

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

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**FORM 10-KSB**

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**Annual report under Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the fiscal year ended December 31, 2007

**Transition report under Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-32188

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**ORAGENICS, INC.**

(Name of small business issuer in its charter)

**Florida**  
(State or Other Jurisdiction of  
Incorporation or Organization)

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

**59-3410522**  
(IRS Employer  
Identification No.)

**32615**  
(Zip Code)

**(386) 418-4018**  
(Issuer's Telephone Number, Including Area Code)

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**Securities registered pursuant to Section 12(b) of the Act: Common stock, par value \$.001 per share,  
American Stock Exchange**

**Securities registered pursuant to Section 12(g) of the Act:**

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Check whether the issuer: (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB

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

The registrant's revenues for the fiscal year ended December 31, 2007 were \$133,088.

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of March 3, 2008 was approximately \$11,954,640 based upon a last sales price of \$0.57 as reported by the American Stock Exchange.

As of March 3, 2008 there were 32,538,807 shares of the registrant's Common Stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE:**

Portions of the Registrant's Definitive Proxy Statement for its 2007 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-KSB Report except with respect to information specifically incorporated by reference in this Form 10-KSB Report, the Definitive Proxy Statement is not deemed to be filed as a part hereof.

Transitional Small Business Disclosure Format (check one):  Yes  No

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## PART I

### Item 1. Description of 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 and elsewhere in this Form 10-KSB. We assume no obligation to update any forward-looking statements contained herein.

#### Overview

We are an early-stage biotechnology company aimed at adding value to novel technologies and products sourced from innovative research from internal discovery, at the University of Florida, at other academic centers, and from in-licensing from other biotechnology companies. Our strategy is first to in-license or internally discover products and technologies, second to develop products up to and through human proof-of-concept studies (Phase II clinical trials of the U.S. Food and Drug Administration's (FDA) regulatory process), and third to partner with major pharmaceutical, biotechnology, or healthcare product firms for advanced clinical development and commercialization. Since our inception, we have funded a significant portion of our operations from the public and private sales of our securities. We have generated no significant revenues from operations during the last two years. All of our revenues have been from a sponsored research agreement and SBIR grants. We have not generated revenues from sales of products. We hope to be in a position to develop the following technologies, each of which addresses potentially large market opportunities:

#### Our Technologies

Oragenics possesses seven technologies in research and development. In the infectious disease area, we have MU 1140™, a novel antibiotic for antibiotic resistant gram positive bacteria and infections, DPOLT™, which is an enabling technology to synthetically and chemically produce MU1140™ and other lantibiotics, and IVIAT™ and CMAT™ for discovery of biomarkers in human, animal, and plant diseases, as well as the possible development of diagnostic tests, vaccines, or drug targets. CMAT™ also may be useful for discovery of potential biomarkers in cancer. In the oral care area, we have Probiora3™, a probiotic product intended for dental and gum disease, and SMaRT Replacement Therapy™, for prevention of dental caries. Further, LPT3-04™ is a nutritional supplement product under development for weight loss.

#### MU 1140™ (MU1140)

**MU 1140 (Mutacin 1140)** is a novel antibiotic peptide that has broad spectrum antimicrobial activity against essentially all gram-positive bacteria including methicillin-resistant and vancomycin-resistant *Staphylococcus aureus*. The antibiotic currently is in preclinical stages of development. A number of clinical isolates of *Streptococcus mutans* secrete peptides, called mutacins, which exhibit antimicrobial activity against closely related streptococcal species and other gram positive bacteria. Two types of mutacins have been characterized at the molecular level: lantibiotics and non-lantibiotics. Scientists have identified approximately 50 lantibiotics to date, including nisin, a substance used as a food preservative that has been given status as "GRAS" or "generally recognized as safe" by regulatory authorities. In general, lantibiotics have a wider spectrum of activity than the non-lantibiotic bacteriocins.

#### Technical Background

MU1140 was discovered by our scientists in the course of research on our replacement therapy (SMaRT) technology; it is the mutacin produced by our genetically modified effector strain of *Streptococcus mutans*. MU1140 is a polycyclic peptide produced by fermentation, and as such is considered the native molecule; MU1140-N or MU 1140-N. MU1140-N is a lantibiotic from a class of lanthionine-containing antibiotics which we believe has the potential to treat a wide variety of infectious diseases. Extensive *in vitro* studies that we have conducted demonstrate its effectiveness against all tested gram-positive bacteria, including such commercially relevant pathogens as *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Enterococcus faecalis*, *Clostridium difficile* and *Listeria monocytogenes*. To date, our research has not identified any pathogen that can develop genetically stable resistant to MU 1140-N.

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Lantibiotics are produced by standard fermentation process using the parent micro-organisms that produce them in appropriate cultures. To date, no one has been able to develop an effective and efficient method to produce and purify any lantibiotic peptide in sufficient quantities for clinical testing and commercialization. Oragenics is developing a synthetic chemical process, named DPOLT™, to produce lantibiotics, which is covered below.

### ***Preclinical Studies***

Our scientists and others have conducted laboratory studies on MU 1140-N to determine its activity as an antibacterial agent. To test MU 1140-N's ability to kill bacteria, standard microbiological testing methods were employed. MU 1140-N 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-N was observed. The minimal inhibitory concentration (MIC) of MU 1140-N to inhibit growth of the test bacterium was recorded. We believe the results of our laboratory studies demonstrate that MU 1140-N 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-N was found to kill all gram-positive bacteria tested at concentrations comparable to therapeutically effective antibiotics. A particularly interesting feature of MU 1140-N is that none of the sensitive species of bacteria tested was able to acquire genetically stable resistance to purified MU 1140-N. During 2006 and 2007, we completed a significant preclinical study and demonstrated that MU 1140-N 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-N, especially against drug resistant organisms, such as methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant *Enterococcus faecalis*, and *Streptococcus pneumoniae*, all common and serious sources of infections in humans. Pilot pharmacokinetics studies were done.

### ***Regulatory Status***

Currently, MU 1140-N is in the later stages of preclinical development, although we have not filed an Investigational New Drug (IND) application with the FDA for the native molecule. We intend to develop synthetic versions of MU 1140-N, hence MU 1140-S. We expect to carry forward with our preclinical testing in 2008, and then schedule a pre-IND meeting with the FDA for MU 1140-N and / or MU 1140-S, to be followed later by an IND to be filed with the FDA.

### ***Intellectual Property***

We have exclusively licensed the intellectual property for our MU1140 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.

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

MU1140 in its native form (MU 1140-N) is produced by fermentation processes, which have been enhanced to produce sufficient quantities for preclinical testing; these manufacturing methods, however, do not yet produce sufficient quantities for full clinical testing and commercialization. Oragenics also is working on the manufacturing of a synthetic version of lantibiotics, including a synthetic form of MU1140, MU 1140-S. Upon completion of preclinical and animal studies for MU1140-N and MU1140-S, we will schedule a pre-IND meeting with the FDA. Afterwards, we plan to file an IND application with the FDA. Once the FDA has approved an IND, and we have completed Phase I clinical trials, we would expect to seek a strategic partner(s) for further clinical development, large-scale manufacturing and commercialization.

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### ***Market Opportunity***

Two million hospital acquired infections occur each year according to the Center for Disease Control, and about 100,000 patients die each year. The critical care market for antibiotics is about \$3.5 billion in U.S.A. Cubicin<sup>®</sup>, a newer gram positive lipopeptide antibiotic, had 2007 sales of \$290 million. 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.

Our antibiotic, MU1140, 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 MU1140. In light of the fact that pathogen resistance has become a major health problem associated with antibiotics in use today, we believe MU1140 offers the potential to fulfill a significant and increasing medical need for non-resistant antibiotics.

### ***Competition***

MU1140 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 MU1140 patented in the U.S. by the University of Laval in Quebec. Successful development of that technology would constitute major competition for MU1140. 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 MU1140 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 MU1140 or would render MU1140 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 MU1140 technology. There can be no assurance that we will be able to do so.

## **DPOLT<sup>™</sup>**

### ***Intellectual Property***

In May 2006 we filed a U.S. patent application for our Differentially Protected Orthogonal Lanthionine Technology (DPOLT<sup>™</sup>), which is a novel solid or liquid phase peptide synthesis platform technology that has broad application for the cost-effective manufacture of a number of commercially important bioactive peptides.

### ***Technical Background***

Lantibiotics, including our lead antibiotic, MU 1140, are a potentially important class of antibiotics, and constitute a family of polycyclic peptides that are produced by bacteria, and are highly modified structurally. Many strains of medically important bacteria have become increasingly resistant to currently marketed antibiotics, for which lantibiotics may prove useful. Attempts to study lantibiotics for their potential usefulness

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to date have been hindered by difficulties in producing sufficiently pure material, in amounts adequate for clinical testing and commercialization. In July, 2006, the Company was awarded a \$100,000 SBIR (Small Business Innovation Research) Phase 1 grant from the National Science Foundation (NSF) to establish proof-of-principal for DPOLT for the creation of synthetic forms of lantibiotics. This effort is on-going and should be completed in the near future. In 2008, a Phase II SBIR NSF grant (\$500,000 for 2 years) had been awarded to expand the research to address a commercial level of production and to demonstrate equivalency between the synthetic MU 1140 and the native MU 1140. DPOLT technology was presented at the 8<sup>th</sup> Annual Florida Heterocyclic and Synthetic IUPAC-sponsored Conference in March 2007.

### ***Market Opportunity and Manufacturing, Marketing and Distribution***

With our patented novel technology for production of any lantibiotic, we plan to eventually synthesize and then study (preclinical and possibly clinical research) a number of novel lantibiotic analogs that may be effective in treating various infections, including ones caused by drug resistant bacteria. DPOLT may further offer Oragenics opportunities to partner with other entities, academic or commercial, that have identified their own lantibiotics, but who cannot produce sufficient quantities for testing. We may collaborate on developing and producing their lantibiotics, as well as our own, and to seek additional commercial partners in the antibiotic business to help further develop and commercialize these lantibiotics.

### **IVIAT™ and CMAT™**

**IVIAT™ and CMAT™** are platform technologies that enable the simple, fast identification of novel and potentially important gene and protein targets associated with the natural onset and progression of infections, cancers, and other diseases in humans, animal, and plants. In 2006, Oragenics acquired 100% of the outstanding capital stock of iviGene Corporation, which held the intellectual property for IVIAT and CMAT. These technologies offer the potential to generate and develop a number of product candidates for diagnosis and treatment, particularly in cancer and infectious diseases, as well as agricultural and animal uses, and represent future out-licensing opportunities.

### ***Technical Background***

The first technology platform was developed by our founder and chief scientific officer, Jeffrey D. Hillman, and University of Florida scientists. It is called In Vivo Induced Antigen Technology (IVIAT). IVIAT can quickly and sensitively identify *in vivo* induced genes of pathogens in human infections, facilitating the discovery of new targets for the development of vaccines, antimicrobials, and diagnostics. We identify *in vivo* induced genes from human sera at any stage of infection, thereby avoiding the unreliability of animal models. Further research with methods based on this approach created the second technology platform, Change Mediated Antigen Technology (CMAT). CMAT can be used to identify gene targets associated with the onset and progression of cancerous processes and autoimmune diseases. It can also be used to identify novel genes in plant diseases, including genes expressed by the pathogen when it causes the disease and genes expressed by the plant in response to the infectious challenge.

### ***Intellectual Property***

As part of our acquisition of iviGene Corporation in 2006, the assets of iviGene, consisting primarily of one patent and two additional patent filings (patents pending) for IVIAT and CMAT, were assigned to Oragenics. Oragenics owns the exclusive worldwide rights to these broad platform technologies in all areas including human cancer and infectious diseases, as well as agricultural and other non-human uses. We believe that these proprietary technologies will position us to create significant future opportunities for Oragenics.

In December 2006, we filed a U.S. patent application covering a collection of 44 novel genes of *Mycobacterium tuberculosis* that are specifically induced during active infection of human patients. We believe the identification of these gene targets, utilizing IVIAT, offers the potential of a new tuberculosis (TB) diagnostic test to meet a critical need and could potentially serve as a basis for an effective new vaccine.

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### **Preclinical Studies**

In 2004, we received a \$100,000 Phase I SBIR grant from the National Institute of Allergy and Infections Diseases (NIAID) of the National Institutes of Health (NIH). This initial research grant helped us discover and identify a collection of 44 genes of *Mycobacterium tuberculosis* (Tb) that are specifically induced during active infection of human patients with Tb. In 2007, we received another Phase I SBIR NIH grant for \$100,000 to study CMAT™ in colorectal cancer to identify biomarkers in its pathogenesis. We are collaborating with outside research institutes and universities to validate the new targets identified in both infectious disease and cancer. These licensed technologies are in their early stages and will require additional capital for further development.

### **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 approximately 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.

### **Technical Background**

Our replacement therapy involves replacing the naturally occurring, lactic acid-producing strains of *Streptococcus mutans* with a genetically modified strain of *Streptococcus mutans* that does not produce lactic acid. Our researchers created a strain of *Streptococcus mutans* that did not produce the decay-causing lactic acid. This strain, however, could not permanently replace the acid-producing strains of *Streptococcus mutans* naturally occurring in the normal flora of the mouth. Thus, it was first necessary to find a strain of *Streptococcus mutans* that could permanently replace the naturally occurring decay-causing strains of *Streptococcus mutans*.

Through extensive scientific research, we eventually found a rare, naturally occurring strain of *Streptococcus mutans*, present in only 1% of the population, which secretes a natural antibiotic capable of killing virtually all other strains of *Streptococcus mutans*. We believe this natural antibiotic, referred to as MU1140, enables the bacteria to persistently and preemptively colonize the oral cavity, displace pre-existing strains and gain dominance in its ecosystem, dental plaque.

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Using this rare strain as the starting strain, we then employed recombinant DNA technology to delete the gene encoding for lactate dehydrogenase. Our research revealed the gene deletion eliminated the strain's ability to produce lactic acid; however, it also caused a metabolic imbalance that prevented the strain from growing. In order to correct the imbalance, an auxiliary gene for alcohol dehydrogenase was inserted, which restored the strain's growth. Instead of lactic acid, the strain produced ethanol and acetoin which are the normal end products of metabolism in many other microorganisms colonizing the oral cavity. We named this strain BCS3-L1, and filed for composition of matter intellectual property protection for the strain.

### **Regulatory Status**

We submitted an Investigational New Drug (IND) for replacement therapy to the U.S. Food and Drug Administration (FDA) in 1998 seeking permission to begin Phase I clinical trials. Orogenics responded to a number of potential safety concerns expressed by the FDA. In order to provide added safety assurance, the FDA requested the development of a recall mechanism to completely eradicate the organism from human subjects, should it be necessary, until complete safety could be experimentally established in the Phase I clinical trials.

In response to this requirement, we genetically engineered a second strain of *Streptococcus mutans* (A2JM) identical in every aspect to the original strain (BCS3-L1) except that it requires exogenous D-alanine for survival. D-alanine was selected because the nutrient is not normally found in human diets; it can be easily administered via a mouth rinse. Without nutrient supplementation, the organism cannot survive. Therefore, the organism can be completely eradicated from human subjects by withdrawing D-alanine nutrient supplementation.

The genetically altered strain of *Streptococcus mutans* requiring D-alanine supplementation was to be administered to study subjects in conjunction with a twice daily dose of a D-alanine mouth rinse. Once safety is experimentally established, the replacement therapy to be commercialized will consist of the original effector strain which does not require D-alanine to maintain colonization. In November 2004, the FDA approved our IND and our clinical design and protocol for the Phase I clinical trial.

We began our initial study in May 2005; however, during the remainder of 2005 we were unable to enroll a sufficient number of qualified subjects into our study. This initial study was expected to be conducted in eleven couples and an additional four unattached males at Hill Top Research in West Palm Beach, Florida (our clinical research organization (CRO) for the study). The study was to look at the safety of Replacement Therapy and the potential for horizontal transmission of the Replacement Therapy organism to the non-treated member of each couple. All of the participants in the trial, according to the FDA approved protocol, were required to be without teeth, with full sets of dentures, and under the age of 55.

On December 2, 2005, due to the enrollment of two subjects and the successful completion of only one subject in our initial clinical study, we re-submitted a new protocol to the FDA that was less restrictive. In January 2006, we held discussions with the FDA about our problems with patient enrollment and how we could modify our protocol. The critical changes to the study are that it will be conducted in 10 patients who have teeth and the patients will be quarantined to a hospital-type setting for up to 12 days with a 2 month follow-up phase. We concluded the initial study and submitted additional proposed changes in the trial to the FDA in March 2006. We addressed additional protocol changes suggested by the FDA and filed a second re-submission July 2006. Additional protocol changes were suggested by the FDA on September 29, 2006. Protocol changes from FDA were addressed in our third re-submission submitted in February 2007. FDA requested further changes during 2007 in the patient consent process, requiring added consents at several stages. A new CRO was recruited to perform the study. At the end of 2007, the FDA approved the study and removed the clinical hold. Only some follow-up non-clinical hold documents need to be provided to the FDA. Subject to available capital, the study is planned to be done in 2008.



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### ***Preclinical Studies***

From 1976 to 2002, our researchers and others have conducted numerous animal studies on replacement therapy for dental caries. We believe these studies support our belief in the ability of our novel technology to prevent tooth decay. Additionally, we believe these studies demonstrate the ability of our genetically engineered strain of *Streptococcus mutans* to persistently and preemptively colonize the oral cavity and aggressively displace the indigenous wild-type strain, filling its bacterial niche in all respects except for the production of lactic acid.

In summary, we believe the preclinical studies demonstrate that our genetically modified strain of *Streptococcus mutans*:

- Does not cause significant tooth decay in the animal test subjects;
- Persistently and preemptively colonizes the tooth surfaces of the animal test subjects;
- Displaces other (decay-causing) strains of *Streptococcus mutans*;
- Is genetically stable in the laboratory and in the animal test subjects;
- Shows no toxicity in acute and chronic animal tests; and
- Does not disrupt the normal flora of the mouths of animal test subjects.

### ***Intellectual Property***

We have exclusively licensed the intellectual property for our replacement therapy from the University of Florida Research Foundation, Inc. ("UFRF"). The license is dated August 4, 1998 and was amended on September 15, 2000, July 10, 2002, September 25, 2002 and March 17, 2003. The agreement provides us with an exclusive worldwide license to make, use and sell products and processes covered by Patent No. 5,607,672, which is dated March 4, 1997 and will expire on March 3, 2014. 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. UFRF has reserved UFRF the right to use and sell such products and services for research purposes only. Our license also provides the UFRF with a license, for research purposes only, to any improvements that we make to the products and processes covered by the patent.

Under the terms of the license, we have entered into an Equity Agreement with the UFRF under which we issued 599,940 shares of our common stock as partial consideration for the license to UFRF. We are obligated to pay 5% of the selling price of any products developed from the licensed technology to the UFRF and, if we sublicense the license, we are obligated to pay 20% of all amounts received from the sublicensee to UFRF. On December 31, 2006 and each year thereafter we are obligated to make a minimum royalty payment of \$50,000 for replacement therapy and \$50,000 for MU1140 to UFRF, for an aggregate of \$100,000. 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 MU1140 technologies combined, until a product which is covered wholly or partially by the claims of the patent, or is manufactured using a process which is covered wholly or partially by the claims of the patent, is sold commercially. We spent in excess of \$1,000,000 in each of 2007 and 2006. If we fail to make these minimum expenditures, the UFRF may terminate our license.

We must also pay all patent costs and expenses incurred by the UFRF for the preparation, filing, prosecution, issuance and maintenance of the patent. In 2003, upon our having received external funding exceeding \$1 million, we reimbursed the university \$100,000 of the initial \$105,000 they paid for patent prosecution. We have agreed to indemnify and hold the UFRF harmless from any damages caused as a result of the production, manufacture, sale, use, lease, consumption or advertisement of the product. Further, we are required to maintain liability insurance coverage appropriate to the risk involved in marketing the products, for which we obtained liability insurance that expires in August, 2008. There is no assurance that we can obtain continued coverage on reasonable terms.

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 UFRF. On September 17, 2006, Celunol notified Oragenics 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

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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.

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

The manufacturing methods for producing our genetically modified strain of *Streptococcus mutans* are standard fermentation methods. These methods 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 suitable for use 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.

Academic institutions, government agencies and other public and private research organizations may conduct research, seek patent protection and establish collaborative arrangements for discovery, research and clinical development of technologies and products that are similar to our replacement therapy technology. Also many of the potential competitors have research and development capabilities that may allow them to develop new or improved products that may compete with products based on our technologies.

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

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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.

### **Probiora3™ (Probiotics)**

Our oral probiotics 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.

#### **Technical Background**

The oral cavity provides an ecological niche for 400-700 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.

Through our research, we have developed a probiotic product (Probiora3) containing three natural strains of beneficial bacteria; *Streptococcus oralis* and *Streptococcus uberis* for the maintenance of periodontal health and a *Streptococcus rattus* strain naturally defective in lactic acid production for the maintenance of dental health. *Streptococcus oralis* and *Streptococcus uberis* are among several hundred bacterial species that constitute normal dental plaque. These bacteria, by virtue of their ability to produce hydrogen peroxide, appear to promote periodontal health by keeping the number of potentially pathogenic organisms below the threshold level necessary to initiate disease, demonstrated in both laboratory and animal studies. Human studies have correlated the presence of these bacteria with the absence of high levels periodontal pathogens. Probiotics containing these bacteria applied frequently could provide a significant benefit in maintaining a healthy balance of periodontal bacteria.

Similarly, we have identified a bacterial strain closely related to *Streptococcus mutans*, *Streptococcus rattus*, which is naturally deficient in its ability to produce lactic acid. Animal studies have shown that daily treatment with this strain results in decreased numbers of *Streptococcus mutans*, most likely by competition for essential nutrients or attachment sites on the tooth surfaces. Daily application of this strain is likely to provide significant benefit in maintaining a healthy balance of bacteria on teeth.

#### **Preclinical Studies**

We believe preclinical studies have demonstrated the ability of our probiotic to maintain a healthy oral environment. The probiotic creates a healthful balance of total bacteria by reducing the numbers of bad bacteria on teeth and gums.

We believe research conducted by our scientists and others has shown that certain types of natural bacteria normally present in dental plaque can prevent the out growth of bacteria that are widely believed to be responsible for periodontal disease. *Streptococcus oralis* and *Streptococcus uberis* have been shown in studies to inhibit the growth of disease-causing bacteria both in laboratory and animal models of infection. Data indicate that the presence of *Streptococcus oralis* and *Streptococcus uberis* provides a good indication of the health of the periodontium (gums). In healthy periodontal sites, *Streptococcus oralis* and *Streptococcus uberis* are commonly found in significant amounts while in diseased periodontal sites, the opposite situation prevails; *Streptococcus oralis* and *Streptococcus uberis* are usually undetectable.

We believe probiotics can also be used to suppress levels of *Streptococcus mutans*, the principal cause of tooth decay. *Streptococcus mutans* converts dietary refined sugar to lactic acid. The lactic acid, in turn, erodes the mineral in enamel and dentin, which weakens the tooth resulting in tooth decay. Research conducted by our scientists has led to the discovery of a close relative of *Streptococcus mutans*, a strain of *Streptococcus rattus*, which is naturally deficient in its ability to produce lactic acid. *Streptococcus rattus* reduces the number of *Streptococcus mutans* by competing for nutrients, attachment sites, and other important colonization and growth factors. As animal studies have revealed, daily treatment with this beneficial strain can promote dental health.

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### ***Clinical Studies***

We recently performed two studies to determine an appropriate and stable delivery system for commercialization. We initiated two human trials in July 2006 to evaluate Probiora 3. The trials were designed to determine safety and beneficial activities of the cosmetic mouth rinse in achieving a healthy bacterial balance in the mouth of healthy subjects. Daily mouth rinsing with Probiora3™ resulted in substantial reductions in the numbers of the bacterium, *S. mutans*, as well as two target periodontal strains, *Porphyromonas gingivalis* and *Campylobacter rectus*. The product was well tolerated by the subjects and no safety issues were identified with the twice daily use of the product over a two-month period.

### ***Regulatory Status***

Probiotic products that claim to confer a health benefit are generally able to enter the market without the need for extensive regulatory filings and clinical testing. This avenue is available for products that do not make any claim that they treat, prevent, or cure a disease, which are considered to be drug claims. We intend to market our probiotic product without drug claims. In the European Union regulatory approval is not required for commercialization as a cosmetic mouthwash product.

### ***Intellectual Property***

In August 2003, we filed a patent application for our probiotic technology for use in developing oral care products for the maintenance of dental and periodontal health. We own the patent rights to this technology.

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

Manufacturing methods used to produce probiotic strains are the standard fermentation methods which involve culturing bacteria in large vessels and harvesting them when mature by centrifugation or filtration. These methods are relatively commonplace and readily available within the probiotics industry. We intend to seek one or more strategic partners for the manufacturing, marketing and distribution of our oral probiotic technology. Companies have indicated their intent to enter into licensing discussions with us. We continue to pursue potential regional and international partners in the oral care and/or food and nutritional supplement industries for the marketing rights to the Probiora3 technology.

### ***Market Opportunity***

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, dietary aide, or other non-prescription products. If successfully developed, we expect our technology will be one of the first probiotics to be marketed for the promotion of oral health.

### ***Competition***

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* aids in the prevention of tooth decay. *Lactobacillus reuteri* is widely used as a probiotic for other indications and may be used in the future for dental health. We are aware of a probiotic product from BioGaia AB, containing a strain of *lactobacillus reuteri*, which is on the market today and is targeted to maintain dental health. Another oral probiotic therapy commercially available from TheraBreath (known as AKTIV K12 probiotic), available in mouthwash, tablets; it is stated to be used for bad breath and contains the bacterium, *Streptococcus salivarius* K12. This bacterium principally colonizes the cheek and tongue surfaces in oral cavity, and as such is promoted only for its activity as an aid for halitosis. As compared to all of these competitors, Probiora3 potentially has greater beneficial actions for maintaining oral health.

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### **LPT3-04™**

**LPT3-04™** is a natural small molecule substance that possesses activity in promoting weight loss. LPT3-04 is orally available, and we believe it has an excellent safety and tolerability profile.

In April 2006, we filed a U.S. patent application to protect our intellectual property rights to a small molecule and its analogs as weight management agents. There can be no assurance that a patent will be issued or that new technology will be successfully developed by us.

Animal studies with LPT3-04 in three rat models have demonstrated significant weight loss activity within a short timeframe and without any significant adverse effects. The mechanism of action is unique and different from other weight loss products. While we are optimistic about the future prospects for this small molecule, we are in mid-to-late discovery stage of this research and development.

A human evaluation is planned to demonstrate a weight loss benefit, as well as safety. We intend to continue our development efforts, but we currently do not have sufficient capital resources to fully develop this technology. Commercial partners for both development and manufacturing are being sought that are actively involved in the weight management field. Interest has been exhibited from several companies to work with Oragenics.

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

We have spent \$1,569,551 and \$2,023,896 on research and development of our technologies in 2007 and 2006, respectively.

#### **Costs of Enforcing Our Licenses**

We have licenses to sell products made using the SMaRT replacement therapy™ and MU1140 technologies. The licenses were granted to us by the University of Florida Research Foundation, Inc., which owns the patents to these technologies. There is no assurance, however, that third parties will not infringe on our licenses or their patents. In order to protect our license rights and their patents, we or the University of Florida Research Foundation, Inc. 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 University of 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.

#### **Our Employees**

We are an early-stage biotechnology research and development company and currently have 9 full-time employees, none of whom is represented by a labor union. We believe that our relationship with our employees is good.

#### **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-KSB, quarterly reports on Form 10-QSB, 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-KSB.

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**Item 2. Description of Property.**

Our administrative office and laboratory facilities are located at 13700 Progress Boulevard, Alachua, Florida 32615. We began leasing this property pursuant to a five-year operating lease in November 2004. 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 rental for 2007 was approximately \$89,524, net of insurance, taxes and utilities that are paid by us. Lease payments escalate by 6% annually. We paid no leasehold improvement in 2007 but in 2006, we paid \$12,000. We also spent approximately \$13,000 and \$12,000 in 2007 and 2006, respectively, for laboratory equipment to outfit our facility. We believe our facilities are sufficient for our current needs and do not expect significant purchases of property in 2008.

**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. Submission of Matters to a Vote of Security Holders.**

None during the fourth quarter of the 2007 fiscal year covered by this report.

**PART II**

**Item 5. Market for Common Equity and Related Stockholder Matters.**

Our common stock began trading on the American Stock Exchange under the symbol ONI on May 20, 2004. Previously our common stock was traded on the TSX Venture Exchange under the symbol ORA.U. We voluntarily de-listed from the TSX Venture Exchange on October 12, 2004. The following sets forth the high and low sales prices for the common stock on the American Stock Exchange for each quarter in the last two fiscal years.

<u>Period</u>	<u>2007</u>		<u>2006</u>	
	<u>High</u>	<u>Low</u>	<u>High</u>	<u>Low</u>
First quarter	\$1.18	\$0.73	\$0.61	\$0.34
Second quarter	\$1.10	\$0.33	\$1.50	\$0.48
Third quarter	\$0.75	\$0.38	\$0.91	\$0.57
Fourth quarter	\$0.59	\$0.28	\$1.45	\$0.60

On March 3, 2008, the closing bid price of the common stock, as reported by the American Stock Exchange, was \$0.57. As of March 3, 2008, there were approximately 49 registered holders of our common stock according to our transfer agent, 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.

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### **Item 6. Management's Discussion and Analysis or Plan of Operation.**

*The following information should be read in conjunction with the Financial Statements, including the notes thereto, included elsewhere in this Form 10-KSB. 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-KSB.*

We are an early-stage biotechnology company aimed at adding value to novel technologies and products sourced from innovative research from internal discovery, at the University of Florida, at other academic centers, and from in-licensing from other biotechnology companies. Our strategy is first to in-license or internally discover products and technologies, second to develop products up to and through human proof-of-concept studies (Phase II clinical trials of the U.S. Food and Drug Administration's (FDA) regulatory process), and third to partner with major pharmaceutical, biotechnology, or healthcare product firms for advanced clinical development and commercialization. Since our inception, we have funded a significant portion of our operations from the public and private sales of our securities. We have generated no significant revenues from operations during the last two years. All of our revenues have been from a sponsored research agreements and SBIR grants. We have not generated revenues from sales of products.

We are in need of substantial additional funds in order to continue the development of our technologies. We are continuing to seek additional funding. Other than the Fusion Capital agreement, we currently do not have any commitments for funding or other strategic options pending and there can be no assurances that we will be able to obtain funding or implement any strategic options in the future. Since the fourth quarter 2005, we have deferred partial payments to our former Chief Executive Officer and President, Chief Scientific Officer, Board of Directors, and Audit Committee members. As we move into more advanced stages concerning our products and their testing, our monthly expenses and use of cash is likely to increase. Our remaining capital resources are expected to be utilized to sustain operations while we continue to explore opportunities to raise additional capital. Our remaining working capital at December 31, 2007 was \$260,534 and we believe is sufficient to enable us to continue to operate through the first quarter of 2008. While we believe additional capital may become available through grants or through possible future exercises of outstanding warrants, there can be no assurance of the same. In the event adequate capital is not raised we would likely need to cease all operations until we are able to raise additional capital. We have a contractual obligation to pay a minimum royalty of \$25,000 quarterly and spend or cause to be spent an aggregate of \$1,000,000 annually toward research, development and regulatory prosecution, in order to maintain our license with the University of Florida Research Foundation, Inc. for SMaRT Replacement Therapy and MU 1140 technologies. While we believe we have met our obligations under the license agreement to date, if we are unable to make future payments, our license could be terminated which will substantially diminish the value of our company.

We hope to be in a position to develop the following technologies, each of which addresses potentially large market opportunities:

**MU 1140™** is a highly potent bactericidal peptide that is produced by our strain of *Streptococcus mutans*. We completed development of a proprietary manufacturing process for MU 1140 and are now refining the fermentation process so that sufficient quantities can be produced to allow us to conduct preclinical studies needed to enable the filing of an Investigational New Drug (IND) application. During the second quarter of 2007, we completed significant preclinical studies including the demonstration that MU 1140 is effective in an animal infection model against *Staphylococcus aureus*. If we are able to secure adequate funding, we plan to continue to perform *in vitro* and animal safety studies using MU 1140™ that will provide sufficient information to permit a pre-IND meeting with the U.S. FDA.

**DPOLT™** (Differentially Protected Orthogonal Lantionine Technology) is a solid or liquid phase peptide synthesis platform technology that has broad application for the cost-effective manufacture of a number of commercially important bioactive peptides. Lantibiotics, including our lead antibiotic, MU1140, are a potentially important class of antibiotics, and constitute a family of polycyclic peptides that are produced by bacteria, and are highly modified structurally. Attempts to study lantibiotics for their potential usefulness as therapeutic agents have been hindered by difficulties in producing sufficiently pure material in amounts adequate for clinical testing and commercialization. In July 2006, the Company was awarded a



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\$100,000 SBIR (Small Business Innovation Research) grant from the National Science Foundation to establish proof-of-principal for DPOLT and on February 15, 2008, a \$500,000 Phase II NSF SBIR grant, for to develop a scale-up method for MU 1140-S synthesis and testing as a therapeutic antibacterial agent was awarded. We filed a U.S. patent application in May 2006, covering the DPOLT technology.

**IVIAT™ and CMAT™** are technologies that enable the simple, fast identification of novel and potentially important identification of gene targets associated with the natural onset and progression of infections, cancers and other diseases in humans and other living organisms, including plants. These technologies offer the potential to generate and develop a number of product candidates as diagnostics or therapeutics for future out-licensing to corporate partners, particularly in the areas of cancer and infectious diseases, as well as agricultural and other non-human uses. We have received funding under SBIR grants with the National Institutes of Health and, if more funding becomes available, we will pursue additional research. We are in collaboration with outside companies and institutes to validate our biomarkers leading to diagnostic products.

**SMaRT Replacement Therapy™** is a single, painless one time topical treatment that has the potential to offer lifelong protection against dental caries (tooth decay). The therapy is based on genetically altering the bacterium, *Streptococcus mutans* (*S. mutans*), which is the primary etiologic agent in tooth decay. Present in the normal flora of the mouth, *S. mutans* converts dietary sugar to lactic acid; the lactic acid, in turn, causes the erosion of tooth enamel that results in the destruction of the tooth surface and eventually the entire tooth. SMaRT Replacement Therapy permanently replaces resident acid-producing *S. mutans* with a patented genetically modified strain of *S. mutans* that does not produce lactic acid. Applied topically to tooth surfaces with a swab, the therapy may require only one application. We have begun Phase I clinical trials and expect to partner with a major healthcare products or pharmaceutical company prior to initiating Phase II and III clinical trials. In our Phase I clinical trial in 2005, we had very limited patient enrollment through December 31, 2005 due to the rigorous requirements for enrollment imposed upon us by the FDA. In January 2006, we terminated this study and discussed with the FDA our problems with patient enrollment and how we could modify our protocol to allow us to move forward in our clinical trials. A formal re-submission of an amended protocol was filed with the FDA on March 9, 2006. We addressed additional protocol changes suggested by the FDA and filed a second re-submission July 20, 2006. Based on further suggestions by the FDA for protocol changes made on September 29, 2006, we filed a third re-submission in early February 2007. Further protocol revisions and requirements in the conduct of the study were designated to be done by the FDA during 2007, which were completed and re-submitted during 2007. We now have a Phase I study and protocol approved by the FDA, as of November 2007. We remain committed to complete the human safety study of SMaRT Replacement Therapy by ourselves or through a partner.

**Probiora3™ (Probiotics)** contains three naturally occurring, live microorganisms that helps maintain dental and oral health when administered to the host in adequate amounts. The use of yogurt containing live *Lactobacillus* cultures is an example of a probiotic application. Because probiotic treatments may be marketed as a cosmetic or as “health supplements” in certain geographic areas without the need for extensive regulatory oversight, we believe that with adequate funding, we may achieve commercialization of our probiotic product (Probiora3) in these markets by the first half of 2009. Two sets of subjects completed our Probiora3 human study, and we believe the results confirmed that the product is safe for human use and demonstrated a substantial effect of Probiora3 in reducing the levels of specific bacteria in the mouths of young, healthy adult subjects. We are continuing our efforts to seek regional and international partners for market opportunities in the oral care and/or food and nutritional supplement industries to determine interest and deal structure preferences for the rights to the Probiora3 technology.

**LPT3-04™** is a small molecule weight management agent for which we filed a U.S. patent application on April 5, 2006 to protect our intellectual property rights to the agent and its analogs. As a natural substance, LPT3-04 is orally available, and we believe it has an excellent safety and tolerability profile. While we are optimistic about the future prospects for this small molecule, we are in mid to late discovery stage of this research and development project. There can be no assurance that a patent will be issued or that new technology will be successfully developed by us. Although we intend to continue our development efforts regarding this technology including undertaking a human study for safety and weight loss, we currently do not have sufficient capital resources to fully develop this technology. We are seeking a commercial partner that is actively involved in the weight management market.

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### **Business Objectives and Milestones**

The specific goal of our business is to discover, successfully develop preclinical, and then clinically test products based on our wholly owned or exclusively licensed, proprietary technologies. Our strategy is to develop novel technologies through human proof-of-concept studies (Phase II clinical trials) prior to partnering through licensing with major pharmaceutical, biotechnology or health care product firms for advanced clinical development and commercialization. One or more strategic partners that would be responsible for advanced clinical development, completing the U.S. Food and Drug Administration's approval process, and manufacturing and marketing our products. In order to accomplish these objectives, we must obtain additional capital and take the following actions:

#### **MU 1140™**

- Complete preclinical studies, including animal toxicity, activity, and pharmacokinetics, required for an investigational new drug application (IND) submission for MU 1140 native and MU 1140 synthetic.
- Schedule a pre-IND meeting with the FDA for MU 1140 native and / or MU 1140 synthetic.
- Continue discussions with biotechnology and pharmaceutical companies for the licensing of MU 1140 or its analogs.

#### **DPOLT™**

- Complete proof-of-principle studies.
- Initiate studies for the scale-up of DPOLT for lantibiotic production.

#### **IVIAT™**

- Validate gene protein markers for *Mycobacterium tuberculosis*.

#### **CMAT™**

- Complete proof-of-principle in colorectal cancer model.
- Validate the biomarkers for colorectal cancer.

#### **SMaRT Replacement Therapy™**

- Initiate second Phase I clinical safety trial.
- Pursue partners for licensing, or further development and commercialization.

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### **Probiora3™**

- Partner with one or more nutritional, oral care, or food manufacturers or distributors.
- Produce scale-up lots and perform all necessary testing.

### **LPT3-04™**

- Conduct human safety and effectiveness study.
- Pursue partners for licensing, or further development and commercialization.

The above actions, 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. The time periods for the expected continued development of our technologies have been extended from those previously indicated due primarily to our insufficient capital position and the time periods expected developments could 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. 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 exceeded the \$1,000,000 per annum threshold for research, development and regulatory prosecution. If we are unable to make the minimum royalty payments, our license could be terminated which will substantially diminish the value of our company.

### **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: Recently Issued Accounting Pronouncements.

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### Results of Operations

#### Operating Results Summary

	Three Months Ended December 31	
	2007	2006
Revenue	\$ 26,743	\$ —
Operating expenses:		
Research and development	460,254	600,198
General and administration	257,930	111,132
Total operating expenses	718,184	711,330
Loss from operations	(691,441)	(711,330)
Other income (expense):		
Interest income	6,590	3,443
Gain (loss) on disposal of property and equipment	(1,979)	—
Interest expense	—	—
Total other income, net	4,611	3,443
Loss before income taxes	(686,830)	(707,887)
Net loss	\$ (686,830)	\$ (707,887)

	Years ended December 31	
	2007	2006
Revenue	\$ 133,088	\$ 66,176
Operating expenses:		
Research and development	1,569,551	2,023,896
General and administration	902,655	1,004,099
Total operating expenses	2,472,206	3,027,995
Loss from operations	(2,339,118)	(2,961,819)
Other income (expense):		
Interest income	29,385	24,931
Gain (loss) on disposal of property and equipment	(1,979)	2,024
Interest expense	—	(855)
Total other income, net	27,406	26,100
Loss before income taxes	(2,311,712)	(2,935,719)
Net loss	\$(2,311,712)	\$(2,935,719)

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### ***For the Quarters Ended December 31, 2007 and 2006***

We had \$26,743 in revenue during the three months ended December 31, 2007 and none during the three months ended in December 31, 2006. Our operating expenses increased 1.1% to \$719,205 in the three months ended December 31, 2007 from \$711,330 in the same period in 2006. Research and development (R&D) expenses decreased 23.3% to \$460,254 in the three months ended December 31, 2007 from \$600,198 in the same period in 2006. This overall decrease reflected the approximately \$134,000 decrease in legal and patent expenses, \$48,961 in clinical trial and consultant expenses, and \$14,382 decrease in lab expenses which included repairs and maintenance of equipment. Staffing expense such as insurance and relocation payments increased by approximately \$38,572. General and administration (G&A) expenses increased 132% to \$257,930 in the three months ended December 31, 2007 from \$111,132 in same period in 2006. This increase reflects the increase in recruiting fees for senior management \$30,931, investor advisors fees \$43,542 and stock option expense of approximately \$85,000.

Interest income increased 96.4% to \$6,590 in the three months ended December 31, 2007 from \$3,443 in the same period in 2006.

Our net loss decreased 2.97% to \$686,830 during the three months ended December 31, 2007 from \$707,887 in the same period in 2006. The decrease in our R&D expense was offset by the increase in recruiting and investor relation and advisory fees.

### ***For the Years Ended December 31, 2007 and 2006***

We had \$133,088 in revenue in the year ended December 31, 2007 as compared to \$66,176 in 2006. This is a result of two grants, one a Small Business Innovation Research (SBIR) grant for DPOLT and the second from a NIH/NCI grant for our CMAT technology. Our operating expenses decreased 18.3% to \$2,473,227 for the year ended December 31, 2007 from \$3,027,995 in 2006. Research and development (R&D) expenses decreased 22.45% to \$1,569,551 in 2007 from \$2,023,896 in 2006, reflecting the reduction in clinical and outside consultants expenses, legal and patent expenses, stock option expense and a decrease in lab expenses, totaling approximately \$508,000. This R&D expense decrease was offset by the increase in salary expenses in hiring a Director of our Microbiology Lab, benefit expenses and vacation accruals of approximately \$56,000. General and administration (G&A) expenses decreased 10% to \$902,655 in 2007 from \$1,004,099 in 2006, reflected by reduction in staff expense, advertising fees, legal and accounting, and general office expenses of approximately \$195,000. This decrease was offset by our increase in contracting with investor relations services of \$84,328, the increase in our stock option compensation expense of approximately \$19,000 and increase in rent and property taxes of approximately \$12,000.

Interest income increased 17.83% to \$29,375 in the year ended December 31, 2007 from \$24,931 in the year ended December 31, 2006. There was no interest expense in 2006.

Our total net loss decreased 21.6% to \$2,311,712 in the year ended December 31, 2007 from \$2,935,719 in 2006. The decrease in our net loss was principally caused by our reduce legal and patent fees and less expense for clinical trials, offset by the increase in our stock option compensation expenses and the contract with investor advisory services.

### **Liquidity and Capital Resources**

Since our inception, we have funded our operations through the sale of equity securities in private placements and our initial public offering, the sale of equity securities and warrants in private placements, debt financings and grants. So far in 2008, the Company has been awarded a \$500,000 NSF Phase II grant for its DPOLT technology and has completed two security events whereby 4,536,364 warrants were exercised for common stock that provided \$1,996,000 in proceeds. Below is a summary of the Company's cash flow activities for 2007.

Our operating activities used cash of \$1,913,760 for the year ended December 31, 2007 and \$2,224,538 for the year ended December 31, 2006. Our working capital was \$260,534 as of December 31, 2007. Cash used by operations in the year ended December 31, 2007 resulted primarily from operating losses from operations of \$2,340,139.

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Our investing activities used cash of \$9,860 for the year ended December 31, 2007 as a result for the acquisition of laboratory equipment. We do not anticipate any significant spending on additional property and equipment during 2008.

Our financing activities provided \$1,691,850 in cash for the year ended December 31, 2007, which came from three sources. In the third quarter of 2007 we issued 4,600,000 common stock and warrants in a private placement in August 2007 that provided gross proceeds of \$1,171,591. In addition, common stock warrants issued in connection with two private placements in December 2005 and March 2006 were also exercised during the first six months of 2007 providing funds of approximately \$478,500. Additional details of these financings are provided below:

**Private Placement, August, 2007**—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 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 warrants expire 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) following which the exercise price reverts back to \$0.58. Prior to the expiration of the August 2007 Warrants, 3,386,364 were issued upon exercise at the amended exercise price resulting in additional working capital proceeds to us of \$1,490,000.

**Private Placement, March 2006**—On March 6, 2006, we issued a total of 1,500,000 shares of our common stock and warrants to purchase 1,500,000 shares of our common stock in a private placement to accredited investors. We received gross proceeds of \$600,000 in the private placement and incurred estimated costs of approximately \$75,000 resulting in net proceeds of approximately \$525,000. Each warrant is exercisable on or before February 8, 2008 to acquire one share of common stock at a price of \$0.60 per share (the “March 2006 Warrants”). On January 17, 2008 we amended the March 2006 Warrants. Pursuant to the amendment, the warrant exercise price was reduced to \$0.44, which was the fair market value on the date of the amendment. Prior to the expiration of the March 2006 Warrants, 1,150,000 were issued upon exercise at the amended exercise price resulting in additional working capital proceeds to us of \$506,000. The remaining unexercised March 2006 Warrants expired and are no longer outstanding.

**Private Placement, December 2005**—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. The issuance of the shares of common stock and warrants was made pursuant to the exemptions from registration provided by Section 4(2) of the Securities Act and Regulation D promulgated thereunder. 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. A total of 1,387,500 warrants were exercised that provided \$832,500 in additional working capital and following the call of the warrants no further warrants associated with the private placement remains outstanding.

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 unidentified additional financings. We have experienced losses from operations during the last three fiscal years and have an accumulated deficit of \$13,970,793 as of December 31, 2007. Cash used in

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operations for 2007, 2006 and 2005 was \$1,913,760, \$2,224,538 and \$3,434,382, respectively. At December 31, 2007, our principal source of liquidity was \$475,508 of cash and cash equivalents. These operating results occurred while developing and attempting to commercialize and manufacture products from entirely new and unique technologies. Our business plan requires significant spending related primarily to 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 depends on our ability to continue to raise capital for our operations.

Because of our limited available financial resources, we have continued to adopt several approaches to reduce expenditures by reducing our matching contributions for the employee retirement plan, appreciably reducing travel and other operating costs, decreasing the use of outside consultants and delaying the production of additional supplies of our SMaRT Replacement Therapy™ technology to be used in later clinical studies. As of December 31, 2007, salary payments of \$26,250 each to Jeffrey D. Hillman, our Chief Scientific Officer, and Robert T. Zahradnik, our former President and Chief Executive Officer and 2005 and 2006 fees of \$34,000 to the Board of Directors and Audit Committee have been deferred. These salary payments and meeting fees were agreed to be deferred until such time as we obtain sufficient funding that payment can be made. There is no time period on the payment of the deferred amounts concerning our officers and directors. The deferrals of payments to our former chief executive officer, current officers and directors, do not reduce our expenses, but serve to preserve our limited cash resources to the extent necessary to maintain our operations.

Our capital requirements for 2008 will depend on numerous factors, including the success 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 raise additional capital, we expect to need to incur substantial expenditures to further 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. Our working capital at December 31, 2007 is not adequate to meet our business objectives as presently structured. 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 recognize that 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.

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 may have rights, preferences, or privileges senior to those of our common stock, and our current stockholders may experience substantial dilution.

To date, we have not obtained financing sufficient to fully support our plans going forward. Until such time as additional financing for our operations is obtained, we expect to continue to need to curtail our spending. While we continue to focus on completing the Phase I clinical trial for our SMaRT Replacement Therapy technology, conducting additional studies for our MU 1140 antibiotic technology and LPT3-04, and developing strategic partners for Probiora3 and LPT3-04, we do not have sufficient capital resources to complete these projects. As we move into more advanced stages concerning our products and their testing our monthly budget and of cash usage rate is likely to increase accordingly. Our available working capital at December 31, 2007 is \$260,534. Our currently available working capital is insufficient to enable us to continue to operate after the first quarter of 2008. Because we were recently awarded a NSF SBIR Phase II grant on February 15, 2008, we believe additional capital may be possible through our arrangement with Fusion Capital or through possible future exercises of outstanding warrants, there can be no assurance of the same. In the event adequate capital is not raised we would likely need to cease all operations until we are able to raise additional capital. Thereafter, without sufficient capital to fund our operations, we will be unable to continue as a going concern and will have to cease operations.

## 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-KSB and shall be deemed to be modified or superseded to the extent that a statement contained in our future filings incorporated herein by reference modifies or replaces such statement. All of these risks may impair our business operations. The forward-looking statements in this Form 10-KSB and in the documents incorporated herein by reference 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 Associated with Our Company**

#### ***We continue to require additional financing to operate through the remainder of the year***

We do not have sufficient capital to sustain our operations beyond the first quarter of 2008 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 cease operations and be unable to pursue further development of our technologies;
- We will be unable to pursue patenting our small molecule weight loss agent and development of our technologies and products;
- We will have to lay-off our personnel;
- We could be unable to continue to make public filings;
- We will be de-listed from the American Stock Exchange; and
- Our licenses for our SMaRT Replacement Therapy technology and MU 1140 technology could be terminated which would significantly harm our business.

At December 31, 2007 and December 31, 2006, we had working capital of approximately \$260,534 and \$453,576, respectively. The independent registered public accounting firm's report as of and for the year ended December 31, 2006, includes an explanatory paragraph to their audit opinion stating that our recurring losses from operations and limited working capital raise substantial doubt about our ability to continue as a going concern. We have an operating cash flow deficit of \$1,913,760 for the year ended December 31, 2007 and have sustained operating cash flow deficits of \$2,224,538 in 2006. Our ability to obtain additional funding will determine our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

#### ***We have a limited operating history with significant losses and expect losses to continue for the foreseeable future.***

We have yet to establish any history of profitable operations. Our limited revenues to date have not been related to the commercialization or licensing of our products and have not been sufficient to sustain our operations. We expect that our revenues will not be sufficient to sustain our operations for the foreseeable future. Our profitability will require the successful commercialization of our MU 1140, SMaRT Replacement Therapy, Probiora3 and other technologies we either license or own. No assurances can be given when this will occur or that we will ever be profitable.

#### ***Our ability to obtain additional financing from Fusion Capital is subject to certain conditions and limitations which could cause us to be unable to obtain such additional financing.***

The extent we are able to rely on our stock purchase agreement with Fusion Capital as a source of funding will depend on a number of factors, conditions and limitations beyond our control including, the prevailing market price of our common stock. Specifically, Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than \$0.75. If obtaining sufficient financing from Fusion Capital were to prove unavailable or prohibitively dilutive and if we are unable to commercialize and sell products resulting from the development of our technologies, we will need to



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secure another source of funding in order to satisfy our working capital needs. Even if we are able to access the full \$9.0 million under the common stock purchase agreement with Fusion Capital, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences would be a material adverse effect on our business, operating results, financial condition and prospects.

We only have the right to receive \$15,000 per trading day under the agreement with Fusion Capital unless our stock price equals or exceeds \$2.20 in which case the daily amount may be increased under certain conditions as the price of our common stock increases. Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than \$0.75.

We have authorized the sale and issuance of up to 4,000,000 shares of our common stock to Fusion Capital under the common stock purchase agreement. In the event that we decide to issue more than approximately 2,900,000 shares, we would first be required to seek stockholder approval in order to be in compliance with American Stock Exchange rules. We have issued 315,421 shares to Fusion Capital as a commitment fee and 205,732 shares pursuant to the common stock purchase agreement and accordingly may issue up to 2,378,847 shares to Fusion Capital before we would be required to seek stockholder approval in order to be in compliance with American Stock Exchange rules.

We are required to maintain an effective registration statement in connection with the shares acquired by Fusion Capital pursuant to the stock purchase agreement.

***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 and 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 developed products take place, we will not be earning revenues from the sale of products and will, therefore, have to raise the money we must spend on development of our technologies by other means, such as the sale of our common stock. There is no assurance we will 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.

***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

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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 operations.

***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.***

All of our product candidates are in the early development stage. Although we have current data which indicates the promise of the concept of our MU 1140, SMaRT Replacement Therapy, Probiora3, and LPT3-04 technologies, we can offer 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 MU 1140, SMaRT Replacement Therapy, Probiora3, and LPT3-04 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.

***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 stockholders. 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 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 product development areas such as, but not limited to, 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 products that are more 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 team of research scientists, who have the 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 Scientific Officer, Dr. Jeffrey D. Hillman, 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 an employment agreement with Dr. Hillman, which automatically renews for one-year terms unless 90 days written notice is given by either party.

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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, MU1140 has been undertaken solely in the laboratory and in animals. We have not yet conducted human studies of MU1140. It is possible that when these studies are conducted, they will show that MU1140 is ineffective or harmful. If MU1140 is shown to be ineffective or harmful, we will be unable to commercialize it and generate revenues from sales of MU1140. 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 MU1140 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, MU1140, 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 MU1140 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.

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***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.

***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

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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. 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. 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 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 in the United States. In the United States more stringent FDA 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. 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.

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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 FDA 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.

***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 if 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 in the United States. If we are not able to obtain third party reimbursement for products based on our technologies, it could limit our revenue.***

In the United States, success in obtaining payment for a new product from third parties such as insurers 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.

***We have limited resources which exposes us to potential risks resulting from new 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

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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.

### **Risk Factors Relating to our Common Stock**

***We may be unable to maintain the listing of our common stock on the American Stock Exchange and that would make it more difficult for stockholders to dispose of their common stock.***

Our common stock is listed on the American Stock Exchange. We cannot guarantee that it will always be listed. The American Stock Exchange rules for continual listing include minimum market capitalization and other requirements, which we may not meet in the future, particularly if the price of our common stock declines or we are unable to raise additional capital to continue operations.

On April 25, 2007 we received notification from the American Stock Exchange ("AMEX") that we were not in compliance with AMEX's continued listing requirements because our shareholders' equity is less than \$2,000,000 and we have experienced losses from continuing operations and/or net losses in two of our most recent fiscal years. On May 1, 2007, we notified AMEX that as a result of the resignation of our independent director, Mr. George Hawes, from our Board of Directors, we were aware that we were no longer in compliance with certain of the AMEX's continued listing standards for Small Business Issuers regarding having at least fifty percent of its Board be comprised of independent directors and maintaining an audit committee of at least two independent directors. On May 3, 2007 we received a Warning Letter from AMEX regarding the aforementioned noncompliance. We submitted a plan on May 24, 2007 to AMEX for regaining compliance with all of the continued listing standards, which included a newly appointed director to the Company's Board.

On September 15, 2007, Dr. Ron Evens was appointed to the Company's Board of Directors. On December 31, 2007, our Board of Directors consisted of six members of which three are independent. On July 2, 2007, AMEX notified the Company that it had completed its review and has determined that the Company's compliance plan makes a reasonable demonstration of the Company's ability to regain compliance with the continued listing standards by the end of the plan period, October 27, 2008 and is therefore continuing the Company's listing pursuant to an extension. The proceeds from our recent August 7, 2007 financing are insufficient, alone, to regain final compliance with AMEX listing requirement. We have until October 27, 2008 to regain AMEX compliance but there can be no assurance that we will be able to do so.

If our common stock is de-listed from the American Stock Exchange, trading in our common stock would be conducted, if at all, on the NASDAQ's OTC Bulletin Board in the United States. This would make it more difficult for stockholders to dispose of their common stock and more difficult to obtain accurate quotations on our common stock. This could have an adverse effect on the price of our common stock.

The Securities and Exchange Commission has adopted Rule 3a51-1 which establishes the definition of a "penny stock," for the purposes relevant to us, as any equity security that has a market price of less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, Rule 15c-9 require:

- that a broker or dealer approve a person's account for transactions in penny stocks; and
- the broker or dealer receives from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

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In order to approve a person's account for transactions in penny stocks, the broker or dealer must:

- obtain financial information and investment experience objectives of the person; and
- make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the SEC relating to the penny stock market, which, in highlight form:

- sets forth the basis on which the broker or dealer made the suitability determination; and
- that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of our common stock and cause a decline in the market value of our stock.

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

***Any sale of our common stock to Fusion Capital under its common stock purchase agreement with us will cause dilution and the sale of the shares of common stock acquired by Fusion Capital thereunder could cause the price of our common stock to decline.***

We have entered into a stock purchase agreement with Fusion Capital to sell up to \$9.0 million of our common stock to them. However, Fusion Capital neither has the right nor the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than \$0.75. Our common stock price has traded below \$0.75 for a significant amount of time since we entered into the stock purchase agreement with Fusion Capital which precludes the availability of funding from Fusion Capital under our agreement with them. The purchase price for the common stock to be sold to Fusion Capital pursuant to the common stock purchase agreement with Fusion Capital will fluctuate based on the price of our common stock. All shares acquired by Fusion Capital and resold pursuant to an effective registration statement covering such shares, will be freely tradable. Fusion Capital may sell none, some, or all of the shares of common stock purchased from us at any time. Depending upon market liquidity at the time, a sale of such shares at any given time could cause the trading price of our common stock to decline. The sale of a substantial number of shares of our common stock, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. If our stock price drops below \$0.75 we will not be able to sell any shares of our common stock to Fusion Capital in which case our ability to acquire needed capital will be adversely affected and our business could be harmed.

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

The market price of our common stock has been and is expected to continue to be highly volatile. Factors, including announcements of technological innovations by us or other companies, regulatory matters, new or existing products or procedures, concerns about our financial position, operating results, litigation, government regulation, developments or disputes relating to agreements, patents or proprietary rights, may have a significant impact on the market price of our stock. In addition, potential dilutive effects of future sales of shares of common stock by us and by stockholders, including Fusion Capital, and subsequent sales of common stock acquired by the holders of warrants and options could have an adverse effect on the market price of our shares.



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Although our common stock began trading on the American Stock Exchange under the symbol “ONI” on May 20, 2004, 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 escrow or other 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. We cannot guarantee that an active public market for our common stock will be sustained or that the average trading volume will remain at present levels or 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 2007 our stock price has fluctuated from \$5.00 to \$0.28 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.

### ***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 3, 2008, there were 32,538,807 shares of our common stock outstanding, with another 1,641,136 shares of common stock issuable upon exercise of warrants to investors, 1,685,000 shares issuable upon exercise of options outstanding and an additional 1,315,000 shares available for option grants under our stock option plans. The issuance of 1,000,000 shares of our stock underlying these options is covered by an S-8 registration statement we filed with the SEC and may be resold into the market. We have issued a significant number of shares in connection with private placements that are available for resale pursuant to registration statements we have filed covering the resale of such shares as well as shares issuable upon exercise of warrants also issued with respect to such private placements. The selling shareholders named in these registration statements may resell the shares they own and the shares they acquire upon exercise of the warrants. Most recently, we issued 4,600,000 shares of our common stock with warrants to acquire an additional 4,600,000 shares of our common stock in a private placement. We were obligated to file a registration covering the resale of such shares. We filed such registration statement and it was declared effective by the SEC on September 26, 2007. The sale of shares by selling shareholders pursuant to such registration statement and other registration statements we have filed for selling shareholders to resell the shares of our common stock they acquired from us in private transactions, could cause our stock price to decline significantly.

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### **Forward-Looking Statements**

This 10-KSB contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements include statements regarding, among other things, (a) our anticipated needs for and availability of working capital, (b) our future financing plans, (c) our strategies, (d) our projected sales and profitability, (e) anticipated trends in our industry. Forward-looking statements, which involve assumptions and describe our future plans, strategies, and expectations, are generally identifiable by use of the words “may,” “will,” “should,” “expect,” “anticipate,” “estimate,” “believe,” “intend,” or “project” or the negative of these words or other variations on these words or comparable terminology. This information may involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from the future results, performance, or achievements expressed or implied by any forward-looking statements. These statements may be found under “Management’s Discussion and Analysis or Plan of Operation” and “Business,” as well as in this 10-KSB generally. Actual events or results may differ materially from those discussed in forward-looking statements as a result of various factors, including, without limitation, the risks outlined under “Risk Factors” and matters described in this 10-KSB generally. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements contained in this filing will in fact occur. In addition to the information expressly required to be included in this filing, we will provide such further material information, if any, as may be necessary to make the required statements, in light of the circumstances under which they are made, not misleading.

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### **Item 7. Financial Statements.**

Incorporated by reference to pages F-1 to F-17 at the end of this report.

### **Item 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

In connection with the two most recent fiscal years or subsequent interim periods, there were no disagreements between Kirkland, Russ, Murphy & Tapp P.A. on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure.

### **Item 8A. Controls and Procedures.**

#### **Evaluation of Disclosure Controls and Procedures**

We maintain “disclosure controls and procedures,” as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the “Exchange Act”), that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. We conducted an evaluation (the “Evaluation”), under the supervision and with the participation of our Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), of the effectiveness of the design and operation of our disclosure controls and procedures (“Disclosure Controls”) as of the end of the period covered by this report pursuant to Rule 13a-15 of the Exchange Act. Based on this Evaluation, our CEO and CFO concluded that our Disclosure Controls were effective as of the end of the period covered by this report.

#### **Changes in Internal Controls**

We have also evaluated our internal controls for financial reporting, and there have been no significant changes in our internal controls or in other factors that could significantly affect those controls subsequent to the date of their last evaluation.

#### **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.

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### **CEO and CFO Certifications**

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

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

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

Our management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2007. 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, 2007, the Company's internal control over financial reporting was 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 8B. Other Information.**

None.

**PART III**

Certain information required by Part III is omitted from this Report in that we expect to file a definitive proxy statement with the Securities and Exchange Commission (the “Commission”) within 120 days after the end of our fiscal year pursuant to Regulation 14A, as promulgated by the Commission, for our 2007 annual meeting of shareholders (the “Proxy Statement”), and certain information included in the Proxy Statement will be incorporated herein by reference.

**Item 9. Directors, Executive Officers, Promoters and Control Persons and Corporate Governance; Compliance with Section 16(a) of the Exchange Act.**

The information required by this Item 9 is incorporated herein by reference to our Proxy Statement under the captions “Proposal I Election of Directors” and “Section 16(a) Beneficial Ownership Reporting Compliance”. We have adopted a Code of Business Conduct and Ethics (the “Code”) that applies to all of our Directors, officers and employees, including our principal executive officer and principal financial officer. The Code is posted on our website at [www.oragenics.com](http://www.oragenics.com). We intend to disclose any amendments to the Code by posting such amendments on our website. In addition, any waivers of the Code for Directors or executive officers of the Company will be disclosed in a report on Form 8-K.

**Item 10. Executive Compensation.**

The information required by this Item 10 with respect to management remuneration and transactions is incorporated herein by reference to our Proxy Statement under the heading “Executive Compensation.”

**Item 11. Security Ownership of Certain Beneficial Owners and Management and Related Stockholders Matters.**

The information required by this Item 11 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.”

**Item 12. Certain Relationships and Related Transactions and Directors Independence.**

The information required by this Item 12 with respect to transactions between us and certain related entities is incorporated herein by reference to our Proxy Statement under the heading “Certain Relationships and Related Transactions and Director Independence.”

**Item 13. Exhibits.**

Incorporated by reference to the Exhibit Index immediately following the signature page.

**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.”

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Oragenics, Inc.  
Financial Statements  
Years ended December 31, 2007 and 2006

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheet of Oragenics, Inc. as of December 31, 2007, and the related statements of operations, stockholders' equity, and cash flows for the years ended December 31, 2007 and 2006. 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. An audit also includes 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, 2007, and the results of its operations and its cash flows for the years ended December 31, 2007 and 2006 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 3, 2008  
Clearwater, Florida

/s/ Kirkland Russ Murphy & Tapp, PA  
Certified Public Accountants

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Oragenics, Inc.  
Balance Sheet  
December 31, 2007

<b>Assets</b>	
Current assets:	
Cash and cash equivalents	\$ 475,508
Prepaid expenses and other current assets	116,520
Total current assets	592,028
Property and equipment, net	559,349
Total assets	<u>\$ 1,151,377</u>
<b>Liabilities and stockholders' equity</b>	
Current liabilities:	
Accounts payable and accrued expenses	\$ 331,494
Total current liabilities	331,494
Stockholders' equity:	
Preferred stock, no par value; 20,000,000 shares authorized; none issued and outstanding	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 28,002,443 shares issued and outstanding	28,002
Additional paid in capital	14,762,674
Accumulated deficit	(13,970,793)
Total stockholders' equity	819,883
Total liabilities and stockholders' equity	<u>\$ 1,151,377</u>

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



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Oragenics, Inc.  
Statements of Operations

	Year ended December 31	
	2007	2006
Revenue	\$ 133,088	\$ 66,176
Operating expenses:		
Research and development	1,569,551	2,023,896
General and administration	902,655	1,004,099
Total operating expenses	2,472,206	3,027,995
Loss from operations	(2,339,118)	(2,961,819)
Other income (expense):		
Interest income	29,385	24,931
Interest expense	—	(855)
Gain (loss) on sale of property and equipment	(1,979)	2,024
Total other income, net	27,406	26,100
Loss before income taxes	(2,311,712)	(2,935,719)
Net loss	\$ (2,311,712)	\$ (2,935,719)
Basic and diluted net loss per share	\$ (0.09)	\$ (0.15)
Shares used to compute basic and diluted net loss per share	25,092,183	20,038,177

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

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Oragenics, Inc.

Statements of Changes in Stockholders' Equity  
Years ended December 31, 2007 and 2006

	<u>Common Stock</u>		<u>Additional Paid In Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>			
Balance at December 31, 2005	18,146,117	18,146	10,476,786	(8,723,362)	1,771,570
Exercise of common stock warrants	2,390,000	2,390	1,424,610	—	1,427,000
Issuance of common stock and warrants	1,683,640	1,684	572,354	—	574,038
Issuance of common stock for the acquisition of iviGene Corporation	185,186	185	199,815	—	200,000
Compensation expense relating to option issuances	—	—	241,385	—	241,385
Net loss	—	—	—	(2,935,719)	(2,935,719)
Balance 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, net of expenses	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)
Balance at December 31, 2007	<b><u>\$28,002,443</u></b>	<b><u>\$28,002</u></b>	<b><u>\$14,762,674</u></b>	<b><u>\$(13,970,793)</u></b>	<b><u>\$ 819,883</u></b>

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

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Statements of Cash Flows

	Year ended December 31	
	2007	2006
<b>Operating activities</b>		
Net loss	<b>\$(2,311,712)</b>	\$(2,935,719)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	273,230	280,901
Stock-based compensation expense	<b>161,471</b>	241,385
Patents acquired from iviGene Corp	—	200,000
(Gain) loss on sale of asset	<b>1,979</b>	(2,024)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	<b>(42,649)</b>	38,176
Accounts payable and accrued expenses	<b>49,421</b>	(86,257)
Deferred compensation	<b>(45,500)</b>	39,000
Net cash used in operating activities	<b>(1,913,760)</b>	(2,224,538)
<b>Investing activity</b>		
Purchases of property and equipment, net	<b>(12,906)</b>	(12,011)
Proceeds from sale of property and equipment	<b>3,046</b>	5,000
Net cash used in investing activity	<b>(9,860)</b>	(7,011)
<b>Financing activities</b>		
Net proceeds from issuance of common stock	<b>1,691,850</b>	2,001,038
Net cash provided by financing activities	<b>1,691,850</b>	2,001,038
Net decrease in cash and cash equivalents	<b>(231,770)</b>	(230,511)
Cash and cash equivalents at beginning of year	<b>707,278</b>	937,789
Cash and cash equivalents at end of year	<b>\$ 475,508</b>	\$ 707,278
<b>Supplemental disclosure of cash flow information</b>		
Non-Cash acquisition of iviGene Corporation	<b>\$ —</b>	200,000
Interest paid	<b>\$ —</b>	\$ 855

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

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Oragenics, Inc.

Notes to Financial Statements

December 31, 2007

**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 dedicated to developing 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 \$2,311,712 for the year ended December 31, 2007 and as of that date had an accumulated deficit of \$13,970,793. Cash used in operations for the year ended December 31, 2007 was \$1,913,760 and cash flow from operations was negative throughout 2007. The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes the working capital at December 31, 2007 will be insufficient to meet the business objectives as presently structured. 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. During 2006 and 2007, the Company conducted private placements to raise capital. 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 stockholders 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.

**Concentrations of Credit Risk**

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.

**Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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 and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

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Oragenics, Inc.

Notes to Financial Statements (continued)

**1. Organization and Significant Accounting Policies (continued)**

**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 Equivalents**

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

**Property and Equipment**

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

**Business Segments**

Pursuant to Statement of Financial Accounting Standards (SFAS) No. 131, *Disclosure About Segments of a Business Enterprise and Related Information*, 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**

In December 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure* (FAS 148). FAS 148 amends an earlier standard on accounting for stock-based compensation, *Accounting for Stock-Based Compensation* (FAS 123), to provide alternative methods of transition to the fair value based method of accounting for stock-based employee compensation which is required beginning January 1, 2006. In December 2004, FASB issued FASB Statement No. 123 (revised 2004), *Share-Based Payment* ("Statement 123(R)"), a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Statement 123(R), which we have adopted in the first quarter of 2006, is generally similar to Statement 123; however, it requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. The Company has elected to adopt the Modified Prospective Method. This method requires the Company to prospectively expense all new grants and unvested pre-adoption grants. The resulting stock-based compensation expense is recorded over the 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. Options and warrants issued to employees and non-employees that are subject to forfeiture are expensed on the vesting date.

**1. Organization and Significant Accounting Policies (continued)**

**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**

Grant revenues are recognized as the reimbursable expenses are incurred over the life of the related grant.

**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, 2007 and 2006.

**Research and Development Expenses**

Expenditures for research and development are expensed as incurred. The majority of the Company's activities are research and development related.

**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.

**Recent Issued Accounting Pronouncements**

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities - Including an Amendment of FASB Statement No. 115* ("SFAS 159"). SFAS 159 provides companies with an option to measure, at specified election dates, certain financial instruments and other items at fair value that are not currently measured at fair value. A company that adopts SFAS 159 will report unrealized gains and losses on items for which the fair value option has been elected in its financial results during each subsequent reporting date. SFAS 159 also establishes presentation and disclosure requirements designed to facilitate comparisons between entities that choose different measurement attributes for similar types of assets and liabilities. SFAS 159 is effective for fiscal years beginning after November 15, 2007. Oragenics' does not expect SFAS 159 to have a material impact on our results of operations or financial condition.

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Oragenics, Inc.

Notes to Financial Statements (continued)

**1. Organization and Significant Accounting Policies (continued)**

In June 2007, the FASB ratified the consensus reached by the Emerging Issues Task Force (“EITF”) in EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities* (“EITF 07-3”), which requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. EITF 07-3 is effective for fiscal years beginning after December 15, 2007. Oragenics’ does not expect EITF 07-3 to have a material impact on our results of operations or financial condition.

In December 2007, the SEC issued Staff Accounting Bulletin No. 110 (“SAB 110”). SAB 110 expresses the views of the staff regarding the use of a “simplified” method, as discussed in SAB No. 107, in developing an estimate of the expected term of “plain vanilla” share options in accordance with SFAS No. 123 (revised 2004). Oragenics’ does not expect SAB 110 to have a material impact on its results of operations or financial condition.

**2. Property and Equipment, net**

Property and equipment, net consists of the following as of December 31, 2007:

Furniture and fixtures	\$ 8,035
Laboratory equipment	894,247
Leasehold improvements	481,606
Office and computer equipment	45,092
	<u>1,428,980</u>
Accumulated depreciation and amortization	<u>(869,631)</u>
	<u>\$ 559,349</u>

Depreciation and amortization expense for 2007 and 2006 was \$273,230 and \$280,901, respectively.

**3. Related Party Transactions**

At December 31, 2007, \$52,500 was owed to our former President and CEO, Robert T. Zahradnik and to the CSO, Jeffrey D. Hillman and included in accounts payable and accrued expenses for consulting services in 2005. After Dr. Zahradnik’s resignation on December 31, 2007, the Company paid this deferred compensation of \$26,250 to him on January 15, 2008. No interest is being accrued on this outstanding debt.

In July 2005, the Company entered into a severance agreement with its former Chief Executive Officer (CEO) agreeing to continue payments of \$15,000 per month for one year post separation from employment with the Company. On July 1, 2007, the full severance pay was remunerated.

As of December 31, 2007, fees of \$34,000 to the Board of Directors and Audit Committee have been deferred. On September 7, 2006, the Board of Directors and the Compensation Committee approved stock option grants to non-employee directors in lieu of future cash fees for Board and Committee services.

As of December 31, 2007, Dr. Robert Zahradnik resigned as President and CEO and from the Board. The Board ratified a twelve month consulting agreement, commencing on January 1, 2008, whereby he will provide certain consulting and advisory services to the Company. His cash compensation is \$50,000 and 150,000 stock options that are to be granted based on the terms stated in the Company’s 2002 stock option plan. The options will be vest at various times within two years of the grant date.

Oragenics, Inc.

Notes to Financial Statements (continued)

**4. Business Loan Agreement**

None during the fiscal year 2007.

**5. Stockholders' Equity**

**Common Stock**

On June 24, 2003, the Company completed the filing of 2,400,000 units at \$1.25 per unit as an initial public offering (IPO) for gross proceeds of \$3,000,000. Each unit consisted of one share of the Company's common stock, one-half Series A Common Share Purchase Warrant and one-half Series B Common Share Purchase Warrant. One whole Series A warrant allowed the holder to purchase a share of the Company's stock at \$2.00 per share until December 24, 2003. All Series A warrants were exercised before the expiration date providing proceeds to the Company of \$2,400,000. One whole Series B warrant allowed the holder to purchase a share of the Company's stock at \$3.00 per share until March 24, 2004. A total of 995,400 Series B warrants were exercised on or before March 24, 2004 providing proceeds of \$2,986,200 and the remaining 204,600 Series B warrants expired unexercised on March 24, 2004. In addition to receiving a cash commission for each share sold, the underwriting agent for the IPO received 100,000 shares of common stock of the Company and warrants to purchase 500,000 shares of common stock of the Company at \$1.25 per share until June 24, 2005. All 500,000 underwriter warrants were exercised, of which 276,180 shares of common stock were issued in 2005 providing additional proceeds to the Company of \$345,225. The cost of the IPO, including the filing of a post effective amended registration statement in October 2004, was \$779,809 including the agent's commission.

On November 30, 2004, the Company completed a private placement of its stock, through a placement agent, selling 25 units at \$27,500 per unit totaling \$687,500. Each unit consisted of 10,000 shares of common stock and 5,000 warrants to purchase common stock at a price of \$3.50 per share until November 30, 2008. The total cost associated with this financing was approximately \$142,500 including the underwriter's commission.

On May 23, 2005, Oragenics entered into a financing arrangement whereby an investor has agreed to purchase from the Company up to \$9,000,000 of its common stock over a 30 month period. The arrangement provides that on each trading day, the Company has the right to sell to the investor \$15,000 of its common stock at a price based upon the market price of the common stock. The investor does not have the right or obligation to purchase shares of our common stock from us in the event that the price of our common stock is less than \$0.75. The Company incurred costs of approximately \$150,000 for legal, accounting, stock exchange, and Oragenics, Inc. regulatory fees in connection with this financing arrangement. During 2005, the Company sold 22,092 of its common stock to the investor pursuant to the arrangement for total proceeds of \$35,000. In December 2006, a post-effective amendment was filed with the SEC.

On December 14, 2005, the Company issued a total of 2,937,500 shares of its common stock and warrants to purchase 2,937,500 shares of our common stock in a private placement to accredited investors. The Company 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 are exercisable by the accredited investors at any time over a two-year period at an exercise price of \$0.60 per share. In connection with the termination of an investment advisor agreement, the Company issued warrants on similar terms as those issued in the private placement. The warrants represent the right to acquire 130,000 shares of common stock, of which 95,000 are at an exercise price of \$0.60 per share and 35,000 are at an exercise price of \$0.40 per share.

On March 6, 2006, the Company issued a total of 1,500,000 shares of our common stock and warrants to purchase 1,500,000 shares of our common stock in a private placement to accredited investors. The Company received gross



Oragenics, Inc.

Notes to Financial Statements (continued)

**5. Stockholders' Equity (continued)**

proceeds of \$600,000 in the private placement and incurred estimated costs of approximately \$75,000 resulting in net proceeds of approximately \$525,000. There was no underwriter or placement agent associated with this transaction. Each warrant is exercisable on or before February 8, 2008 to acquire one share of common stock at a price of \$0.60 per share.

On November 17, 2006 we acquired the outstanding stock of iviGene Corporation in exchange for 185,186 shares of our common stock to the holders of iviGene Corporation, which included one of our directors, who received 20,480 shares. Following the consummation of this transaction, iviGene Corporation will be dissolved and as a result, Oragenics will acquire all of iviGene's assets, including issued and pending patents to two broad based platform technologies.

On August 7, 2007, our Securities Purchase Agreement with accredited investors, including our new director, Dr. Ronald P. Evens, 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 AMEX requirements, Dr. Evens acquired his shares at \$0.44 per share, which was the closing share price on August 7, 2007. Each participating investor, including Dr. Evens, 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 become exercisable in February, 2008 and expire after one year from the date of issuance. The private placement offering and sale of the common stock and warrants was made in reliance upon the exemption from registration provided by Section 4(2) of the Securities Act of 1933 as a transaction by the issuer not involving a public offering. We intend to use the net proceeds of the private placement, including any proceeds from exercise of the warrants, for working capital and general corporate purposes. While management is encouraged by the aforementioned financing, the proceeds are insufficient, alone, to regain final compliance with AMEX listing requirements. We have until October 27, 2008 to regain AMEX compliance but there can be no assurance that we will be able to do so.

A summary of the status of the Company's outstanding and exercisable warrants as of December 31, 2007 is presented below:

<u>Shares Underlying Warrant Outstanding</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
4,600,000	\$0.58	8/8/2008
1,465,000	\$0.60	2/8/2008
35,000	\$1.59	8/16/2008
25,000	\$2.25	11/30/2008
52,500	\$2.75	11/30/2008

**Stock Compensation Plan**

The Company's 2002 Stock Option and Incentive Plan (the Plan) was adopted by the Board of Directors (the Board). The purpose 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, 2007, the Company had not awarded stock appreciation rights or restricted

## Oragenics, Inc.

## Notes to Financial Statements (continued)

**Stock Compensation Plan (continued)**

stock under the Plan. The Company has reserved an aggregate of 3,000,000 shares of common stock for grants under the Plan, of which 1,655,000 shares are available for future grants as of December 31, 2007 and 1,745,000 shares as of December 31, 2006. The exercise price of each option shall be determined by the Board and an option's maximum term is ten years.

In September 2002, the Company issued 195,000 options that were re-priced upon the change in the initial public offering price. As a result, these options were subjected to variable accounting treatment. In accordance with Financial Accounting Standards Board Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation* (FIN 44), stock options must be accounted for as variable under such circumstances. Variable accounting requires companies to re-measure compensation costs for the variable options until the options are exercised, cancelled, or forfeited without replacement. Compensation is dependent on fluctuations in the quoted stock prices for the Company's common stock. Such compensation costs will be recognized over a three-year vesting schedule until the options are fully vested, exercised, cancelled, or forfeited. During the years ended December 31, 2007 and 2006, the Company recognized a stock compensation expense of \$161,471 and \$241,385, respectively based on FAS 123 (R). A summary of the status of the Company's outstanding stock options as of December 31, 2007 and 2006 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 January 1, 2006	1,260,000	\$ 0.53 – 4.25	\$ 1.90
Forfeited	(535,000)	0.59 – 4.00	2.15
Granted	530,000	0.53 – 0.74	0.67
Outstanding at December 31, 2006	1,255,000	0.53 – 4.25	1.90
Forfeited	(155,000)	0.74 – 1.25	0.96
Granted	245,000	0.32 – 1.03	0.59
Outstanding at December 31, 2007	<u>1,345,000</u>	<u>0.32 – 4.25</u>	<u>\$ 1.25</u>
Exercisable at end of year	<u>1,005,001</u>	<u>\$ 0.53 – 1.25</u>	<u>\$ 1.12</u>

The range of exercise price is \$0.32 to \$4.25 per share. The weighted-average per option fair value of options granted during 2007 was \$0.59 and the weighted average remaining contractual life of those options is 8.3 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 2.38%; dividend yields of 0%; weighted-average volatility factors of the expected market price of the Company's common stock of 53.8%; and an expected life of the option of eight years.

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Oragenics, Inc.

Notes to Financial Statements (continued)

**6. 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. Beginning in 2004, 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 is 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.

In February 2004, the Company licensed from iviGene Corporation (iviGene), a company whose major shareholders also own a significant number of shares of the Company’s common stock, applications of two novel technologies referred to as IVIAT and CMAT. On November 17, 2006 we acquired the outstanding stock of iviGene Corporation in exchange for 185,186 shares of our common stock to the holders of iviGene Corporation, which included one of our directors, who received 20,480 shares. Following the consummation of this transaction, iviGene Corporation will be dissolved and as a result, Oragenics will acquire all of iviGene’s assets, including issued and pending patents to two broad based platform technologies. These technologies are capable of identifying gene and protein biomarkers for application to the improve diagnosis and treatment of a wide range of infectious diseases and cancers. Besides human diseases, other potential applications for these technologies include animal disease, industrial and marine biofilm formation and plant diseases.

**7. Retirement Plan**

In January 2004, the Company established a defined contribution retirement 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. During 2007 and 2006, employee contributions were limited to \$16,000 and \$15,000, respectively, except for individuals 50 years or older for which the contribution limitations were \$12,000 and \$20,000, respectively. Total matching contributions made by the Company in 2007 and 2006 were \$5,383 and \$6,409, respectively.

**8. Income Taxes**

At December 31, 2007, 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:

Deferred tax assets:	
Net operating loss carryforward	\$ 5,030,163
Compensation to Directors & Offices and consulting services	17,121
Total deferred tax assets	5,047,284
Less valuation allowance	(5,047,284)
Total net deferred taxes	\$ —

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Oragenics, Inc.

Notes to Financial Statements (continued)

**8. Income Taxes (continued)**

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, 2007 and 2006:

	Year ended December 31	
	2007	2006
Income tax benefit computed at statutory federal rate of 34%	\$(785,982)	\$ (998,144)
State income tax benefits, net of federal expense/benefit	(83,915)	(106,567)
Change in valuation allowance	814,662	1,042,086
Non-deductible expenses	61,144	91,198
Research and development credit	—	(40,792)
Other	(5,909)	12,219
Total	\$ —	\$ —

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based upon the levels of historical taxable income and projections of future taxable income over which the deferred tax assets are deductible, the Company believes that it is more likely than not that it will not be able to realize the benefits of some of these deductible differences. Accordingly, a valuation allowance of \$5,047,284 has been provided in the accompanying financial statements. The 2007 net change in valuation allowance related to deferred tax assets was an increase of \$561,835 primarily relating to net operating loss carryforwards.

At December 31, 2007, the Company has federal and state tax net operating loss carryforwards of approximately \$13,367,427. The federal and state tax loss carryforward will expire through 2021, unless previously utilized. The Company also has federal research and development tax credit carryforwards of approximately \$290,329. The federal tax credit carryforward will expire through 2021, unless previously utilized.

Pursuant to Internal Revenue Service Code Sections 382 and 383, use of the Company's net operating loss and credit carryforwards may be limited if a cumulative change in ownership of more than 50% occurs within a three-year period. However, the Company does not believe such limitations will have a material impact upon the utilization of these carryforwards.

In July 2006, the FASB issued Interpretation No. 48, which clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with FASB Statement No. 109 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 Interpretation 48, 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, Interpretation 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. Interpretation 48 is effective for fiscal years beginning after December 15, 2006.

The Company adopted Interpretation 48 on January 1, 2007, which did not have a material impact on the Company's consolidated financial statements. As a result of the implementation of Interpretation 48, the Company recognized a \$252,827 increase in the liability for unrecognized tax benefits that are related to research and development credits,

Oragenics, Inc.

Notes to Financial Statements (continued)

**8. Income Taxes (continued)**

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 period ended December 31, 2007, the Company incurred \$37,502 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 2003.

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

Balance as of January 1, 2007	\$252,827
Additions based on tax positions related to the current year	37,502
Additions for tax positions of prior years	—
Reductions for tax positions of prior years	—
Balance as of December 31, 2007	<u>\$290,329</u>

Included in the balance at December 31, 2007, are \$290,329 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 year 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.

**9. Commitments and Contingencies**

The Company's facility is being leased from a real estate developer for a term of five years subject to renewal provisions that include 3% increases in lease payments. This operating lease agreement required the Company to pay a deposit of \$6,400 and provides for monthly lease payments of \$6,793, exclusive of utilities, insurance, sales taxes and real estate taxes. Total rent expense under this lease was \$89,524 and \$84,131 for the years ended December 31, 2007 and 2006, respectively. In addition, the Company has entered into operating leases for office equipment.

Future annual minimum payments under all non-cancelable operating leases are approximately as follows:

Year ended:	
2008	91,400
2009	91,600
Thereafter	—
	<u>\$183,000</u>

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Oragenics, Inc.

Notes to Financial Statements (continued)

**10. 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.

	2007			
	First	Second	Third	Fourth
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)

  

	2006			
	First	Second	Third	Fourth
Revenue	\$ —	\$ —	\$ 66,176	\$ —
Total operating expenses	\$ 865,131	\$ 801,831	634,132	711,330
Net loss	(856,389)	(796,713)	(559,160)	(707,887)
Loss per share:				
Basic and Diluted	\$ (0.05)	\$ (0.04)	\$ (0.03)	\$ (0.03)

**11. Subsequent Event**

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 expired 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. Following the amendment, a total of 1,150,000 shares were exercised which provided \$506,000 in proceeds.

On January 29, 2008 the Company approved an amendment to the outstanding warrants that were originally issue 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 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. A total of 5,851,364 shares were exercised that provided \$1,996,000 in proceeds.

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**SIGNATURES**

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

Dated: March 4, 2008

ORAGENICS, INC.

(Registrant)

By: /s/ Stanley B. Stein

Stanley B. Stein, President, Chief Executive Officer, Interim

By: /s/ Dorothy J. Delfino

Dorothy J. Delfino, Chief Financial Officer  
Secretary and Treasurer  
(Principal Financial and Principal Accounting Officer)

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Stanley B. Stein</u> Stanley B. Stein	President, Chief Executive Officer, Interim and a Member of the Board of Directors	March 4, 2008
<u>/s/ David J. Gury</u> David J. Gury	Chairman of the Board of Directors	March 4, 2008
<u>/s/ Jeffrey D. Hillman</u> Jeffrey D. Hillman	Chief Scientific Officer and Member of the Board of Directors	March 4, 2008
<u>/s/ Richard Welch</u> Richard Welch	Member of the Board of Directors	March 4, 2008
<u>/s/ Derek Hennecke</u> Derek Hennecke	Member of the Board of Directors	March 4, 2008
<u>/s/ Ronald P. Evens</u> Ronald P. Evens	Member of the Board of Directors	March 4, 2008

[Table of Contents](#)**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	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	Form of November 2004 private placement warrant	10-KSB	000-50614	4.3	03/14/05	
4.3	Form of November 2004 private placement Subscription Agreement (including registration rights)	10-KSB	000-50614	4.4	03/14/05	
4.4	Warrant Amendment Agreement (including form of replacement warrant) between the Company and The Arbitrage Fund, Mark Campbell, The Harold T. Grisham Living Trust and Westminster Securities dated May 31, 2005 to November 2004 warrant	SB-2	333-125660	4.5	06/09/05	
4.5	Common Stock Purchase Agreement with Fusion Capital Fund II, LLC, dated as of May 23, 2005	8-K	000-50614	4.5	05/23/05	
4.6	Registration Rights Agreement with Fusion Capital Fund II, LLC, dated as of May 23, 2005	8-K	000-50614	4.6	05/23/05	
4.7	Securities Purchase Agreement, dated November 20, 2005, among the purchasers and Oragenics, Inc.	S-3	333-131015	4.2	01/13/06	
4.8	Registration Rights Agreement dated November 20, 2005, among the investors and Oragenics, Inc.	S-3	333-131015	4.3	01/13/06	
4.9	Specimen private placement December 2005 warrant certificate	S-3	333-131015	4.4	01/13/06	
4.10	Securities Purchase Agreement dated January 6, 2006	8-K	001-32188	4.1	3/10/06	
4.11	Registration Rights Agreement dated January 6, 2006	8-K	001-32188	4.2	3/10/06	
4.12	Specimen Warrant Certificate dated march 7, 2006	8-K	001-32188	4.3	3/10/06	
4.13	First Amendment to March Warrant dated January 11, 2008	8-K	001-32188	4.2	1/11/08	
4.14	Stock Purchase Agreement by and among Oragenics, Inc. and iviGene Corporation and the stock holders of iviGene Corporation and amendment thereto (including registration rights)	SB-2/A	333-125660	4.10	12/22/06	
4.15	Securities Purchase Agreement and Form of Warrant Agreement dated August 7, 2007 (the "August Warrant")	10-QSB	001-32188	4.1	8/13/07	
4.16	Registration Rights Agreement dated August 7, 2007 among the purchasers and Oragenics, Inc.	10-QSB	001-32188	4.2	8/13/07	
4.17	First Amendment to the August Warrant dated January 28, 2008	8-K	001-32188	4.2	1/17/08	



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<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Form</u>	<u>File No</u>	<u>Exhibit</u>	<u>Filing Date</u>	<u>Filed Herewith</u>
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	
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	10-QSB/A	001-32188	10.1	9/29/06	
10.11	Proprietary Information and Invention Agreement between ourselves, Robert Zahradnik, Howard Kuramitsu, and Steven Projan	SB-2	333-100568	99.23	10/16/02	
10.12*	Proprietary Information and Invention Agreement between the Company and Jeffrey D. Hillman	SB-2	333-100568	99.4	10/16/02	
10.13	Employment Agreement of Jeffrey D. Hillman	10-KSB	000-50614	10.43	3/17/04	
10.14	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	
10.15	Termination Agreement between Westrock Advisors, Inc. and Oragenics, Inc.	S-3	333-131015	10.1	1/13/06	
10.16	Agreement of Separation and Release between the Company and Mento S. Soponis	10-QSB	001-32188	10.1	08/11/05	
10.17	Employment Agreement of Robert Zahradnik	10-QSB	001-32188	10.2	08/11/05	

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<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Form</u>	<u>File No</u>	<u>Exhibit</u>	<u>Filing Date</u>	<u>Filed Herewith</u>
23.1	Consent of Kirkland Russ Murphy & Tapp, PA					X
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

\* management contract

+ compensatory plan or arrangement

**Consent of Independent Registered Public Accounting Firm**

We consent to the inclusion in this Annual Report (Form 10-KSB) of Oragenics, Inc. of our report dated March 3, 2008, with respect to the 2007 financial statements of Oragenics, Inc.

We consent to the incorporation by reference in the following Registration Statements:

- (i) Registration Statement (Form S-8 No. 333-110646) of Oragenics, Inc. pertaining to the Oragenics, Inc. 2002 Stock Incentive Plan;
- (ii) Post Effective Amendment No. 2 to the Registration Statement on Form S-3 to Form SB-2 (No. 333-125660) and related Prospectus of Oragenics, Inc. for the registration of 4,109,689 shares of its common stock issuable upon by Fusion Capital; and
- (iii) Registration Statements (Form S-3 Nos. 333-131015, 333-132516 and 333-140097) and related Prospectus of Oragenics, Inc. for the registration of 7,205,000, 3,000,000 and 185,186 shares of its common stock, respectively.

of our report dated March 3, 2008, with respect to the financial statements of Oragenics, Inc. included in this Annual Report (Form 10-KSB) of Oragenics, Inc.

/s/ Kirkland, Russ, Murphy & Tapp, P.A.

Kirkland, Russ, Murphy & Tapp P.A.

Certified Public Accountants

Clearwater, Florida

March 3, 2008

## CERTIFICATION

I, Stanley B. Stein, certify that:

1. I have reviewed this annual report on Form 10-KSB 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)) 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. 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
  - c. 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 4, 2008

/s/ Stanley B. Stein

Stanley B. Stein  
President (Chief Executive Officer), Interim

## CERTIFICATION

I, Dorothy J. Delfino, certify that:

1. I have reviewed this annual report on Form 10-KSB 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)) 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. 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
  - c. 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 4, 2008

/s/ Dorothy J. Delfino

Dorothy J. Delfino  
Chief Financial Officer

**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 Orogenics, Inc. (the "Company") on Form 10-KSB/A for the period ended December 31, 2007 as filed with the Securities and Exchange Commission on the date here of (the "Report"), I, Stanley B. Stein, Interim 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 March 4, 2008

/s/ Stanley B. Stein  
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Stanley B. Stein  
Chief Executive Officer, Interim

**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-KSB for the period ended December 31, 2007 as filed with the Securities and Exchange Commission on the date here of (the "Report"), I, Dorothy J. Delfino, 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 March 4, 2008

/s/ Dorothy J. Delfino  
Dorothy J. Delfino  
Chief Financial Officer