit</u>	<u>Total Shareholders' Equity (Deficit)</u>
	<u>Shares</u>	<u>Amount</u>			
Balances at December 31, 2006	22,404,943	\$ 22,405	\$12,914,950	\$ (11,659,081)	\$ 1,278,274
Exercise of common stock warrants	997,500	997	599,502	-	600,499
Issuance of common stock and warrants	4,600,000	4,600	1,086,751	-	1,091,351
Compensation expense relating to option issuances	-	-	161,471	-	161,471
Net loss	-	-	-	(2,311,712)	(2,311,712)
Balances at December 31, 2007	28,002,443	\$ 28,002	\$14,762,674	\$ (13,970,793)	\$ 819,883
Exercise of common stock warrants	4,536,364	4,536	1,991,464	-	1,996,000
Issuance of common stock and warrants	5,777,778	5,778	2,509,222	-	2,515,000
Compensation expense relating to option issuances	-	-	513,611	-	513,611
Net loss	-	-	-	(6,021,742)	(6,021,742)
Balances at December 31, 2008	38,316,585	\$ 38,316	\$19,776,971	\$ (19,992,535)	\$ (177,248)
Exercise of common stock options and warrants	1,200,000	1,200	118,800	-	120,000
Issuance of common stock and warrants, net of expenses	66,566,564	66,567	7,757,527	-	7,824,094
Compensation expense relating to option issuances	-	-	392,129	-	392,129
Net loss	-	-	-	(5,519,348)	(5,519,348)
Balances at December 31, 2009	<u>106,083,149</u>	<u>\$106,083</u>	<u>\$28,045,427</u>	<u>\$ (25,511,883)</u>	<u>\$ 2,639,627</u>

*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, 2009, 2008 and 2007

	<b>Year Ended December 31</b>		
	<b>2009</b>	<b>2008</b>	<b>2007</b>
<b>Cash flows from operating activities:</b>			
Net loss	\$(5,519,348)	(6,021,742)	(2,311,712)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash bonus paid in common stock	100,000	-	-
Non-cash services paid in common stock	115,000	-	-
Non-cash settlement of amounts owed to employees	113,439	-	-
Depreciation and amortization	239,760	253,857	273,230
Stock-based compensation expense	392,129	513,611	161,471
Gain on extinguishment of payables	(832,959)	-	-
(Gain) loss on sale of property and equipment	(22,743)	(4,860)	1,979
Changes in operating assets and liabilities:			
Accounts receivable, net	(156,527)	(6,286)	-
Inventory	(120,298)	(11,814)	-
Prepaid expenses and other current assets	128,939	29,854	(42,649)
Accounts payable and accrued expenses	(286,959)	1,412,190	3,921
Deferred grant revenue	50,086	-	-
Net cash used in operating activities	(5,799,481)	(3,835,190)	(1,913,760)
<b>Cash flows from investing activities:</b>			
Purchase of property and equipment, net	(9,073)	(55,322)	(12,906)
Proceeds from sale of property and equipment, net	40,000	42,250	3,046
Net cash (used in) provided by investing activities	30,927	(13,072)	(9,860)
<b>Cash flows from financing activities:</b>			
Borrowings under short term note payable	100,000	79,518	-
Borrowings under long term note payable	1,000,000	-	-
Payments on short term note payable	(215,787)	(51,831)	-
Net proceeds from issuance of common stock	6,470,000	4,511,000	1,691,850
Restricted cash from common stock issuance proceeds	(2,450,000)	-	-
Net cash provided by financing activities	4,904,213	4,538,687	1,691,850
Net increase (decrease) in cash and cash equivalents	(864,341)	690,425	(231,770)
Cash and cash equivalents at beginning of year	1,165,933	475,508	707,278
Cash and cash equivalents at end of year	<u>\$ 301,592</u>	<u>1,165,933</u>	<u>475,508</u>
Interest paid	<u>\$ 25,915</u>	<u>10,054</u>	<u>-</u>
Non-cash investing and financing activities:			
Issuance of common stock to employees as settlement of amounts owed	<u>\$ 32,556</u>	<u>-</u>	<u>-</u>
Borrowings under short term notes payable for prepaid expense	<u>\$ 123,112</u>	<u>-</u>	<u>-</u>
Long-term note payable converted into common stock	<u>\$ 1,000,000</u>	<u>-</u>	<u>-</u>

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

## 1. Organization and Significant Accounting Policies

Oragenics, Inc. (formerly known as Oragen, Inc.) (the Company) 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.

### 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 incurred a net loss of \$5,519,348 for the year ended December 31, 2009 and as of that date had an accumulated deficit of \$25,511,883. Cash used in operations for the year ended December 31, 2009 was \$5,799,481 and cash flow from operations was negative throughout 2009. The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes the working capital at December 31, 2009 will be sufficient to meet the business objectives as presently structured through June 2010. 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.

### Recently Adopted Accounting Pronouncements

In August 2009, the FASB issued ASU 2009-05, "Fair Value Measurements and Disclosures (ASC Topic 820) — Measuring Liabilities at Fair Value" ("Update 2009-05"). Update 2009-05 provides clarification regarding valuation techniques when a quoted price in an active market for an identical liability is not available in addition to treatment of the existence of restrictions that prevent the transfer of a liability. Update 2009-05 also clarifies that both a quoted price in an active market for an identical liability at the measurement date and the quoted price for an identical liability when traded as an asset in an active market (when no adjustments to the quoted price of the asset are required) are Level 1 fair value measurements. This standard is effective for the first reporting period, including interim periods, beginning after issuance. Adoption of Update 2009-05 did not have a material effect on Company's financial statements.

On July 1, 2009 the Financial Accounting Standards Board ("FASB") Accounting Standards Codification<sup>™</sup> ("ASC") became the authoritative source of accounting principles to be applied to financial statements prepared in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). In accordance with the ASC, citations to accounting literature in this report are to the relevant topic of the ASC or are presented in plain English. This standard is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Company adopted this standard at its effective date.

### New Accounting Pronouncements

In June 2003, the SEC adopted final rules under Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404"), as amended, by SEC Release No. 33-8760 on December 15, 2006. Commencing with the Company's annual report for the year ended December 31, 2007, the Company is required to include a report of management on the Company's internal control over financial reporting. The internal control report must include a statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting for the Company; of management's assessment of the effectiveness of the Company's internal control over financial reporting as of year-end; and of the framework used by management to evaluate the effectiveness of the Company's internal control over financial reporting. Furthermore, beginning with the Company's annual report for fiscal year 2010, the Company is required to file the auditor's attestation report separately on the Company's internal control over financial reporting on whether it believes that the Company has maintained, in all material respects, effective internal control over financial reporting.

Oragenics, Inc.  
Notes to Financial Statements (continued)  
December 31, 2009 and 2008

In October 2009, the FASB issued ASU No. 2009-13, "Revenue Recognition (Topic 605) — Multiple-Deliverable Revenue Arrangements." ASU No. 2009-13 addresses the accounting for multiple-deliverable arrangements to enable vendors to account for products or services (deliverables) separately rather than as a combined unit. This guidance establishes a selling price hierarchy for determining the selling price of a deliverable, which is based on: (a) vendor-specific objective evidence; (b) third-party evidence; or (c) estimates. This guidance also eliminates the residual method of allocation and requires that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method. In addition, this guidance significantly expands required disclosures related to a vendor's multiple-deliverable revenue arrangements. ASU No. 2009-13 is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010 and early adoption is permitted. A company may elect, but will not be required, to adopt the amendments in ASU No. 2009-13 retrospectively for all prior periods. Management is currently evaluating the requirements of ASU No. 2009-13 and has not yet determined the impact on the Company's consolidated financial statements.

#### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (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, 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.

#### **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, 2009, the Company had \$2,450,000 of cash that was restricted and held in escrow for three days pursuant to the Common Stock Purchase Agreement dated December 30, 2009. On January 2, 2010, \$1,450,000 was released from restrictions. In accordance with this agreement, the Company shall reserve and allocate \$1,000,000 of the proceeds from this common stock sale solely to the expenses incurred in the further development of the Company's DPOLT synthetic chemistry platform.

#### **Accounts Receivable**

Accounts receivable are recorded at their net realizable value and consist of trade receivables from the sale of product to customers. Management analyzes accounts receivable on a regular basis and determines the collectability based on the facts and circumstances relating to each customer. The Company does not have a history of accounts receivable or write offs, therefore, the Company estimated their allowance for doubtful accounts based on sales trend. As of December 31, 2009 and 2008, the Company has recorded an allowance for doubtful accounts of \$5,410 and \$0, 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.

#### **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).

Oragenics, Inc.  
Notes to Financial Statements (continued)  
December 31, 2009 and 2008

**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 grant date fair values. Stock-based compensation expense is recorded over the requisite service period in which the employee or non-employee provides services to Oragenics, to the extent the options or warrants do not vest at the grant date and are not 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.

**Revenue Recognition**

The Company recognizes revenue 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.

The Company records allowances for discounts and product returns at the time of sales as a reduction of revenue 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.

**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, 2009, 2008 and 2007.

**Advertising Expenses**

The Company's policy is to expense advertising and marketing costs as incurred. For the years ended December 31, 2009, 2008 and 2007, advertising and marketing expense was \$421,038, \$45,308 and \$0, respectively.

**Research and Development Expenses**

Expenditures for research and development are expensed 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.

**Concentrations**

The Company is dependent on three key suppliers to provide probiotics, blending and packaging of its EvoraPlus, EvoraPlus Kids and Teddy's Pride products.

Oragenics, Inc.  
Notes to Financial Statements (continued)  
December 31, 2009 and 2008

**2. Inventory**

Inventory consists of the following as of December 31, 2009 and 2008:

	2009	2008
Finished goods	\$ 77,826	\$ 11,814
Work-in-process	27,286	-
Raw materials	27,000	-
Total inventory	<u>\$ 132,112</u>	<u>\$ 11,814</u>

**3. Property and Equipment, net**

Property and equipment, net consists of the following as of December 31, 2009 and 2008:

	2009	2008
Furniture and fixtures	\$ 17,109	\$ 8,035
Laboratory equipment	804,279	825,193
Leasehold improvements	476,777	481,606
Office and computer equipment	33,908	82,915
	<u>1,332,073</u>	<u>1,397,749</u>
Accumulated depreciation and amortization	(1,256,593)	(1,074,325)
Property and equipment, net	<u>\$ 75,480</u>	<u>\$ 323,424</u>

Depreciation and amortization expense for the years ending December 31, 2009, 2008, and 2007 were \$239,760, \$253,857 and \$273,230 respectively.

**4. Related Party Transactions**

At December 31, 2009 deferred payments totaling \$34,000 were owed to former directors in connection with their service on our Board and are included in the accompanying balance sheet in accrued expenses as of December 31, 2009. These meeting fees were 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.

At December 31, 2008 deferred payments totaling \$143,583 were owed to Jeffrey D. Hillman, David Hirsch, Stanley Stein and \$34,000 to the former directors and are included in the accompanying balance sheet in accounts payable and accrued expenses as of December 31, 2008. Amounts were repaid through stock issuances or cash payments during 2009, excluding \$34,000 due to former directors which remain outstanding as of December 31, 2009.

**5. Accounts Payable and Accrued Expenses**

	2009	2008
Accounts payable trade	\$ 194,025	\$ 493,599
Legal fees	107,656	909,881
Vacation	88,473	65,907
Deferred compensation	34,000	143,583
Royalties payable	25,000	50,000
Interest	18,377	-
Other	6,291	10,714
Consulting fees	4,289	70,000
Total accounts payable and accrued expenses	<u>\$ 478,111</u>	<u>\$1,743,684</u>

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Accounts payable and accrued expenses as of December 31, 2009 and 2008 were \$478,111 and \$1,743,684, respectively. Excluding accounts payable trade, legal fees represent the most significant expense totaling \$107,656 as of December 31, 2009 and \$909,881 as of December 31, 2008. In 2009, accrued legal fees are primarily for general counsel and patent work. The fees incurred during 2008 supported legal activities related to the delisting from the NYSE Alternext US (formerly known as the American Stock Exchange), listing on the Alternext – Paris exchange, requirements for trading on the Over-the-Counter (OTC) Bulletin Board and global expansion activities in Mexico and France. During 2009, the Company recorded \$832,959 of extinguished accounts payable due to the reduction in payments owed to several creditors following the June 29, 2009 financing transaction.

#### **6. Short Term Note Payable**

On August 6, 2009 the Company entered into a short term note payable for \$70,025 with an interest rate of 5.75% to finance directors and officers liability insurance. This note matures on May 24, 2010. At December 31, 2009 the balance due was \$35,012.

On April 15, 2009 we entered into a loan agreement with an accredited investor for a short term note in the amount, of \$100,000. On August 21, 2009 we paid the short term note and outstanding accrued interest in full. The note included an interest rate of 15% per annum and its maturity date was April 15, 2011. In connection with this borrowing we also issued warrants to acquire 100,000 shares of our common stock at an exercise price of \$.50 per share and such warrants are exercisable for five years. The fair value of the warrants was determined to be immaterial by the Company.

In March 2009, the Company entered into a short term note payable for \$53,087 with an interest rate of 5.75% to finance product liability insurance. This note matures on January 10, 2010. At December 31, 2009 the balance was paid off.

The Company entered into a short term note payable in June of 2008 with an interest rate of 5.75% to finance D&O and employment related practices liability insurance at December 31, 2008, the balance due was \$27,687. The amount was paid off as of April 30, 2009.

#### **7. Line of Credit**

There were no lines of credit established by the Company during 2009.

The Company opened a Line of Credit with Signature Bank, NY during 2008. The line of credit was established for short term loans for working capital purposes, provided the aggregate principal amount of loans at any time outstanding would not exceed \$1,000,000. Signature Bank was entitled to receive interest at a fluctuating rate per annum equal to the Prime Rate and the interest rate was subject to change as the Prime Rate changes. The Company agreed to pay the Bank an additional compensation facility fee in the amount of \$10,000 which was payable upon the Company's acceptance. The Line of Credit was fully secured by the Company's Signature Bank Fidelity Prime Fund money market. As of December 31, 2008 there were no amounts outstanding on the line of credit. The Company canceled the line of credit on January 24, 2009 without ever drawing upon it.

#### **8. Shareholders' Equity**

##### **Common Stock**

On August 7, 2007, our Securities Purchase Agreement with accredited investors, including a former director, became binding and we closed on \$1,171,591 in equity based financing. We issued a total of 4,600,000 shares of restricted common stock in the private placement. The shares were sold to accredited investors at \$0.25 per share, except that per the exchange listing, our former director acquired his shares at \$0.44 per share, which was the closing share price on August 7, 2007. Each participating investor also received warrants to purchase shares of common stock at the price of \$0.58 per share. One warrant was issued for each share of common stock issued for a total of up to 4,600,000 shares that may be acquired upon exercise of the warrants. The warrants became exercisable in February, 2008 and expired on August 7, 2007 after one year from the date of issuance.

On June 12, 2008, we issued an aggregate of 5,777,778 shares of common stock accredited to investors, including an affiliate, George T. Hawes at a price of \$0.45 per share pursuant to a private offering of the Company's stock. Net proceeds of \$2,515,000 were received from this private offering.

In November, 2008, the Company began the process of listing on the NYSE Euronext Alternext Paris exchange. We were sponsored by Bryan Garnier, a European investment banking firm. We were approved in early December, and on Monday, December 15, 2008, trading of the Company's shares on Alternext Paris commenced.

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On December 10, 2008, the Company received notice from NYSE Alternext US LLC (formerly known as the American Stock Exchange\* hereinafter the "Exchange" or "Alternext US") that the Listings Qualifications Panel of the Exchange's Committee on Securities (the "Panel"), denied the Company's appeal and affirmed the Staff's previous decision to delist the Company's common stock. The notice from the Exchange indicated that the Panel agreed with the Staff's determination that the Company did not meet the continued listing standards under the Alternext US Company Guide: Section 1003(a)(ii) in that the Company's shareholders' equity is less than \$4 million and it has sustained losses in three of its four most recent fiscal years. Accordingly, the delisting became effective at the close of market on December 19, 2008. On Monday, December 22, 2008, quotations for the Company's shares became available on the Over-the-Counter (OTC) Bulletin Board under the ticker symbol ORNI. Quotes became available, among other places, on the OTCBB website [www.otcbb.com](http://www.otcbb.com).

On May 4, 2009 and June 10, 2009, we borrowed \$32,556 and \$13,100, respectively, from Dr. Jeffery Hillman, our founder, Chief Science Officer and director. These borrowings were to be repaid upon demand by Dr. Hillman, were unsecured and did not bear interest. The proceeds from these borrowings were used to purchase inventory for our Consumer Healthcare products division. On June 29, 2009 the aggregate amount of these obligations of \$45,656 were repaid by us in full through the issuance of 456,564 shares of our common stock at a price of \$.10 per share, which was the closing price of our common stock on June 29, 2009.

On June 29, 2009, we successfully entered into and consummated a private placement of equity and debt financing pursuant to a Securities Purchase Agreement with an accredited investor (the "June 2009 Private Placement"). Pursuant to the terms of the Securities Purchase Agreement the Company issued 50,000,000 shares of its Common Stock to the Koski Family Limited Partnership ("KFLP") and issued warrants to the KFLP to acquire 1,000,000 shares of Company common stock at an exercise price of \$0.10 per share in exchange for \$4,000,000, the payment of which consisted of the following: \$1,500,000 in cash at closing and \$2,500,000 pursuant to a non-interest bearing promissory note providing for five consecutive monthly installment payments of \$500,000 commencing July 31, 2009 and the KFLP provided a secured convertible loan of \$1,000,000 to the Company. The loan is secured by substantially all of the Company's assets (excluding receivables) and bears interest at the rate of Prime plus 4.0% which is payable quarterly. The principal of the loan is due in five years. The warrants expire in five years and are immediately exercisable. Immediately following the closing of the aforementioned June 2009 Private Placement, our Chief Executive Officer Mr. Hirsch was awarded a bonus of \$100,000 which was paid in 1,000,000 shares of our common stock at a price per share of \$0.10. We issued 250,000 shares of our common stock to our newly appointed Chief Financial Officer for deferred compensation we owed to him and we issued 343,750 shares of our common stock to another employee for deferred compensation we owed to him.

As a result of the transaction the board of directors believes there was a change of control of the Company with the KFLP acquiring a controlling interest of approximately 56.6 % of our outstanding voting common stock. Two Koski family members, Robert C. Koski and Christine L. Koski were appointed to our Board of Directors. In addition, following the transaction, the KFLP also has the ability to consent to the selection and appointment of two outside directors.

The KFLP was also granted registration rights in connection with any offerings by the Company of its shares. Such registration rights require the Company to include a certain amount of the KFLP shares in a Company offering determined based upon 15% of the shares to be publicly offered.

In connection with, and as a condition to the Securities Purchase Agreement, the purchasers, including George Hawes our largest shareholder prior to this transaction, under that certain securities purchase agreement dated June 12, 2008, (the "Hawes Agreement") entered into waiver and release agreements with us. In addition, such individuals waived and relinquished any special rights they possessed pursuant to agreements with the Company, including, but not limited to, (i) rights of first refusal (ii) antidilution regarding future equity sales and (iii) covenants regarding secured lending. In connection with such waivers and releases, warrants to acquire 3,220,000 shares of our common stock at an exercise price of \$1.30 per share that were previously issued under the Hawes Agreement were subject to the right of exchange for new replacement warrants to acquire the same number of shares under the same terms except for a change in the exercise price from \$1.30 to \$0.75.

In addition to the above, as a further condition to the consummation of the transaction contemplated by the Securities Purchase Agreement the Company was required to obtain satisfactory arrangements with three main creditors for reductions in the amounts payable by the Company to such creditors. As of June 29, 2009 the agreed upon reductions in accounts payable with such creditors amounted to \$707,674 in aggregate and the reductions were conditioned upon prompt payment of the remaining balances owed to such creditors after taking into account the reductions agreed to by such creditors. Further reductions to amounts owed to creditors were agreed to during the three months ending December 31, 2009 in the amount of \$79,017. The total amount of reductions for the year ending December 31, 2009 was \$832,959 which was recorded as a gain on extinguishment of payables and reported as Other Income.

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In September 2009, the Company issued 500,000 shares of restricted common stock to Media4Equity LLC ("M4E") pursuant to an agreement with M4E effective September 3, 2009 whereby M4E will provide consulting services to us with respect to national media exposure of placements of print and radio features. The agreement also requires us to pay a monthly fee to M4E of \$10,000 during the three year term of the agreement, subject to certain termination rights. The shares of common stock have a fair market value of \$115,000 based on a price of \$0.23 per share. This amount is included in selling, general and administrative expenses in the accompanying 2009 statement of operations.

On October 28, 2009 at our annual shareholder meeting our proposal to amend the Company's articles of incorporation to increase the authorized shares of common stock from 100,000,000 to 300,000,000 was approved by shareholders and the amendment to our articles of incorporation was filed with the Florida Department of State. In addition, at our annual meeting our shareholders also approved a second amendment to our Amended and Restated 2002 Stock Option and Incentive Plan to increase the shares available for grant thereunder from 5,000,000 to 12,500,000.

On December 30<sup>th</sup>, 2009, we completed the initial closing of a private placement of equity pursuant to a Common Stock Purchase Agreement with accredited investors (the "December 2009 Private Placement"). The Company issued 10,016,250 shares of its Common Stock at a price of \$0.25 per share to the investors for \$2,504,062, the payment of which consisted of the following: \$2,450,000 in cash at closing and \$54,062 pursuant to the cancellation of the same dollar amount of outstanding deferred compensation obligation owed by the Company to Dr. Jeffrey Hillman. Approximately half of the total investment, or \$1,250,000, was made by the Koski Family Limited Partnership (the "KFLP"). In conjunction with, and as a condition to the initial closing of the December 2009 Private Placement, the KFLP was issued 4,000,000 shares of the Company's Common Stock at \$0.25 per share, which was the same price per share paid by the investors, in exchange for the cancellation of its \$1,000,000 secured note. The loan originally had been secured by substantially all of the Company's assets (excluding receivables) and required interest payments at the rate of Prime plus 4.0% which were payable quarterly. The transaction was consummated pursuant to, and in reliance upon, an exemption from registration set forth under Section 4(2) of the Securities Act of 1933 as amended, as this transaction did not involve a public offering.

Contemporaneously with the December 2009 Private Placement contemplated by the Common Stock Purchase Agreement, the KFLP also elected to exercise previously issued warrants (issued on June 30, 2009) to purchase 1,000,000 shares of Company Common Stock. The warrants were exercised through the payment by the KFLP of the warrant exercise price of \$0.10 per share. Additionally, Christine L. Koski and Robert C. Koski, as Directors of the Company, each exercised previously issued options to purchase 100,000 shares of the Company's Common Stock at the option exercise price of \$0.10 per share. These options were automatically granted to both Christine and Robert Koski when they became non-employee directors of the Company on June 30, 2009.

#### **Warrants**

On December 14, 2005, we issued a total of 2,937,500 shares of our common stock and warrants to purchase 2,937,500 shares of our common stock in a private placement to accredited investors. We received gross proceeds of \$1,175,000 in the private placement and incurred estimated costs of approximately \$70,000 resulting in net proceeds of approximately \$1,105,000. The warrants representing shares of common stock were exercisable by the accredited investors at any time over a two-year period at an exercise price of \$0.60 per share. On January 16, 2007, we called all outstanding warrants associated with our December 2005 private placement pursuant to the terms of the warrant. During 2007, a total of 997,500 warrants were exercised that provided \$478,500 in additional working capital and following the call of the warrants no further warrants associated with the private placement remain outstanding.

On January 11, 2008 the Company approved an amendment to the outstanding warrants that were originally issued in connection with the Company's private placement on March 6, 2006. The warrants were to expire on February 8, 2008 and the Board of Directors determined it would be in the best interest of the Company to amend the exercise price from \$0.60 to \$0.44 for the balance of the remaining term. The outstanding warrants totaled 1,500,000 shares of common stock. On February 8, 2008, we issued an aggregate of 1,150,000 shares of common stock to warrant holders in connection with their exercise of the warrants at a reduced price of \$0.44. The warrants were originally issued to accredited investors in connection with our March 6, 2006 private placement. The 350,000 remaining unexercised warrants expired as of February 8, 2008 in accordance with the terms of the warrants. Proceeds of \$506,000 were received by us from the exercise of the warrants. As holders of these outstanding warrants, Jeffery Hillman, our Chief Science Officer; Robert Zahradnik, our former Chief Operating Officer; and an affiliate, George Hawes; acquired 62,500 shares, 62,500 shares and 737,500 shares, respectively.

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On January 29, 2008 the Company approved an amendment to the outstanding warrants that were originally issued in connection with the Company's private placement on August 7, 2007. The original warrants that totaled 4,600,000 shares of common stock and expire on

August 7, 2008, were amended prior to expiration by the Board of Directors from the original \$0.58 to \$0.44. This amended price was only exercisable during the period from January 28, 2008 to February 29, 2008. On February 29, 2008, we issued an aggregate of 3,386,364 shares of common stock to warrant holders in connection with their exercise of the warrants at a reduced exercised price of \$0.44. The warrants were originally issued to accredited investors in connection with our August 7, 2007 private placement. The remaining 1,213,636 outstanding warrants associated with this original private placement expired August 8, 2008 at an exercise price of \$0.58. Proceeds of \$1,490,000 were received from the exercise of warrants. As part of the warrant exercises, George T. Hawes, an affiliate, acquired 500,000 shares of the Company.

Coupled with the private offering on June 12, 2008 investors also received warrants to purchase 5,777,778 shares common stock at a price of \$1.30 per share. These warrants expire five years from their date of issuance. A portion of these warrants to acquire 3,220,000 shares of our common stock were amended in connection with the June 2009 Private Placement to reduce the exercise price from \$1.30 to \$0.75.

In connection with the June 2009 Private Placement the Company issued warrants to the KFLP to acquire 1,000,000 shares of Company common stock at an exercise price of \$0.10 per share. The warrants expired in five years and were immediately exercisable. In connection with the December 2009 Private Placement, the KFLP elected to exercise its warrants to purchase 1,000,000 shares of Company Common Stock through the payment by the KFLP of the warrant exercise price of \$0.10 per share. Additionally, Christine L. Koski and Robert C. Koski, as Directors of the Company, each exercised previously issued options to purchase 100,000 shares of the

Company's Common Stock at the option exercise price of \$0.10 per share. These options were automatically granted to both Christine and Robert Koski when they became non-employee directors of the Company on June 30, 2009.

On September 14, 2009 the Company issued 250,000 warrants to Strategic Growth International to purchase common stock at an exercise price of \$0.30 per share. These shares were issued in connection with a contract to provide investor relations services.

A summary of the status of the Company's outstanding and exercisable warrants as of December 31, 2009 is presented below:

<u>Shares Underlying Warrant Outstanding</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
2,557,778	\$ 1.30	5/30/2013
3,220,000	0.75	5/30/2013
100,000	0.50	4/15/2014
250,000	0.30	9/14/2012
<u>6,127,778</u>		

A summary of the status of the Company's outstanding and exercisable warrants as of December 31, 2008 is presented below:

<u>Shares Underlying Warrant Outstanding</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
5,777,778	\$ 1.30	5/30/2013

### Stock Compensation Plan

The Company originally adopted the Oragenics, Inc. 2002 Stock Option and Incentive Plan on September 17, 2002. An Amended and Restated 2002 Stock Option and Incentive Plan was subsequently adopted by our Board and approved by our shareholders in May 2006 (the "Plan"). The First Amendment to the Plan, which increased the number of shares from 3,000,000 to 5,000,000 was approved by our shareholders in April 2008. Our stockholders approved the Second Amendment to the Plan to increase the shares available for issuance under the Plan from 5,000,000 to 12,500,000 shares in October 2009. The purpose of the 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 Plan authorizes the grant of stock options (incentive and non-statutory), stock appreciation rights and restricted stock. As of December 31, 2009 and 2008, the Company had not awarded any stock appreciation rights or restricted stock under the Plan. The Company has reserved an aggregate of 12,500,000 and 5,000,000 shares of common stock for grants under the Plan at December 31, 2009 and 2008, respectively, of which 4,780,700 and 430,000 shares, respectively, are available for future grants as of December 31, 2009 and 2008. The exercise price of each option shall be determined by the Board and an option's maximum term is ten years.

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During the years ended December 31, 2009, 2008 and 2007, the Company recognized a stock compensation expense of \$392,129, \$513,611 and \$161,471, respectively, in accordance with GAAP.

During 2009, there were 2,645,000 options forfeited due to lack of exercise of employees and directors. On August 13, 2009, the compensation committee approved the acceleration of the vesting of certain outstanding option awards, the vesting of which was tied to our share price reaching certain levels in the future. Option awards previously made to Mr. David Hirsch, our President and Chief Executive Officer, Dr. Jeffrey Hillman, our Chief Science Officer and certain other Company employees were impacted by the accelerated vesting of these options (433,333 shares for Mr. Hirsch, 500,000 shares for Dr. Hillman, 563,333 for other Company employees). Following the acceleration of vesting by the compensation committee, Mr. Hirsch's grant of options to acquire 500,000 shares of our common stock at \$0.49 per share is now fully vested and exercisable (including the 433,333 shares impacted by the acceleration of vesting), Dr. Hillman's grant of options to acquire 700,000 shares of our common stock at \$0.85 per share is now fully vested and exercisable (including the 500,000 shares impacted by the acceleration of vesting). The options previously had a performance condition that was not probable. They are vested without any condition and a compensation expense of \$177,800 was recognized at the modification date, no compensation expense was previously recognized. All other terms of the prior option awards, including the share amounts covered by the options and exercise prices remained the same.

On December 30<sup>th</sup>, 2009, we completed the initial closing of a private placement of equity pursuant to a Common Stock Purchase Agreement with accredited investors. Contemporaneously with the financing transaction, Christine L. Koski and Robert C. Koski, as Directors of the Company, each exercised previously issued options to purchase 100,000 shares of the Company's Common Stock at the option exercise price of \$0.10 per share. These options were automatically granted to both Christine and Robert Koski when they became non-employee directors of the Company on June 30, 2009.

As of the date of this filing there are approximately 6,127,778 warrants outstanding and there are approximately 7,881,800 stock options have been granted that have not been forfeited. The total number of outstanding warrants and unexercised stock options is 14,009,578. If all warrants and stock options were exercised, the total number of outstanding shares would be approximately 122,212,726.

A summary of the status of the Company's outstanding stock options as of December 31, 2009 and 2008 and changes during the periods ending on those dates is presented below:

	<u>Options</u>	<u>Option Price Per Share</u>	<u>Weighted Average Exercise Price</u>
Outstanding at December 31, 2007	1,345,000	\$ 0.32 - 4.25	\$ 1.25
Forfeited	(930,000)	0.32 - 4.25	1.37
Granted	<u>4,155,000</u>	0.28 - 2.00	<u>0.56</u>
Outstanding at December 31, 2008	4,570,000	0.28 - \$ 4.25	\$ 0.60
Forfeited	(2,645,000)	0.28 - 4.00	0.60
Granted	5,994,300	0.10 - 0.30	0.27
Exercised	(200,000)	0.10 - 0.10	0.10
Outstanding at December 31, 2009	7,719,300	0.27 - \$ 0.85	\$ 0.35
Exercisable at the end of the year	<u>5,622,118</u>	0.28 - <u>\$ 0.85</u>	<u>\$ 0.62</u>

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The range of exercise price for outstanding options at December 31, 2009 is \$0.27 to \$0.85 per share. The weighted-average per option fair value of options granted during 2009 and 2008 was \$0.27 and \$0.56, respectively, and the weighted average remaining contractual life of those options is 9.5 years. Options vest over a period of two to three years from respective grant dates and the options expire 10 years after the date of grant. The fair value of these options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions: weighted average risk-free interest rate of 0.04%; dividend yields of 0%; weighted-average volatility factors of the expected market price of the Company's common stock of 146.0%; and an expected life of the option of ten years. Future compensation expense related to the outstanding options as of December 31, 2009 is \$1,421,982.

#### 9. Licenses

The Company has two license agreements with the University of Florida Research Foundation, Inc. ("UFRF") for their technologies. The Company issued 599,940 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 and \$50,000 of royalties payable to UFRF recorded in the accompanying balance sheets in accounts payable and accrued expenses at December 31, 2009 and 2008, respectively.

#### 10. 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 in 2009, 2008, and 2007 were \$24,718, \$17,644, and \$5,383, respectively.

#### 11. Income Taxes

At December 31, 2009 and 2008, 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:

	2009	2008
Deferred tax assets:		
Net operating loss carryforward	\$ 8,702,188	\$ 7,075,638
Compensation to Directors & Officers and consulting services	14,486	38,601
Total deferred tax assets	8,716,674	7,114,239
Less valuation allowance	(8,716,674)	(7,114,239)
Total net deferred taxes	\$ -	\$ -

The following is a reconciliation of tax computed at the statutory federal rate to the income tax benefit in the statements of operations for the years ended December 31, 2009, 2008 and 2007:

	Years Ended December 31		
	2009	2008	2007
Income tax benefit computed at statutory federal rate of 34%	\$(1,876,579)	\$(2,047,392)	\$ (785,982)
State income tax benefits, net of federal expense/benefit	(200,352)	(218,589)	(83,915)
Change in valuation allowance	1,602,435	2,066,955	814,662
Non-deductible expenses	474,496	199,026	61,144
Other	-	-	(5,909)
Total	\$ -	\$ -	\$ -

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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 \$8,716,674 and \$7,114,239 has been provided in the accompanying financial statements as of December 31, 2009 and 2008, respectively. The 2009 net change in valuation allowance related to deferred tax assets was an increase of \$1,602,435 primarily relating to net operating loss carryforwards.

At December 31, 2009, the Company has federal and state tax net operating loss carryforwards of approximately \$23,125,665. The federal and state tax loss carryforward will expire through 2022, unless previously utilized. The Company also has federal research and development tax credit carryforwards of approximately \$384,276. 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.

In July 2006, the FASB issued guidance which clarifies accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with GAAP and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. 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.

As of January 1, 2007, the Company recognized a \$252,827 increase in the liability for unrecognized tax benefits that are related to research and development credits, which was accounted for as a reduction to the January 1, 2007 balance of the deferred tax asset valuation allowance. 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.

For the years ended December 31, 2009 and 2008, the Company incurred \$43,057 and \$50,890, 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 2006.

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

Balance as of December 31, 2007	\$ 290,329
Additions based on tax positions related to the current year	50,890
Additions for the tax positions of prior years	-
Reductions for the tax positions of prior years	-
Balance as of December 31, 2008	<u>\$ 341,219</u>
Additions based on tax positions related to the current year	43,057
Additions for the tax positions of prior years	-
Reductions for the tax positions of prior years	-
Balance as of December 31, 2009	<u>\$ 384,276</u>

Included in the balance at December 31, 2009 and 2008, are \$384,276 and \$341,219, 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 2009, 2008 and 2007 the Company did not recognize any interest and penalties. Due to the potential offset of the Company's operating loss carryforward for any future activity, the amount attributed to interest and penalties would be immaterial.

## 12. Commitments and Contingencies

The Company's Alachua facility is being leased from a real estate developer for a term of two years renewed in December 2009. 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 \$97,187, \$89,753, and \$89,524 for the years ended December 31, 2009, 2008, and 2007, respectively. 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 seven 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 \$15,828 for the year ended December 31, 2009.

The Company terminated two lease agreements in August and October 2009 for office spaces which were located in Alachua and St. Petersburg, Florida, respectively.

Future annual minimum payments under all non-cancelable operating leases are approximately as follows as of December 31, 2009:

Year ended:	
2010	171,229
2011	162,236
2012	63,317
2013	<u>5,276</u>
	<u>\$ 402,058</u>

Oragenics, Inc.  
Notes to Financial Statements (continued)  
December 31, 2009 and 2008

**13. Unaudited Quarterly Financial Information**

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

	<b>2009</b>			
	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
Revenue	\$ 124,272	\$ 41,895	\$ 199,675	\$ 275,444
Total operating expenses	2,092,819	1,605,328	1,593,353	1,460,091
Net loss	(1,980,350)	(869,048)	(1,437,184)	(1,232,766)
Loss per share:				
Basic and Diluted	\$ (0.06)	\$ (0.02)	\$ (0.02)	\$ (0.01)

	<b>2008</b>			
	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
Revenue	\$ 125,000	\$ -	\$ 100,000	\$ 8,539
Total operating expenses	926,095	1,111,553	1,253,200	2,983,596
Net loss	(791,636)	(1,095,112)	(1,138,117)	(2,996,877)
Loss per share:				
Basic and Diluted	\$ (0.03)	\$ (0.03)	\$ (0.03)	\$ (0.08)

	<b>2007</b>			
	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
Revenue	\$ 33,088	\$ 26,673	\$ 46,584	\$ 26,743
Total operating expenses	584,070	627,631	542,321	719,205
Net loss	(541,156)	(596,392)	(487,333)	(686,832)
Loss per share:				
Basic and Diluted	\$ (0.03)	\$ (0.03)	\$ (0.02)	\$ (0.03)

**14. Subsequent Events**

On January 13, 2010 the Company completed the \$3,004,062 private placement contemplated by the Common Stock Purchase Agreement and December 2009 Private Placement and issued another 2,000,000 shares of common stock at a price of \$0.25 per share to accredited investors for \$500,000. Of this amount the KFLP again participated in one half of the remainder of the aggregate investment by acquiring 1,000,000 of the shares for \$250,000.

## EXHIBIT INDEX

### Incorporated by Reference

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Form</b>	<b>File No</b>	<b>Exhibit</b>	<b>Filing Date</b>	<b>Filed Herewith</b>
3.1	Amended and Restated Articles of Incorporation	SB-2	333-100568	3.3	10/16/02	
3.2	Amendment to Amended and Restated Articles of Incorporation	8-K	001-32188	10.2	10/30/09	
3.3	Bylaws	SB-2	333-100568	3.2	10/16/02	
4.1	Specimen Stock Certificate	SB-2	333-100568	4.1	10/16/02	
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	
4.3	Securities Purchase Agreement dated June 29, 2009 by and between the Company and the Koski Family Limited Partnership (including the Form of the Promissory Note and Form of the Warrant)	8-K	001-32188	10.1	7/6/09	
4.4	Secured Promissory Note issued to the Koski Family Limited Partnership	8-K	001-32188	10.2	7/6/09	
4.5	Security Agreement between the Company and the Koski Family Limited Partnership	8-K	001-32188	10.3	7/6/09	
10.1	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 and Antimicrobial Polypeptide License Agreement dated March 2003	SB-2/A-3	333-100568	10.36	4/9/03	
10.6	License Agreement 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	

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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Form</b>	<b>File No</b>	<b>Exhibit</b>	<b>Filing Date</b>	<b>Filed Herewith</b>
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	10.7	10/16/02	
10.10+	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	
10.11	First Amendment to Amended and Restated Stock Option Plan	8-K	001-32188	4.2	4/14/08	
10.12	Second Amendment to Amended and Restated Stock Option Plan	8-K	001-32188	10.1	10/30/09	
10.13	Proprietary Information and Invention Agreement between the Company and Jeffrey D. Hillman	SB-2	333-100568	99.4	10/16/02	
10.14	Employment Agreement of Jeffrey D. Hillman	10-KSB	000-50614	10.43	3/17/04	
10.15	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	
10.16	Employment Agreement of David Hirsch dated May 14, 2008 and the Addendum of June 27, 2008	10-Q	001-32188	10.1	08/14/08	
10.17	Lease Agreement between the Company and Astrazenca LP dated October 12, 2009(3000 Bayport Drive, Suite 685, Tampa, FL 33607)					X
10.18	Lease Agreement between the Company and Hawley-Wiggins LLC dated October 23, 2009 (13700 Progress Blvd, Alachua, FL 32615)					X
10.19	Common Stock Purchase Agreement dated December 30, 2009					X
23.1	Consent of Kirkland Russ Murphy & Tapp, PA, an independent public accounting firm					X
24.	Powers of Attorney (included on signature page)					
31.1	Rule 13a-14(a)/15d-14(a) Certification					X
31.2	Rule 13a-14(a)/15d-14(a) Certification					X
32.1	Section 1350 Certifications					X
32.2	Section 1350 Certifications					X

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**SUBLEASE AGREEMENT**

**THIS SUBLEASE AGREEMENT** (the "Sublease") made as of Oct. 12, 2009 (the "Effective Date"), by and between **ASTRAZENECA LP**, a Delaware limited partnership (the "Sublessor"), and **ORAGENICS INC.**, a Florida corporation (the "Sublessee").

**BACKGROUND**

A. By lease dated June 28, 2007 (the "Prime Lease"), Bayport Plaza Investors LLC (the "Prime Landlord") leased to Sublessor certain premises (the "Premises") in an office building located at and known as Bayport Plaza, located at 3000 Bayport Drive, Tampa, Florida 33607 (the "Building"). A copy of the Prime Lease is attached to this Sublease as **Exhibit A**. Capitalized terms which are used but not otherwise defined in this Sublease shall have the meanings ascribed to them in the Prime Lease.

B. The Premises consists of approximately 17,339 rentable square feet located on the 6<sup>th</sup> floor of the Building, identified as Suites 600 and 685, as further described in the Prime Lease.

C. The Expiration Date of the Prime Lease is January 31, 2013.

D. Sublessor now desires to sublease to Sublessee, and Sublessee desires to sublease from Sublessor, a portion of the Premises, which portion contains approximately 3,150 rentable square feet (Suite 685) and is shown on **Exhibit B** attached hereto (the "Subleased Premises"), upon the terms and conditions set forth in this Sublease.

**NOW, THEREFORE**, for and in consideration of the covenants and agreements set forth in this Sublease, and intending to be legally bound, Sublessor and Sublessee agree as follows:

**1. Demise; Term.**

1.1. Demise. Sublessor hereby subleases the Subleased Premises to Sublessee, and Sublessee hereby subleases the Subleased Premises from Sublessor, together with all fixtures installed in the Subleased Premises by or for the benefit of Sublessor, and also together with all appurtenances and rights ancillary to the Subleased Premises, including but not limited to the proportionate share of parking spaces provided to Sublessor under the Prime Lease, subject to the terms and parking rates set forth in "Reserved Parking Spaces" and "Unreserved Parking Spaces" in Basic Lease Information and Section 44 of the Prime Lease, which is one (1) reserved space and twelve (12) unreserved spaces. Sublessee shall pay Sublessor for the charge of parking, which is currently \$75.00 per reserved space per month as of the date of this Sublease, and is subject to change in accordance with the Prime Lease.

1.2. Term. The term of this Sublease (the "Sublease Term") shall begin on the later of (A) the Effective Date, or (B) the date that Sublessor receives the Prime Landlord's

Consent (as defined in Article 12 of this Sublease) (the "Commencement Date"). The Sublease Term shall expire on January 31, 2013, unless sooner terminated by Sublessor as provided in this Sublease. Tenant may have access to the Subleased Premises solely for the purpose of installing data/telecommunications systems, furniture, fixtures, equipment and similar improvements, but not for the conduct of its business, subject to Prime Landlord's Consent. Such early access of the Subleased Premises shall be subject to all of the terms of this Sublease, except Sublessee will not be obligated to pay Base Rent until the Commencement Date.

## 2. Prime Lease.

2.1. Terms of Sublease Identical With Prime Lease. It is intended that the terms and conditions of this Sublease shall be identical to the terms and conditions of the Prime Lease as they relate to the Subleased Premises, except to the extent inconsistent with the express terms of this Sublease and except as set forth in Section 2.2 of this Sublease. Therefore, Sublessor and Sublessee agree that:

- 2.1.1. each and every term, condition, covenant and agreement of the Prime Lease, as it relates to the Subleased Premises, is a term, condition, covenant and agreement of this Sublease, and is incorporated in this Sublease by reference, except to the extent inconsistent with the express terms of this Sublease and except as set forth in Section 2.2 of this Sublease;
- 2.1.2. Sublessee shall perform all obligations and comply with all terms, conditions, covenants and agreements of Sublessor as tenant under the Prime Lease, as they relate to the Subleased Premises, for the Sublease Term, except to the extent inconsistent with the express terms of this Sublease and except as set forth in Section 2.2 of this Sublease; and
- 2.1.3. the term "Landlord" as set forth in the Prime Lease shall mean Sublessor in this Sublease and the term "Tenant" as set forth in the Prime Lease shall mean Sublessee in this Sublease.

2.2. Terms Not Incorporated. Notwithstanding the provisions of Section 2.1 of this Sublease, the following provisions of the Prime Lease are not incorporated in or made part of this Sublease: Landlord's Address [see Basic Lease Information]; the amount of Base Rent payable by Sublessor to Prime Landlord [see Basic Lease Information]; Length of Term [see Basic Lease Information]; Commencement Date [see Basic Lease Information]; Brokers [see Basic Lease Information]; Term [Section 3, except Expiration Date shall remain January 31, 2013]; address for payment of Base Rent and Additional Rent [Section 4(d)]; Brokers [Section 38]; Option to Extend Lease Term [Section 56]; Release Space [Exhibit A-1]; Tenant Improvements [Exhibit B]; and Form of Subordination, Non-Disturbance and Attornment Agreement [Exhibit F].

2.3. Sublease Controls. If there is a conflict between the stated terms and conditions in this Sublease and those set forth in the Prime Lease, the terms and conditions set forth in this Sublease shall control.

2.4. Performance To Be Tendered To Prime Landlord. Except as otherwise provided in this Sublease, Sublessee shall tender performance of its obligations directly to Prime Landlord so that all of Sublessor's obligations under the Prime Lease accruing during the Sublease Term with respect to the Subleased Premises shall be fully satisfied and discharged by Sublessee's performance.

2.5. Covenant Against Actions Causing Default Under Prime Lease. Neither Sublessor nor Sublessee shall do or cause to be done or suffer or permit to be done any act or thing which would constitute a default under the Prime Lease or which would cause the Prime Lease or any of Sublessor's rights under the Prime Lease to be cancelled, terminated, forfeited or prejudiced or which would render Sublessor liable for any damages, fines, claims, penalties, costs or expenses under the Prime Lease.

2.6. Abatement of Rent. Rent shall not abate under this Sublease unless if and to the extent Rent payable by Sublessor to Prime Landlord abates (and only in proportion to the obligation of Sublessee to Sublessor to amounts payable by Sublessor to Prime Landlord with respect to the Subleased Premises).

### 3. **Performance.**

#### 3.1. Sublessor Not Liable For Prime Landlord's Obligations.

3.1.1. Although the terms, conditions, covenants and agreements of the Prime Lease are incorporated as terms and agreement of this Sublease, Sublessor shall not be liable to Sublessee for performance or non-performance of obligations of Sublessor under this Sublease which are also the obligations of Prime Landlord under the Prime Lease (the "Prime Landlord's Obligations"). It is intended that Sublessee shall look solely to and hold solely responsible Prime Landlord for the performance of the Prime Landlord's Obligations under the Prime Lease.

3.1.2. Without limiting the generality of Section 3.1.1 of this Sublease, Sublessor shall have no obligation or responsibility for any of the following: (A) maintenance or repair of the Subleased Premises, or the common areas or mechanical systems of the Property; (B) providing heating, ventilating, air conditioning or any utility service; or (C) providing Building services, such as janitorial or security services. Sublessor shall have no liability by reason of any failure by Prime Landlord to provide any of the foregoing services or to otherwise perform any of the Prime Landlord's Obligations.

3.2. Assignment of Remedies.

3.2.1. If Prime Landlord shall fail at any time to perform the Prime Landlord's Obligations, Sublessee shall give notice thereof to Sublessor. In order to enable Sublessee to enforce the Prime Landlord's Obligations as they relate to the Subleased Premises, Sublessor hereby assigns to Sublessee the rights and remedies of Sublessor under the Prime Lease for the enforcement of the Prime Landlord's Obligations, as they relate to the Subleased Premises. Sublessee's right to enforce the Prime Landlord's Obligations shall be non-exclusive, and Sublessor reserves to itself also the right to exercise any rights and remedies under the Prime Lease for the enforcement of the Prime Landlord's Obligations. Landlord's current notice address is: 3000 Bayport Drive, suite 585, Tampa, Florida 33607 (attn: Sheri Forte, Property Manager)

3.2.2. Notwithstanding the provisions of Subsection 3.2.1 of this Sublease, Sublessee shall not have the right to:

3.2.2.1. terminate, alter or amend the Prime Lease;

3.2.2.2. withhold Rent or any other sum payable under this Sublease;

3.2.2.3. set off or deduct any amount from Rent or any other sum payable under this Sublease.

4. **Rent.**

4.1. Base Rent. Sublessee shall pay rent ("Base Rent") at the times provided for the payment of Base Rent in the Prime Lease, in the amounts set forth below, prorated for any partial month, commencing on the Commencement Date; provided, however, that the first monthly payment of \$4,856.25 plus applicable sales and use taxes (currently 7% of Base Rent as of the date of this Sublease), shall be paid by Tenant to Landlord upon execution and delivery of this Sublease by Tenant to Landlord:

<b>Lease Period</b>	<b>S/RSF</b>	<b>Annual</b>	<b>Monthly</b>
Commencement Date – 08/31/10	\$18.50	\$ 58,275.00	\$ 4,856.25*
09/01/10 – 08/31/11	\$18.50	\$ 58,275.00	\$ 4,856.25
09/01/11 – 08/31/12	\$18.50	\$ 58,275.00	\$ 4,856.25
09/01/12 – 01/31/13	\$18.50	\$ 58,275.00	\$ 4,856.25

\*Notwithstanding the foregoing, Subtenant shall not be obligated to pay Base Rent during the first full calendar month of the Sublease Term.

4.2. Additional Rent. In addition to Base Rent, Sublessee shall pay as Additional Rent all sales and use tax levied upon the use and occupancy of the Subleased Premises and the cost of any additional utility services or other services requested by Sublessee, at the times and in the amounts set forth in Prime Lease. Sublessor shall have the same rights and remedies for nonpayment of Additional Rent as Sublessor has for nonpayment of Base Rent. Sublessee shall not be responsible to pay for the items in Section 4(b) of the Prime Lease identified as Tenant's Proportionate Share of the total dollar increase, if any, in: (a) Operating Expenses over Base Operating Expenses; (b) Insurance Expenses over Base Insurance Expenses (c) Utility Expenses over Base Utility Expenses; (d) Taxes over Base Taxes.

4.3. Rent In General.

4.3.1. All Base Rent and Additional Rent (collectively, "Rent") shall be paid to Sublessor at its address set forth in Article 11 of this Sublease, or at such other address as Sublessor may direct.

4.3.2. All Rent shall be paid without notice or demand and without any setoff or deduction whatsoever. Sublessee's covenant and agreement to pay Rent shall for all purposes be construed as a separate and independent covenant.

5. Use.

Sublessee shall use and occupy the Subleased Premises for the Permitted Use as defined in the Prime Lease.

6. Subleased Premises Accepted "AS-IS"; Furniture.

The Subleased Premises is accepted by Sublessee in its present condition, "AS-IS," without any representation or warranty by Sublessor, subject to the state of title on the date of this Sublease, and also subject to all applicable legal requirements and any violation of legal requirements which may exist on the date of this Sublease; provided, however, Sublessor shall complete the drywall partition between the Subleased Premises and Premises by infilling the existing door size opening in accordance with applicable building code requirements and in a good and workmanlike manner. Sublessee has examined and approved the Subleased Premises and acknowledges that all improvements and fixtures included in the Subleased Premises are in good condition and working order. Sublessor shall have no obligation to make any improvements to the Subleased Premises or provide Sublessee any allowance for so doing. Sublessee shall accept the furniture located in the Subleased Premises as of the Effective Date, a list of which is attached as **Exhibit C** (the "Furniture"), which is accepted by Sublessee in its present condition, "AS-IS." Sublessee shall remove the Furniture from the Subleased Premises at the end of the Term in accordance with the terms of the Prime Lease. Upon written request of Sublessee, Sublessor shall promptly execute and deliver to Sublessee the Bill of Sale attached to this Sublease as **Exhibit D**.

**7. Indemnification.**

7.1. Sublessee covenants and agrees to indemnify, defend, and hold harmless Sublessor, and its respective partners, shareholders, officers, directors, agents, and employees from and against any and all claims, demands, costs, expenses, judgments, losses, suits, and damages proximately resulting from (a) negligence on the part of Sublessee, its agents, or employees arising from their use or occupancy of the Subleased Premises, or (b) breach of this Sublease by Sublessee.

7.2. Sublessor covenants and agrees to indemnify, defend, and hold harmless Sublessee, and its respective partners, shareholders, officers, directors, agents, and employees from and against any and all claims, demands, costs, expenses, judgments, losses, suits, and damages proximately resulting from a breach of this Sublease by Sublessor.

**8. Security Deposit.**

8.1. Amount. Simultaneously with the execution of this Sublease, Sublessee shall deposit the sum of \$3,500.00 with Sublessor to secure Sublessee's performance of its obligations under this Sublease (the "Security Deposit").

8.2. No Interest. Sublessee shall receive no interest on the Security Deposit. Sublessor may commingle the Security Deposit with other moneys of Sublessor.

8.3. Application. Upon the occurrence of a Default, Sublessor may, without prejudice to Sublessor's other remedies, apply part or all of the Security Deposit (A) to cure the Default, in whole or in part, and (B) to any losses or damages suffered by Sublessor by reason of such Default. If Sublessor so applies part or all of the Security Deposit, Sublessee shall within ten (10) days after written demand, pay Sublessor the amount necessary to restore the Security Deposit to its original amount.

8.4. Transfer of Sublessor's Interest In Sublease. In the event of a sale, assignment or other transfer of Sublessor's interest in this Sublease, Sublessor shall have the right to transfer the Security Deposit to the purchaser, assignee or transferee. Upon such transfer, Sublessee shall look only to the new sublessor for the return of the Security Deposit and Sublessor shall be released from all liability for the return of the Security Deposit.

8.5. Return of Security Deposit. Any part of the Security Deposit not used by Sublessor shall be returned to Sublessee upon the latest to occur of (A) the expiration of the Sublease Term; (B) the surrender of the Subleased Premises by Sublessee in accordance with the terms of the Sublease; and (C) the computation of all Base Rent and Additional Rent by Sublessor and payment by Sublessee.

**9. Quiet Enjoyment.**

Subject to the terms and conditions of this Sublease, Sublessor warrants to Sublessee that it will take no action to disturb the quiet enjoyment of Sublessee for so long as

Sublessee performs all obligations of the Sublessee under this Sublease. Sublessor makes no warranty respecting action by any other party, including, without limitation, Prime Landlord.

**10. Sublease Subordinate to Prime Lease; Termination of Prime Lease.**

10.1. Sublease Subordinate. This Sublease and the rights of the parties under this Sublease are subject and subordinate to the Prime Lease.

10.2. Termination of Prime Lease. This Sublease shall terminate as of the date of termination of the Prime Lease. Sublessor shall have no liability to Sublessee as a result of such termination, unless the Prime Lease is terminated because of a Default on the part of Sublessor, except to the extent caused by Sublessee, its agents or employees.

**11. Notices.**

Any notices required or permitted to be given under this Sublease shall be given in writing and shall be delivered by (a) hand delivery, (b) commercial overnight courier that guarantees next day delivery and provides a receipt, or (c) legible facsimile (followed by hard copy sent concurrently with such facsimile, in accordance with preceding subsections (a) or (b)), and such notices shall be addressed as follows:

If to Sublessor:

Corporate Real Estate  
AstraZeneca Pharmaceuticals LP  
1800 Concord Pike  
P.O. Box 15437  
Wilmington, DE 19850-5437  
Attention: Debra Haufler FOC-G  
Facsimile No.: 302-886-1825

with a copy to:

General Counsel  
AstraZeneca Pharmaceuticals LP  
1800 Concord Pike  
P.O. Box 15437  
Wilmington, DE 198540-5437  
Facsimile No.: 302-886-2459

If to Sublessee:

Oragenics, Inc.  
3000 Bayport Drive  
Suite 685  
Tampa, FL 33607  
Attention: President / CEO

or to such other address as either party may from time to time specify in writing to the other party. Any notice shall be effective only upon receipt (or refusal by the intended recipient to accept delivery). Notice given by facsimile shall be effective upon receipt of such facsimile (subject to the requirement that hard copy be sent concurrently in accordance with this Section). Any notice which is received on a Saturday, Sunday or a legal holiday, or after 5:00 p.m. prevailing local time at the place of receipt, shall be deemed received on the next business day.

## 12. **Prime Landlord's Consent.**

12.1. Sublease Conditioned Upon Consent. This Sublease is subject to, and conditioned upon, Sublessor's obtaining the written consent of Prime Landlord to this Sublease (the "Prime Landlord's Consent"). As set forth in Section 1.2 of this Sublease, the Sublease Term shall not commence until Sublessor has obtained the Prime Landlord's Consent, required under Section 23 of the Prime Lease, in form and substance acceptable to Sublessor and Sublessee.

12.2. Delivery of Information. Sublessee shall promptly deliver to Sublessor any information reasonably required by Prime Landlord (in connection with the Prime Landlord's Consent) with respect to the nature and operation of Sublessee's business and/or the financial condition of Sublessee. Such information shall be maintained in strict confidence by Sublessor.

12.3. Agreements for Benefit of Prime Landlord. Sublessor and Sublessee hereby agree, for the benefit of Prime Landlord, that neither this Sublease nor the Prime Landlord's Consent shall:

12.3.1. create privity of contract between Prime Landlord and Sublessee;

12.3.2. be deemed to amend the Prime Lease in any way (unless Prime Landlord shall have expressly agreed in writing to such amendment); or

12.3.3. be construed as a waiver of Prime Landlord's right to consent to any assignment of the Prime Lease by Sublessor or any further subletting of the Subleased Premises.

12.4. Effect of Failure to Obtain Prime Landlord's Consent. If Prime Landlord fails to consent to this Sublease within thirty (30) days after the execution and delivery of this Sublease by the parties, either Sublessor or Sublessee may terminate this Sublease by giving written notice to the other at any time thereafter, but before Prime Landlord grants such consent. Upon such termination, (A) Sublessor will return the Security Deposit to Sublessee, (B) this Sublease will become null and void, and (C) neither party will have any liability or obligation to the other under this Sublease.

13. **Brokers.**

Sublessor and Sublessee represent and warrant to each other that no broker or finder other than Jones Lang LaSalle representing Sublessor and Cushman & Wakefield representing Sublessee (together, the “Brokers”), was instrumental in arranging or bringing about this transaction and that there are no claims or rights for commissions, finders’ fees or other compensation (collectively, “compensation”) by any person or entity other than the Brokers. Sublessor shall be solely responsible for all compensation payable to the Brokers. If any broker or finder asserts a claim for compensation based upon any actual or alleged contact, dealings or communication with Sublessor or Sublessee, then the party through whom such broker or finder makes its claim shall indemnify and hold the other party (the “Indemnified Party”) harmless from and against any and all claims, damages, judgments, suits, liabilities, losses, costs and expenses (including without limitation, reasonable attorneys’ fees and court costs) suffered or incurred by or brought against the Indemnified Party in connection with such claim for compensation.

14. **Patriot Act; Executive Order 13224; Anti-Money Laundering Act.**

14.1. Representation and Warranty. Sublessee represents and warrants that (a) no Benefited Party is a Prohibited Person, and (b) no Benefited Party is in violation of the Executive Order, the Patriot Act, the Anti-Money Laundering Act, or any order, rule, regulation or recommendation promulgated under or in connection with the Executive Order, the Patriot Act or the Anti-Money Laundering Act.

14.2. Covenants. Sublessee covenants and agrees to ensure that throughout the Term (a) no Benefited Party will be a Prohibited Person, and (b) no Benefited Party will be in violation of the Executive Order, the Patriot Act, the Anti-Money Laundering Act, or any order, rule, regulation or recommendation promulgated under or in connection with the Executive Order, the Patriot Act or the Anti-Money Laundering Act.

14.3. Certification. On request by Landlord from time to time, Sublessee covenants and agrees promptly to deliver to Sublessor such certification or other evidence as Sublessor may request, confirming that all Benefited Parties are in compliance with the requirements of this Section.

14.4. Definitions.

14.4.1. “Benefited Party” means and includes (a) Sublessee; (b) any officer, director, shareholder, partner or member of Sublessee; (c) any direct or indirect holder of any equity interest in Sublessee; and (d) any affiliate of Sublessee.

14.4.2. “Prohibited Person” means and includes any person or entity with whom US persons or entities are prohibited or restricted from doing business pursuant to (a) the Executive Order and the Annex thereto, (b) the regulations of the Office of Foreign Asset Control of the Department of the Treasury (including the Specially Designated Nationals and Blocked Persons List, as updated from

time to time, and (c) any other statute, law, executive order, rule, regulation or other governmental action.

14.4.3. "Executive Order" means Executive Order 13224 signed on September 24, 2001 and titled "Blocking Property and Prohibiting Transactions With Persons Who Commit, Threaten to Commit, or Support Terrorism."

14.4.4. "Patriot Act" means the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001.

14.4.5. "Anti-Money Laundering Act" means the International Money Laundering Abatement and Financial Anti-Terrorism Act of 2001.

**15. Miscellaneous.**

15.1. Interpretation of Sublease. The headings and captions in this Sublease are inserted for convenience of reference only and in no way define, describe or limit the scope or intent of this Sublease or any of its provisions. Where the context so requires, the use of the singular shall include the plural and vice versa and the use of the masculine shall include the feminine and the neuter.

15.2. Governing Law, Jurisdiction and Venue. This Sublease shall be governed by and construed in accordance with the laws of the State of Florida

15.3. No Recording. Neither this Sublease nor any memorandum or short form thereof may be recorded by Sublessee.

15.4. Survival. Any covenants set forth in this Sublease which, by their nature, would reasonably be expected to be performed after the expiration or earlier termination of this Sublease, shall survive the expiration or earlier termination of this Sublease.

15.5. Counterparts. This Sublease may be executed in two or more counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

15.6. Transmission of Sublease by Facsimile or PDF. The transmission of a signed counterpart of this Sublease by facsimile or by portable document file ("PDF") shall have the same force and effect as delivery of an original signed counterpart of this Sublease, and shall constitute valid and effective delivery for all purposes. If either party delivers a signed counterpart of this Sublease by transmission of a facsimile or PDF, it shall also send promptly thereafter by overnight courier or personal delivery a signed original counterpart of this Sublease to the other party, but failure to do so shall not render this Sublease void or voidable by either party.

15.7. Binding Effect; Assignment. This Sublease shall be binding upon, and inure to the benefit of, the parties to this Sublease and their respective successors and assigns.

15.8. Joint and Several Liability. If two or more individuals, corporations, partnerships, or other entities (or any combination of two or more thereof) sign this Sublease as Sublessee, the liability of each such individual, corporation, partnership or other entity to pay Rent and perform all other obligations of Sublessee under this Sublease shall be joint and several.

15.9. Entire Agreement; Requirement for Writing.

15.9.1. This Sublease and the Exhibits attached to this Sublease contain the final and entire agreement of Sublessor and Sublessee and are intended to be an integration of all prior negotiations and understandings. Neither Sublessor nor Sublessee shall be bound by any covenants, agreements, statements, representations or warranties, oral or written, not contained in this Sublease.

15.9.2. No change or modification to this Sublease shall be valid unless the same is in writing and signed by the parties to this Sublease.

15.9.3. No waiver of any of the provisions of this Sublease shall be valid unless the same is in writing and is signed by the party against which it is sought to be enforced.

15.10. Severability. If any provision of this Sublease, or the application thereof to any person, place or circumstance, shall be held by a court of competent jurisdiction to be invalid, unenforceable or void, the remainder of this Sublease and such provisions as applied to other persons, places and circumstances shall remain in full force and effect.

15.11. Time of Essence. Time is of the essence of each and every provision of this Sublease of which time is an element.

15.12. Drafts not an Offer to Enter into a Legally Binding Contract. The submission of a draft of this Sublease by one party to another is not intended by either party to be an offer to enter into a legally binding contract. The parties shall be legally bound pursuant to the terms of this Sublease only if and when Sublessor and Sublessee have fully executed and delivered to each other a counterpart of this Sublease.

IN WITNESS WHEREOF, Sublessor and Sublessee have duly executed this Sublease as of the day and year first above written.

SUBLESSOR:

**ASTRAZENECA LP**

Witness:

        G M C          
Name: Coir Matthews

        [Signature]          
Name: Debra Hudson

By:         [Signature]          
Name: **Amie Caine**  
Title: **Vice President**  
**US Business Services**

(CM)  
10-5-09

SUBLESSEE:

**ORAGENICS, INC.**

Witness:

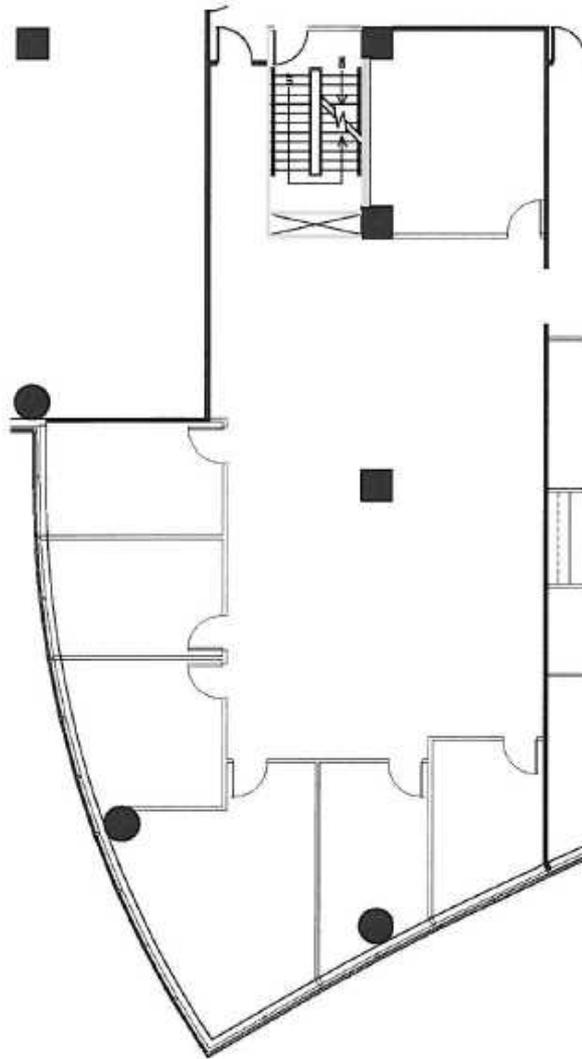
        [Signature]          
Name: MICHAEL DiBLASI

        [Signature]          
Name: Tammy Roque

By:         [Signature]          
Name: David Hirsch  
Title: CEO

**EXHIBIT A**  
**PRIME LEASE**

**EXHIBIT B**  
**SUBLEASED PREMISES**



**Bayport Plaza**

August 11, 2009

**Suite 685 - 3,150 rsf**

Scale: 3/32" = 1'-0"

INTERIORS ARCHITECTURE GRAPHICS

A S D

**EXHIBIT C**

**FURNITURE**

- 7 Workstations
- 5 Wooden Bookshelves
- 5 Traditional Office Desks & Credenzas
- 1 Wooden Four Drawer Cabinet
- 8 Five-Drawer File Cabinets
- 6 Wooden End Tables
- 11 Black Low Back Chairs
- 2 Portable White Boards

**EXHIBIT D**

**BILL OF SALE**

**THIS BILL OF SALE** (the "Bill of Sale") is made as of the \_\_\_\_\_ day of \_\_\_\_\_, 2009, by **ASTRAZENECA LP**, a Delaware corporation (the "Seller"), in favor of **ORAGENICS INC.**, a \_\_\_\_\_ corporation (the "Purchaser").

**WITNESSETH:**

Seller and Purchaser are parties to a Sublease Agreement dated \_\_\_\_\_ (the "Sublease"). This Bill of Sale is being delivered pursuant to Section 6 of the Sublease.

**NOW, THEREFORE**, for good and valuable consideration received by Seller, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, Seller hereby sells, assigns and transfers to Purchaser all of the personal property described in Exhibit A attached to this Bill of Sale (the "Furniture").

No covenant or warranty on the part of Seller is made or implied to be made to Purchaser with respect to the Furniture. Without limiting the generality of the foregoing, Seller hereby expressly disclaims any warranties as to merchantability and fitness for a particular purpose and any other warranties or representations as to the condition of the Furniture. Purchaser acknowledges and agrees that it has inspected the Furniture and accepts the same in its present condition, "**AS IS, WHERE IS, WITH ALL FAULTS.**"

**IN WITNESS WHEREOF**, Seller has executed this Bill of Sale the day and year first above written.

SELLER:

**ASTRAZENECA LP**

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_



LEASE

THIS LEASE AGREEMENT (Lease) is made this 23rd day of October, 2009 between "Landlord" and "Tenant" hereafter set forth.

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, 2009 and this lease shall expire on November 30, 2011. (unless sooner terminated or extended as provided herein)
- (f) "Term": Not less than twenty four (24) months commencing on the Commencement Date, this Lease to end on the last day of the twenty fourth 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	\$18.00	\$101,088.00	\$8,424.00
2	\$18.00	\$101,088.00	\$8,424.00

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 Six Thousand Four Hundred Four and 16/100 (\$6,404.16) Dollars Security Deposit is due and payable upon execution of this 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) months 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 (1st) 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 fail to pay any rents, additional rents or other charges within ten (10) (business) days after the same become due and payable or fifteen (15) days after invoice whichever is later, then Tenant shall also pay to Landlord a late payment service charge of Three Percent (3%) 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 PERSONAL PROPERTY TAXES: Tenant shall be liable for all taxes levied against personal property and trade fixtures placed by Tenant in the Premises.

3.2 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 2009. 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.

3.3 INSURANCE ADJUSTMENT: Landlord shall pay all hazard 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 2009. 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 term 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 not do, order or cause any work to be done or installations to be made in, on or to the roof of the Premises without first obtaining Landlord's prior written consent. 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 its 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 its 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, alterations, 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: Tenant 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 attorneys' 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: Tenant 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 termination 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, Tenant 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, Tenant 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 from 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 Government 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, nor suffer or permit the occupation of all or any part thereof by any other party, without the 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 tortious 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 \$1,000,000.00 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 TENANT'S 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, either 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 and 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 personalty 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 if 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's 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 termination 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 proceedings), 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, alteration 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, term, 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 be 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 statute 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 statute 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 cure period set forth herein, Landlord may, at its option, without waiving any claim 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 said 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 is 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 thereof, 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 an 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, nor its rights under this Lease affected by, any 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 part to be observed and performed hereunder, Tenant may peacefully 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 Six Thousand Four Hundred Four and 16/100 (\$6,404.16) Dollars 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 this 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.

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, lockouts, 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 this Lease is unmodified and is in full force and effect, or if there have been modifications, that the same is in full force and effect as modified (stating the modifications), 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 or 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 or 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 venturer of or with Tenant in the conduct of Tenant's business or otherwise.

49. LIABILITY OF LANDLORD:

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.

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

WITNESSES:

*Danna Murray*  
Printed Name: DANNA MURRAY  
*Eric Fields*  
Printed Name: Eric Fields

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

BY: *Phillip L. Hawley*  
Phillip L. Hawley, Manager

TENANT:  
Oragenics, Inc., a Florida corporation

*David Hirsch*  
Printed Name: DAVID HIRSCH  
*Jeffrey Hillman*  
Printed Name: JEFFREY HILLMAN

BY: *J. Hillman*  
ITS: CHIEF FINANCIAL OFFICER

STATE OF FLORIDA  
COUNTY OF ALACHUA

The foregoing instrument was acknowledged before me this 23 day of October, 2009, 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 drivers license as identification and who did take an oath.



*Danna Murray*  
NOTARY PUBLIC STATE OF FLORIDA  
Printed Name: \_\_\_\_\_

STATE OF FLORIDA  
COUNTY OF \_\_\_\_\_

The foregoing instrument was acknowledged before me this \_\_\_\_\_ day of October, 2009, by \_\_\_\_\_ as \_\_\_\_\_ on behalf of Oragenics, Inc., a Florida corporation, who is personally known to me or who has produced his \_\_\_\_\_ drivers license as identification and who did take an oath.

\_\_\_\_\_  
NOTARY PUBLIC STATE OF FLORIDA  
Printed Name: \_\_\_\_\_

**COMMON STOCK PURCHASE AGREEMENT**

This Common Stock Purchase Agreement (this "Agreement") is dated as of December 30, 2009, by and among Oragenics, Inc, a Florida corporation (the "Company") and Carol E. Martin ("Martin"), The Koski Family Limited Partnership, a Texas limited partnership ("KFLP") and the individuals or entities set forth on the signature pages of this Agreement (each a "Purchaser" and collectively, the "Purchasers").

**WHEREAS**, the Company desires to raise a minimum of \$2,500,000 and a maximum of \$3,000,000 (which maximum amount may be increased by the Company's Board of Directors in its discretion) in a private placement of shares of Common Stock of the Company solely to accredited investors.

**WHEREAS**, subject to the terms and conditions set forth in this Agreement and pursuant to applicable exemptions from registration under the Securities Act of 1933, the Company desires to issue and sell to the Purchasers, and the Purchasers desire to purchase from the Company shares of Common Stock of the Company in the private placement as set forth herein.

**NOW, THEREFORE, IN CONSIDERATION** of the mutual covenants contained in this Agreement, and for other good and valuable consideration the receipt and adequacy of which are hereby acknowledged, the parties agree as follows:

**ARTICLE I  
DEFINITIONS**

Section 1.1. Definitions. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the meanings indicated in this Section 1.1:

"Action" shall have the meaning ascribed to such term in Section 3.1(j).

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person as such terms are used in and construed under Rule 144. With respect to a Purchaser, any investment fund or managed account that is managed on a discretionary basis by the same investment manager as Purchaser will be deemed to be an Affiliate of Purchaser.

"Business Day" means any day except Saturday, Sunday and any day which shall be a federal legal holiday or a day on which banking institutions in the State of New York are authorized or required by law or other governmental action to close.

"Closing" means the closing of the purchase and sale of the Shares pursuant to Section 2.1.

"Closing Date" means the date of the Closing.

“Commission” means the Securities and Exchange Commission.

“Common Stock” means the common stock of the Company, \$0.001 par value per share, and any securities into which such common stock may hereafter be reclassified.

“Disclosures” means the Disclosure Schedules, if any, attached as Annex I hereto.

“Exchange Act” means the Securities Exchange Act of 1934, as amended.

“Intellectual Property Rights” shall have the meaning ascribed to such term in Section 3.1(o).

“Liens” means a lien, charge, security interest, encumbrance, right of first refusal or other restriction.

“Material Adverse Effect” shall have the meaning ascribed to such term in Section 3.1(b).

“Material Permits” shall have the meaning ascribed to such term in Section 3.1(m).

“Person” means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

“Purchase Price” means, as to the Purchasers and the Closing, the amounts set forth below Purchaser’s signature block on the signature page hereto, in United States dollars and in immediately available funds. This amount is \$0.25 per share of Common Stock.

“SEC Reports” shall have the meaning ascribed to such term in Section 3.1(h).

“Securities” means the Shares.

“Securities Act” means the Securities Act of 1933, as amended.

“Shares” means the shares of Common Stock, of which are being issued and sold by the Company to the Purchasers at the Closing.

“Trading Market” means the following markets or exchanges on which the Common Stock may be listed or quoted for trading on the date in question: the Nasdaq Capital Market, the American Stock Exchange, the New York Stock Exchange, the Nasdaq National Market or the OTC Bulletin Board (“OTC-BB”).

“Transaction Documents” means this Agreement and any other documents or written agreements executed by the Company and the Purchasers in connection with the transactions contemplated hereunder.

**ARTICLE II  
PURCHASE AND SALE**

Section 2.1. Purchase and Sale of Common Stock and Closing. At the Closing, the Purchasers shall purchase, severally and not jointly, and the Company shall issue and sell to the Purchasers that number of shares of Common Stock as set forth opposite each Purchaser's name on the signature page hereto for the aggregate purchase price as set forth opposite each Purchaser's name on the signature page hereto. The Closing shall occur on the date of this Agreement at the offices of Shumaker, Loop & Kendrick, LLP, 101 Kennedy Boulevard, Suite 2800, Tampa, Florida 33602, or such other time and/or location as the parties shall mutually agree.

Section 2.2. Closing Deliveries and Conditions.

(a) At the Closing, the Company shall be obligated to deliver or cause to be delivered to the Purchasers:

(i) Instructions to the transfer agent of the Company to issue stock certificates in the name of the respective Purchaser evidencing the Shares being sold to the respective Purchaser; and

(ii) And a duly executed signature page to this Agreement.

(b) At the Closing, the Purchasers shall deliver or cause to be delivered to the Company the following:

(i) the Purchase Price by wire transfer to the trust account of the Company's legal counsel, Shumaker, Loop & Kendrick, LLP; and

(ii) A duly executed signature page to this Agreement.

(c) All representations and warranties of the other party contained herein shall be true and correct as of the Closing Date (except for representations and warranties that speak as of a specific date, which representations and warranties must be correct as of such date), all necessary consents and waivers of third parties shall have been obtained and each party shall have performed and complied in all material respects with the covenants and conditions required by this Agreement to be performed or complied with by the party at or prior to the Closing.

(d) The KFLP shall have surrendered that certain \$1,000,000 Secured Promissory Note dated June 29, 2009 to the Company for cancellation in exchange for the issuance by the Company of 4,000,000 shares of Company Common Stock to the KFLP and the payment by the Company of any unpaid interest on such Secured Promissory Note.

**ARTICLE III  
REPRESENTATIONS AND WARRANTIES**

Section 3.1. Representations and Warranties of the Company. Except as set forth in the SEC Reports or under the corresponding section of the Annex I Disclosure Schedules delivered concurrently herewith, the Company makes the following representations and warranties as of the date hereof to the Purchasers:

(a) Subsidiaries. Except for one direct Subsidiary in Mexico, ONIBIOTEC SAPI de C.V., the Company has no direct or indirect Subsidiaries.

(b) Organization and Qualification. The Company is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of its incorporation or organization (as applicable), with the requisite corporate power and authority to own and use its properties and assets and to carry on its business as currently conducted. The Company is not in violation of any of the provisions of its certificate or articles of incorporation, bylaws or other organizational or charter documents. The Company is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, would not have or reasonably be expected to result in (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document, (ii) a material adverse effect on the results of operations, assets, prospects, business or condition (financial or otherwise) of the Company, taken as a whole, or (iii) adversely impair the Company's ability to perform fully on a timely basis its obligations under any Transaction Document (any of (i), (ii) or (iii), a "Material Adverse Effect").

(c) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by each of the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of each of the Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further consent or action is required by the Company, its Board of Directors or its stockholders. Each Transaction Document has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof, will constitute the valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. The execution, delivery and performance of the Transaction Documents by the Company and the consummation by the Company of the transactions contemplated hereby and thereby do not and will not (i) conflict with or violate any provision of the Company's certificate or articles of incorporation, bylaws or other organizational or charter documents, or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company debt or otherwise) or other understanding to which the Company is a party or by which any property or asset of the Company is bound or affected, or (iii) result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company is bound or affected; except in the case of each of clauses (ii) and (iii), such as would not have or reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than (a) any applicable Blue Sky filings, (b) such as have already been obtained or such exemptive filings as are required to be made under applicable securities laws, and (c) such other filings as may be required following the Closing Date under the Securities Act, the Exchange Act and corporate law.

(f) Issuance of the Securities. The Shares are duly authorized and, the Shares, when issued and paid for in accordance with the Transaction Documents, will be duly and validly issued, fully paid and nonassessable, free and clear of all Liens and shall not be subject to preemptive rights or similar rights of stockholders. The Company has reserved from its duly authorized capital stock the number of Shares issuable pursuant to this Agreement.

(g) Capitalization. The number of shares and type of all authorized, issued and outstanding capital stock, options and other securities of the Company (whether or not presently convertible into or exercisable or exchangeable for shares of capital stock of the Company) is as set forth in the SEC Reports. All outstanding shares of capital stock are duly authorized, validly issued, fully paid and nonassessable and have been issued in compliance with all applicable securities laws. Except as disclosed in the SEC Reports, there are no outstanding options, warrants, script rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any shares of Common Stock, or contracts, commitments, understandings or arrangements by which the Company is or may become bound to issue additional shares of Common Stock, or securities or rights convertible or exchangeable into shares of Common Stock. Except as set forth in the SEC Reports, there are no anti-dilution or price adjustment provisions contained in any security issued by the Company (or in any agreement providing rights to security holders) and the issue and sale of the Company Securities will not obligate the Company to issue shares of Common Stock or other securities to any Person (other than the Purchaser) and will not result in a right of any holder of Company securities to adjust the exercise, conversion, exchange or reset price under such securities.

(h) SEC Reports; Financial Statements.

(i) The Company has filed all reports required to be filed by it under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) of the Exchange Act, for the two years preceding the date hereof (or such shorter period as the Company was required by law to file such material) (the foregoing materials, including the exhibits thereto (together with any materials filed by the Company under the Exchange Act, whether or not required), being collectively referred to herein as the “SEC Reports” and, together with this Agreement and (the “Disclosure Materials”) on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. True and complete copies of the SEC Reports are available at [www.sec.gov](http://www.sec.gov).

(ii) As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act and the rules and regulations of the Commission promulgated thereunder, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(iii) The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP or may be condensed or summary statements, and fairly present in all material respects the financial position of the Company and its consolidated subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(iv) All material agreements to which the Company is a party or to which the property or assets of the Company are subject are included as part of or specifically identified in the SEC Reports. Other than the material contracts listed in the SEC Reports, as otherwise provided to the Purchaser, the Company has no material contracts. Except as set forth in the SEC Reports, the Company is not in breach or violation of any material contract, which breach or violation would have a Material Adverse Effect.

(i) Absence of Material Changes. Since the date of the latest audited financial statements included within the SEC Reports, except as disclosed in the SEC Reports, (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or required to be disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting or the identity of its auditors, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock and (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company stock option plans and agreements.

(j) Litigation. Except as disclosed in the SEC Reports, there is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, or its properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an “Action”) which (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents or the Securities or (ii) could, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect.

(k) Labor Relations. The Company is not involved in any material union labor dispute nor, to the knowledge of the Company, is any such dispute threatened. The Company believes that their relations with their employees are good. No executive officer (as defined in Rule 501(f) of the Securities Act) has notified the Company that such officer intends to leave the Company or otherwise terminate such officer’s employment with the Company. The Company is in compliance with all federal, state, local and foreign laws and regulations respecting employment and employment practices, terms and conditions of employment and wages and hours, except where failure to be in compliance would not, either individually or in the aggregate, result in a Material Adverse Effect.

(l) Compliance. Except as disclosed in the SEC Reports, the Company (i) is not in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is not in violation of any order of any court, arbitrator or governmental body, or (iii) is not or has been in violation of any statute, rule or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws applicable to its business, except in the case of clauses (i), (ii) and (iii) as would not have or reasonably be expected to result in a Material Adverse Effect.

(m) Regulatory Permits. The Company possesses all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct its current business as described in the SEC Reports, except where the failure to possess such permits would not have or reasonably be expected to result in a Material Adverse Effect (“Material Permits”), and the Company has not received any notice of proceedings relating to the revocation or modification of any Material Permit.

(n) Title to Assets. The Company has good and marketable title in fee simple to all real property owned by it and good and marketable title in all personal property owned by it, in each case free and clear of all Liens, except for Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and Liens for the payment of federal, state or other taxes, the payment of which is neither delinquent nor subject to penalties. To the knowledge of the Company, any real property and facilities held under lease by the Company are held by it under valid, subsisting and enforceable leases with which the Company is in material compliance.

(o) Patents and Trademarks. The Company has, or has rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, copyrights, licenses and other similar rights that are necessary or material for use in connection with their respective businesses as described in the SEC Reports and which the failure to so have could have or reasonably be expected to result in a Material Adverse Effect (collectively, the “Intellectual Property Rights”). Except as disclosed in its SEC Reports, the Company has not received a written notice that the Intellectual Property Rights used by the Company violates or infringes the rights of any Person. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights.

(p) Insurance. The Company is insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which the Company is engaged. The Company has no reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business.

(q) Transactions with Affiliates and Employees. Except as set forth in the SEC Reports, none of the officers or directors of the Company and, to the knowledge of the Company, none of the employees of the Company is presently a party to any transaction with the Company (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee or partner.

(r) Certain Fees. No brokerage or finder’s fees or commissions are or will be payable by the Company to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by this Agreement, the Company has not taken any action that would cause any of the Purchasers to be liable for any such fees or commissions and the Company agrees to indemnify the Purchasers for any such fees or commissions.

(s) Private Placement. Assuming the accuracy of each Purchaser’s representations and warranties set forth in Section 3.2 and assuming no unlawful distribution of the Securities by the Purchaser, no registration under the Securities Act is required for the offer and sale of the Securities by the Company to the Purchaser as contemplated hereby. The issuance and sale of the Securities hereunder does not contravene the rules and regulations of the OTC-BB. Neither the Company nor any Person acting on the Company’s behalf has sold or offered to sell or solicited any offer to buy the Securities by means of any form of general solicitation or advertising. The Company has offered the Shares for sale only to such Persons it believes to be an accredited investor.

(t) Registration Rights. Except as described in the SEC Reports, no Person has any right to cause the Company to effect the registration under the Securities Act of any securities of the Company.

(u) Exchange Act. The Company's Common Stock is registered pursuant to Section 12(g) of the Exchange Act and trades on the OTC-BB.

(v) Disclosure. All disclosure provided to the Purchaser regarding the Company, its business and the transactions contemplated hereby, including the Disclosure Schedules to this Agreement, furnished by or on behalf of the Company are true and correct and do not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading. No event or circumstance has occurred or information exists with respect to the Company or its business, properties, prospects, operations or condition (financial or otherwise), which, under applicable law, rule or regulation, requires public disclosure or announcement by the Company but which has not been so publicly announced or disclosed.

(w) Taxes. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company has filed all necessary federal, state and foreign income and franchise tax returns and has paid or accrued all taxes shown as due thereon, and the Company has no knowledge of a tax deficiency which has been asserted or threatened against the Company.

Purchaser acknowledges and agrees that the Company does not make or has not made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in this Section 3.1.

Section 3.2 Representations and Warranties of the Purchasers. Each Purchaser severally and not jointly represents and warrants as of the date hereof to the Company as follows:

(a) Organization; Authority. The Purchaser is either a person or an entity duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization with full right, corporate or partnership power and authority to enter into and to consummate the transactions contemplated by the Transaction Documents and otherwise to carry out its obligations thereunder. The execution, delivery and performance by such Purchaser of the transactions contemplated by this Agreement have been duly authorized by all necessary corporate or similar action on the part of such Purchaser. Each Transaction Document to which it is a party has been duly executed by such Purchaser, and when delivered by such Purchaser in accordance with the terms hereof, will constitute the valid and legally binding obligation of such Purchaser, enforceable against it in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) Purchase for Own Account. The Purchaser is acquiring the Shares as principal for its own account and not with a view to or for distributing or reselling such Shares or any part thereof, without prejudice, however, to Purchaser's right, subject to the provisions of this Agreement, at all times to sell or otherwise dispose of all or any part of such Shares pursuant to an effective registration statement under the Securities Act or under an exemption from such registration and in compliance with applicable federal and state securities laws. The Purchaser is acquiring the Shares hereunder in the ordinary course of its business. Purchaser does not have any agreement or understanding, directly or indirectly, with any Person to distribute any of the Shares.

(c) Purchaser Status. At the time the Purchaser was offered the Shares, it was, and at the date hereof it is an “accredited investor” as defined in Rule 501(a) under the Securities Act. The Purchaser is not required to be registered as a broker-dealer under Section 15 of the Exchange Act.

(d) Experience of Purchaser. The Purchaser has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Securities, and has so evaluated the merits and risks of such investment. The Purchaser is able to bear the economic risk of an investment in the Securities and, at the present time, is able to afford a complete loss of such investment.

(e) Reliance on Exemptions. The Purchaser understands that the Securities are being offered and sold to it in reliance upon specific exemptions from the registration requirements of United States federal and state securities laws and that the Company is relying upon the truth and accuracy of, and the Purchaser’s compliance with, the representations, warranties, agreements, acknowledgments and understandings of the Purchaser set forth herein in order to determine the availability of such exemptions and the eligibility of the Purchaser to acquire the Securities.

(f) Information. The Purchaser and its advisors, if any, have had access to all materials relating to the business, finances and operations of the Company including, without limitation, the Company’s most recent SEC Reports, that have been requested by the Purchaser or its advisors, if any. The Purchaser has been afforded the opportunity to ask questions of the Company and receive answers from the Company. The Purchaser has requested, received and considered all information it deems relevant to make an informed decision to purchase the Securities. The Purchaser acknowledges and understands that its investment in the Securities involves a significant degree of risk.

(g) Governmental Review. The Purchaser understands that no United States federal or state agency or any other government or governmental agency has passed upon or made any recommendation or endorsement of the Securities or an investment therein.

(h) Residency. The Purchaser is a resident of (or, if an entity, has its principal place of business in) the jurisdiction set forth by the Purchaser’s name on the signature of this Agreement.

(i) Certain Fees. No brokerage or finder’s fees or commissions are or will be payable by the Purchaser to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by this Agreement, the Purchaser has not taken any action that would cause the Company or any other Purchaser to be liable for any such fees or commissions and each Purchaser agrees to indemnify the Company and each other Purchaser for any such fees or commissions.

(j) Short Sales. The Purchaser has not directly or indirectly, nor has any Person acting on behalf of or pursuant to any understanding with such Purchaser, executed any Short Sales or granted any option for the purchase of or entered into any hedging or similar transaction with the same economic effect as a Short Sale, in the securities of the Company since the time period beginning two weeks prior to the time that such Purchaser was first contacted regarding an investment in the Company ("Discussion Time") through the date hereof. During such period, neither Purchaser nor any Person acting on behalf of or pursuant to any understanding with Purchaser, has taken, directly or indirectly, any actions to trade in the Company's Securities that might reasonably be expected to cause or result, under the Securities Act or Exchange Act, or otherwise, or that has constituted, stabilization or manipulation of the price of the Common Stock. Additionally, Purchaser is familiar with and agrees to comply with Regulation M under the Exchange Act.

(k) No General Solicitation. The Purchaser is not purchasing the Securities as a result of any advertisement, article, notice or other communication regarding the Securities published in any newspaper, magazine or other media or broadcast over television or radio or presented at any seminar or any other general solicitation or advertisement.

(l) Confidentiality. Other than to other Persons party to this Agreement, the Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction).

(m) Acknowledgement of Communication by the Company of 3 Day Voidability Privilege. The Purchaser acknowledges and understands that Section 517.061 (11)(a)5 of the Florida Statutes provides that "When sales are made to five or more persons in this state, any sale in this state made pursuant to this subsection is voidable by the purchaser in such sale either within 3 days after the first tender of consideration is made by such purchaser to the issuer, an agent of the issuer, or an escrow agent or within 3 days after the availability of that privilege is communicated to such purchaser, whichever occurs later" and that this Section 3.2(m) is intended to constitute the required communication under Section 517.061(11)(a)5 of the Florida Statutes.

The Company acknowledges and agrees that the Purchasers do not make or has not made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in this Section 3.2.

#### **ARTICLE IV OTHER AGREEMENTS OF THE PARTIES**

Section 4.1. Use of Proceeds. The Company covenants and agrees that \$1,000,000 of the proceeds received under this Agreement shall be reserved for and allocated solely to the expenses incurred in the further development of the Company's DPOLT synthetic chemistry platform, essential to the production of its lead antibiotic, MU 1140, subject to the goals set forth by the two year NSF SBIR Phase II grant the Company received on February 15, 2008. The remaining proceeds received under this Agreement shall be used as the Company's management and the Board of Directors shall determine in their sole discretion.

Section 4.2 Transfer Restrictions.

(a) The Securities may only be disposed of pursuant to an effective registration statement under the Securities Act or pursuant to an available exemption from the registration requirements of the Securities Act, and in compliance with any applicable state securities laws. The Securities shall contain a restrictive legend in the following form:

THESE SECURITIES HAVE NOT BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT.

(b) Each Purchaser agrees that the removal of the restrictive legend from certificates representing Securities as set forth in this Section 4.2 is expressly predicated upon the Purchaser's covenant and agreement in this Section 4.2(b) that the Purchaser shall in all cases sell or otherwise transfer the Securities pursuant to: (i) an effective registration statement under the Securities Act, in full compliance with all prospectus delivery requirements under the Securities Act and in accordance with the plan of distribution described in the prospectus delivered by Purchaser, or (ii) an available exemption from registration under the Securities Act.

Section 4.3 Furnishing of Information.

(a) For such period as the Purchaser continues to own the Shares, the Company covenants to use its reasonable efforts to timely file (or obtain extensions in respect thereof and file within the applicable grace period) all reports required to be filed by the Company after the date hereof pursuant to the Exchange Act. In addition, the Company shall use its reasonable efforts to take all actions necessary to meet the "registrant eligibility" requirements set forth in the general instructions to Form S-3 or any successor form thereto, to continue to be eligible to register the resale of its Common Stock on a registration statement on Form S-3 under the Securities Act.

(b) For such period as the Purchaser continues to own the Shares, if the Company is not required to file reports pursuant to the Exchange Act, it will prepare and furnish to the Purchaser and make publicly available in accordance with Rule 144 such information as is required for the Purchaser to sell the Securities under Rule 144 and the Company further covenants that it will take such further action as any holder of Securities may reasonably request, all to the extent required from time to time to enable such Person to sell such Securities without registration under the Securities Act within the limitation of the exemptions provided by Rule 144.

(c) For such period as the Purchaser continues to own the Shares, the Company shall ensure that each of the following reports are available at [www.sec.gov](http://www.sec.gov): (i) within ten days after the filing thereof with the SEC, a copy of its Annual Report on Form 10-K, its Quarterly Reports on Form 10-Q, its proxy statements and any Current Reports on Form 8-K; and (ii) within one day after release, copies of all press releases issued by the Company or any of its Subsidiaries.

Section 4.4 Trading Market of Common Stock. The Company hereby agrees to use its reasonable efforts to maintain the eligibility for trading of the Common Stock on the Trading Market. The Company further agrees, if the Company applies to have the Common Stock traded on any other trading market, it will include in such application the Shares, and will take such other action as is necessary or desirable in the opinion of the Purchaser to cause the Shares to be listed on such other trading market as promptly as possible. The Company will take all action reasonably necessary to continue the listing and trading of its Common Stock on a trading market and will comply in all respects with the Company's reporting, filing and other obligations under the bylaws or rules of the trading market.

Section 4.5 Sales by Purchasers. Each Purchaser covenants to sell any Securities sold by it in compliance with applicable prospectus delivery requirements, if any, or otherwise in compliance with the requirements for an exemption from registration under the Securities Act. Each Purchaser will not make any sale, transfer or other disposition of the Securities in violation of federal or state securities laws.

## **ARTICLE V MISCELLANEOUS**

Section 5.1. Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, contain the entire understanding of the parties with respect to the Securities and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules.

Section 5.2. Amendments; Waivers. No provision of this Agreement may be waived or amended except in a written instrument signed, in the case of an amendment, by the Company and the Purchaser or, in the case of a waiver, by the party against whom enforcement of any such waiver is sought. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of either party to exercise any right hereunder in any manner impair the exercise of any such right.

Section 5.3. Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns. The Company may not assign this Agreement or any rights or obligations hereunder without the prior written consent of the Purchaser; provided, however, that no consent shall be required in connection with a merger, consolidation or sale of substantially all of the Company's assets. Any Purchaser may assign any or all of its rights under this Agreement to any Person in connection with the transfer of the Securities, provided such transferee agrees in writing to be bound, with respect to the transferred Securities, by the provisions hereof that apply to the "Purchaser".

Section 5.4. No Third-Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person.

Section 5.5. Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the State of Florida, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, employees or agents) shall be commenced exclusively in the United States federal courts and the state courts located in the County of Hillsborough, State of Florida. Each party hereto hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the County of Hillsborough, State of Florida for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper. Each party hereto hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by delivering a copy thereof via overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. Each party hereto (including its affiliates, agents, officers, directors and employees) hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby. If either party shall commence an action or proceeding to enforce any provisions of a Transaction Document, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

Section 5.6. Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to the other party, it being understood that both parties need not sign the same counterpart. In the event that any signature is delivered by facsimile or other electronic transmission, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and affect as if such facsimile or other electronically transmitted signature page were an original thereof.

Section 5.7. Severability. If any provision of this Agreement is held to be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Agreement shall not in any way be affected or impaired thereby and the parties will attempt to agree upon a valid and enforceable provision that is a reasonable substitute therefor, and upon so agreeing, shall incorporate such substitute provision in this Agreement.

Section 5.8. Construction. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof. The parties agree that each of them and/or their respective counsel has reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments hereto.

Section 5.9. Legal Counsel. The Company and KFLP acknowledge that the law firm Shumaker, Loop & Kendrick, LLP ("Shumaker") currently represents the Company and KFLP on unrelated matters. The Company and KFLP hereby waive any potential conflict of interest arising from the representation by Shumaker and consents to the continued representation by Shumaker of the Company in connection with the matters covered by this Agreement. The KFLP further acknowledges and represents that it has had an opportunity to retain its own separate legal counsel to represent it in this matter.

Section 5.10. Notice of Three-Day Right of Rescission. **PURSUANT TO SECTION 517.061(11)(a)5 OF THE FLORIDA STATUTES, PURCHASERS HAVE A THREE-DAY RIGHT OF RESCISSION. IF A PURCHASER HAS EXECUTED THIS AGREEMENT AND TENDERED THE PURCHASE PRICE FOR THE PURCHASE OF SHARES, THE PURCHASER MAY ELECT, WITHIN THREE BUSINESS DAYS AFTER SIGNING THIS AGREEMENT OR BEING FIRST NOTIFIED OF THIS RIGHT, WHICHEVER IS LATER, TO WITHDRAW FROM THIS AGREEMENT AND RECEIVE A FULL REFUND AND RETURN (WITHOUT INTEREST) OF ANY MONEY PAID BY PURCHASER. A PURCHASER'S WITHDRAWAL WILL BE WITHOUT ANY FURTHER LIABILITY TO ANY PERSON. TO ACCOMPLISH SUCH WITHDRAWAL, A PURCHASER NEED ONLY SEND A LETTER OR E-MAIL TO THE COMPANY AT 3000 BAYPORT DRIVE, SUITE 685, TAMPA, FLORIDA ATTN: DAVID B. HIRSCH, PRESIDENT AND CHIEF EXECUTIVE OFFICER (dhirsh@oragenics.com), INDICATING THE INTENTION TO WITHDRAW. SUCH LETTER OR E-MAIL MUST BE SENT AND POSTMARKED PRIOR TO THE END OF THE AFOREMENTIONED THIRD BUSINESS DAY. IF A PURCHASER SENDS A LETTER, IT IS PRUDENT TO SEND IT BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED, TO ENSURE THAT IT IS RECEIVED AND ALSO TO EVIDENCE THE TIME AND DATE WHEN IT IS MAILED. SHOULD A PURCHASER MAKE THIS REQUEST ORALLY, SUCH PURCHASER SHOULD ASK FOR WRITTEN CONFIRMATION THAT HIS REQUEST HAS BEEN RECEIVED. THE FOREGOING IS INTENDED TO CONSTITUTE THE NOTICE REQUIRED UNDER THE FLORIDA STATUTES. ACCORDINGLY, EACH PURCHASER WILL HAVE THREE DAYS AFTER THE FIRST TENDER OF THE PURCHASE PRICE IS MADE BY SUCH PURCHASER TO VOID THEIR PURCHASE OF THESE SECURITIES.**

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK  
AND SIGNATURE PAGES FOLLOW]

IN WITNESS WHEREOF, the parties hereto have caused this Common Stock Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

**COMPANY**

**ORAGENICS, INC.**

By: /s/ David Hirsch

David Hirsch, President and Chief Executive Officer

**PURCHASERS**

/s/Carol E. Martin

**Carol E. Martin**

**Investment Amount: \$1,000,000 for 4,000,000 shares of common stock**

**Address:**

P.O. Box 1291

Tarpon Springs, FL 34688

**THE KOSKI FAMILY LIMITED PARTNERSHIP**

By: /s/ Christine L. Koski

Christine L. Koski, Managing General Partner

**Investment Amount: \$1,500,000 for 6,000,000 shares of common stock**

**Address:**

3525 Turtle Creek Boulevard, Unit 19-B

Dallas, Texas 75219

/s/ Jeffrey D. Hillman

Jeffrey D. Hillman

**Investment Amount: \$54,062.50 for 216,250 shares of common stock**

**Paid pursuant to cancellation of the same dollar amount of outstanding preferred compensation obligations owed by the Company.**

**/s/DH**

**/s/JH**

**[signature pages to Common Stock Purchase Agreement]**

**Address:** 6424 SW 26th Place  
Gainesville, FL 32608

/s/Kelly H. Leaird  
Kelly H. Leaird

**Investment Amount:** \$100,000.00 for 400,000 shares of common stock

**Address:** 4969 SW 2<sup>nd</sup> Ct.  
Ocala, FL 34471

/s/Mark Bailey  
Mark Bailey

**Investment Amount:** \$100,000.00 for 400,000 shares of common stock

**Address:**  
1200 Plantation Drive, Suite 210  
St. Augustine, FL 32080

/s/Kris A. Persinger  
Kris A. Persinger

**Investment Amount:** \$50,000 for 200,000 shares of common stock

**Address:**  
4360 Van Ness St. NW  
Washington, DC 20016

/s/First Clearing, LLC C/F Roth IRA FBO Kris A. Persinger  
First Clearing, LLC C/F Roth IRA FBO Kris A. Persinger

**Investment Amount:** \$50,000 for 200,000 shares of common stock

**Address:**  
P.O. Box 66701  
St. Louis, MO 63166

/s/Richard Dresden  
Richard Dresden

**Investment Amount:** \$75,000 for 300,000 shares of common stock

**Address:**  
1511 W. Superior  
Chicago, IL 60642

/s/John Diana

**John Diana**

**Investment Amount: \$50,000 for 200,000 shares of common stock**

**Address:**

1101 Castle Oaks Drive

Napa, CA 94558

/s/Michael Wells

**Michael Wells**

**Investment Amount: \$25,000 for 100,000 shares of common stock**

**Address:**

3636 Woodridge Pl.

Pam Harbor, FL 34684

**[signature pages to Common Stock Purchase Agreement]**

**Consent of Independent Registered Public Accounting Firm**

We consent to the inclusion in this Annual Report (Form 10-K) of Oragenics, Inc. of our report dated March 31, 2010, with respect to the 2009 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/ Kirkland, Russ, Murphy & Tapp, PA

Certified Public Accountants

Clearwater, Florida

March 31, 2010

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## CERTIFICATION

I, David B. Hirsch, 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: March 31, 2010

/s/David B. Hirsch

David B. Hirsch, President and Chief Executive Office

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## CERTIFICATION

I, Brian J. Bohunicky, 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: March 31, 2010

/s/ Brian J. Bohunicky

Brian J. Bohunicky, Chief Financial Officer

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**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, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David B. Hirsch, 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 31 day of March, 2010.

/s/David B. Hirsch  
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David B. Hirsch  
Chief Executive Officer

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**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, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian J. Bohunicky, 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 31 day of March, 2010.

/s/ Brian J. Bohunicky  
Brian J. Bohunicky  
Chief Financial Officer

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