

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

FORM 10-KSB/A  
(Amendment No. 1)

Annual report under Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the fiscal year ended December 31, 2005

Transition report under Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 000-50614

**ORAGENICS, INC.**

\_\_\_\_\_  
(Name of small business issuer in its charter)

**Florida**

\_\_\_\_\_  
(State or Other Jurisdiction of Incorporation or Organization)

**59-3410522**

\_\_\_\_\_  
(IRS Employer Identification No.)

**13700 Progress Blvd., Alachua, Florida**

\_\_\_\_\_  
(Address of Principal Executive Offices)

**32615**

\_\_\_\_\_  
(Zip Code)

**(386) 418-4018**

\_\_\_\_\_  
(Issuer's Telephone Number, Including Area Code)

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

Securities registered pursuant to Section 12(g) of the Act: Common stock, par value \$.001 per share

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

The registrant had no revenues for the fiscal year ended December 31, 2005.

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of March 6, 2006 was approximately \$5,465,756 based upon a last sales price of \$0.48 as reported by the American Stock Exchange.

As of March 6, 2006 there were 19,646,117 shares of the registrant's Common Stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE:**

Portions of the Registrant's Definitive Proxy Statement for its 2006 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 X

## EXPLANATORY NOTE

This Amendment No. 1 to the Registrant's Form 10-KSB Annual Report filed with the Securities and Exchange Commission ("SEC") on March 8, 2006 (the "Original Filing") is being filed solely for the purpose of correcting two errors in the audit report of Kirkland Russ Murphy & Tapp, PA, our independent registered public accounting firm in part II, Item 7, Financial Statements. Specifically, the date of the report of Kirkland Russ Murphy & Tapp, PA has been changed to read "February 15, 2006, except for Note 11 as to which the date is March 6, 2006" and the firm's location is changed to read "Clearwater, FL." In addition, pursuant to rule 12b-25 of the Securities and Exchange Act of 1934, the Exhibits referenced in Item 13 are also amended to reflect the inclusion of updated certificates of certain officers and updated consents from Kirkland Russ Murphy & Tapp, PA and Ernst & Young LLP. Except as described, no other changes have been made to the Original Filing. This Amendment continues to speak as of the date of the Original Filing, and we have not updated the disclosures contained herein to reflect any events that occurred at a date subsequent to the filing of the Original Filing.

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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 at the University of Florida and other academic centers, as well as discovered internally. Our strategy is to in-license or internally discover and to develop products through human proof-of-concept studies (Phase II clinical trials of the U.S. Food and Drug Administration's ("FDA") regulatory process) prior to partnering with major pharmaceutical, biotechnology or healthcare product firms for advanced clinical development and commercialization. Since 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 which have expired, however, we have not generated revenues from sales of products.

We hope to be in a position to continue to develop several products, each of which addresses potentially large market opportunities.

**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, *Streptococcus 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. Replacement therapy permanently replaces resident acid producing *Streptococcus mutans* with a patented genetically engineered strain of *Streptococcus mutans* that does not produce lactic acid. Applied topically to tooth surfaces with a swab, the therapy requires 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 III clinical trials. To facilitate further patient recruitment in our Phase I clinical trial, we opened an additional clinical site in June 2005, however, we have 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 concluded 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 is expected to be filed with the FDA in March 2006 and we anticipate instituting a second Phase I clinical study by the end of the second quarter of 2006. We remain committed to complete the human safety study of replacement therapy to the satisfaction of the FDA and we expect the cost in 2006 will be approximately \$350,000.

**Mutacin 1140** is a highly potent bactericidal peptide that is produced by our strain of *Streptococcus mutans*. Our proprietary mutacin was discovered by our researchers during the course of developing replacement therapy and is a novel antibiotic that has broad-spectrum antimicrobial activity against essentially all Gram-positive bacteria including vancomycin-resistant *Staphylococcus aureus*. The antibiotic currently is in preclinical stages of development. During the second quarter of 2005, we completed development of a proprietary manufacturing process for mutacin 1140, which overcame a previous hurdle to that molecule's development. We are now able to manufacture in sufficient quantities to allow us to conduct preclinical studies needed to enable the filing of an Investigational New Drug (IND) application. If we are able to secure adequate funding, we plan to continue to perform in vitro antimicrobial susceptibility and toxicity testing during the first half of 2006 before performing more detailed animal safety and efficacy studies using mutacin 1140. For example, in March and April 2006 we plan to conduct two preclinical studies with MU 1140™ (which is mutacin 1140), utilizing independent testing labs, that will provide information on Tier 2 spectrum of activity against clinically important Gram-positive bacteria and the effectiveness in a drug resistant *Staphylococcus aureus* infected animal model system. Upon adequate funding and successful completion of this testing and the animal studies we expect to be positioned to file an IND in the fourth quarter of 2006.

**Probiotics** are live microorganisms that confer health benefits to the host when administered in adequate amounts; the use of yogurt containing live *Lactobacillus* cultures is an example of a probiotic application. We have identified three natural strains of bacteria that provide significant protection against the causative organisms of periodontal disease and dental caries. 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 in these markets by late 2006. We are continuing our efforts to seek partners in Europe and Asia for market opportunities for our oral probiotic technology. European and Asian companies have signaled their intent to establish a licensing agreement with us, while another potential partner is completing a laboratory evaluation of the product before moving forward with possible licensing discussions. We expect to initiate a human trial within the next two months to support product claims for Probiora 3™. While there can be no assurances, this study should be completed by early in the third quarter of 2006. If successfully developed, our oral rinse product will be one of the first probiotics to be marketed for the maintenance of oral health.

**IVIAT and CMAT** are technologies we licensed from iviGene Corporation. Two of our directors own an aggregate 19.1% interest in iviGene Corporation. These technologies enable the simple, fast identification of novel and potentially important gene targets associated with the natural onset and progression of infections, cancers and other diseases in humans and other living organisms, including plants. These licensed technologies offer the potential to generate and develop a number of product candidates for future out-licensing to corporate partners, particularly in the area of cancer and tuberculosis, as well as agricultural and other non-human uses.

We were founded in 1996, became operational in 1999 and currently employ 10 full-time employees. Our registered office is located at 532 SW 117<sup>th</sup> Street, Gainesville, FL 32607, and our headquarters are located at 13700 Progress Boulevard, Alachua, Florida 32615.

### **Business Objectives and Milestones**

The specific goal of our business is to successfully develop, clinically test and obtain FDA approval for sales of products based on our licensed, patented technologies. Our strategy is to develop novel technologies through human proof-of-concept studies (Phase II clinical trials) prior to partnering with major pharmaceutical, biotechnology or health care product firms for advanced clinical development and commercialization. Upon successful completion of proof-of-concept studies, we intend to consider sublicensing our licensed, patented technologies to 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:

#### **Replacement Therapy**

1. Initiate second Phase I safety trial.

#### **Mutacin 1140**

1. Complete preclinical studies, including animal toxicity and efficacy, required for an investigational new drug application submission.
2. Submit an investigational new drug application to the FDA.

#### **Probiotic Technology**

1. Develop appropriate manufacturing and packaging systems.
2. Complete one human study.

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 period for the development of our technologies could change depending on the progress of our ability to negotiate a partnering arrangement, as well as our efforts to raise additional capital.

## **Our Technologies**

### **Replacement Therapy**

Dental caries (tooth decay) 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 infectious disease, affecting approximately 5 billion people. Much of the tooth decay in low-income countries remains untreated until the teeth are extracted.

Tooth decay is characterized by the dissolution of enamel and dentin which eventually results in the destruction of the entire tooth. The immediate cause of tooth decay is organic acid produced by microorganisms on the tooth surface. Studies suggest that of the 400 to 500 microbial species in the mouth, *Streptococcus mutans*, a common bacterium found in virtually all humans, is the principal causative agent in the development of tooth decay. Residing within dental plaque, *Streptococcus 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 employs a genetically modified strain of *Streptococcus mutans* that does not produce lactic acid. When applied to the teeth, this non acid-producing organism displaces and permanently replaces the indigenous acid-producing strains of *Streptococcus mutans*, thereby potentially providing lifelong protection against most forms of tooth decay.

Replacement therapy is suitable for use by the general population. The ideal application would be to treat infants at the onset of tooth eruption when initial bacterial colonization of the tooth surfaces is occurring. Replacement therapy requires only a single 5-minute application. Applied topically to the teeth with a swab, the therapy can be administered by dentists to patients during routine office visits.

We submitted an IND for replacement therapy to the FDA in 1998 seeking permission to begin Phase I clinical trials. In March 2003, we submitted a new IND. In November 2004, the FDA approved our clinical design and protocol for the Phase I clinical trial. In March 2005, we initiated enrollment in the clinical trial. We are in the process of seeking permission to modify the design and protocol of our Phase I clinical trial with the FDA due to patient enrollment difficulties discussed below under regulatory status.

#### ***Technical Background***

Replacement therapy represents a novel approach to preventing bacterial infections by capitalizing on interactions between different 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 a potential pathogen. In the case of dental caries, beneficial bacteria are implanted in the mouth of the host to prevent colonization of the harmful bacteria that cause tooth decay.

Our replacement therapy involves replacing the naturally occurring, acid-producing strains of *Streptococcus mutans* with a genetically engineered strain of *Streptococcus mutans* that does not produce lactic acid. Our researchers discovered 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 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 mutacin 1140, enables the bacteria to persistently and preemptively colonize the oral cavity, displace pre-existing strains and gain dominance in its ecosystem, dental plaque.

Using clinical isolates of 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. So as 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 application for our replacement therapy to the U.S. Food and Drug Administration in 1998 seeking permission to begin clinical trials. Subsequent to review by the Office of Vaccines Research and Review Division of Vaccines and Related Products Application at the Center for Biologics Evaluation and Research (CBER), the FDA placed the application on clinical hold pending 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; humans do not produce it; and it can be easily administered via a mouth rinse. With d-alanine nutrient supplementation, the organism lives; without nutrient supplementation, the organism cannot survive. Therefore, the organism can be completely eradicated from human subjects by withdrawing d-alanine nutrient supplementation.

In the initial studies to assess product safety (Phase I clinical trials) that began in March 2005, the genetically altered strain of *Streptococcus mutans* requiring d-alanine supplementation was 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.

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 and would 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. The study required four days of pretreatment with an antibiotic (chlorhexidine) to kill resident *S. mutans* in each participant's mouth. Male study subjects were to receive Replacement Therapy. The non-treated member of each couple was to be tested repeatedly to see if there was any horizontal transmission of the Replacement Therapy organism from one person to another. The investigators were to determine the genetic stability of the Replacement Therapy organism over time. Seven days after treatment, the subjects were to undergo an eradication phase of the study for one month, using the same antibiotic and the withholding of a D-alanine amino acid supplement that the Replacement Therapy organism requires for its survival. Finally, the protocol required investigators to subsequently follow each study participant for three months to ensure that the eradication was effective.

On December 2, 2005, due to the enrollment 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 have concluded the initial study and expect to submit additional proposed changes in the trial to the FDA in March 2006. We anticipate instituting a second Phase I clinical study by the third quarter of 2006. We believe these changes, if approved in a timely manner by the FDA, will allow the Company to complete the enrollment of patients and thereby complete the study by the end of 2006.

### ***Preclinical Studies***

From 1976 to 2002, our researchers and others have conducted several 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 the most recent animal study, our patented effector strain (BCS3-L1) and the wild-type strain were both grown in culture in the presence of sugar. The wild-type strain produced mostly lactic acid from the metabolism of sugar; it also produced small amounts of other acids as well as the non-acidic compounds, ethanol and acetoin. By contrast, our genetically modified strain produced mostly the non-acidic compounds, ethanol and acetoin, from the metabolism of sugar. No lactic acid was detectable. Two identical groups of conventional rats were then infected with either the wild-type strain or the genetically modified strain. A third identical group was not infected and served as the control group.

In both preemptive colonization and aggressive displacement rat model studies, the genetically engineered effector strain performed well and was able to occupy the niche normally occupied by wild-type *Streptococcus mutans*. The mutacin 1140 produced by the effector strain appeared to provide a selective advantage in colonization suitable for use in replacement therapy for dental caries.

A six-month study was also conducted to evaluate possible toxic effects of exposure to the genetically modified effector strain. No adverse gross or histological side effects were observed in conventional rats. Sufficient amounts of mutacin 1140 have not yet been purified to be able to directly test its toxicity but it belongs to the same class of antibiotics as nisin, which has very low toxicity and is used as a food preservative worldwide.

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 strains of *Streptococcus mutans*;
- Is genetically stable in the laboratory and in the animal test subjects;
- Shows no toxicity in acute and chronic tests; and
- Does not disrupt the normal flora of the mouth.

### ***Intellectual Property***

We have exclusively licensed the intellectual property for our replacement therapy from the University of Florida Research Foundation, Inc. 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. The University of Florida Research Foundation, Inc. has reserved for itself and the University of Florida the right to use and sell such products and services for research purposes only. Our license also provides the University of Florida Research Foundation, Inc. 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 University of Florida Research Foundation, Inc. under which we issued 599,940 shares of our common stock as partial consideration for the license. We are obligated to pay 5% of the selling price of any products developed from the licensed technology to the University of Florida Research Foundation, Inc. and, if we sublicense the license, we are obligated to pay 20% of all amounts received from the sublicensee. On December 31, 2005 and each year thereafter we are obligated to make a minimum royalty payment of \$50,000 for replacement therapy and \$50,000 for mutacin 1140, for an aggregate of \$100,000 which is required to be paid in equal quarterly installments of \$25,000. We spent in excess of \$1,000,000 in each of 2005 and 2004 which were the minimum amounts required under our license in order to maintain it. In each future calendar year and in addition to the royalty payment obligations, we are obligated to spend, or cause to be spent, an aggregate of \$1,000,000 on the research, development and regulatory prosecution of our replacement therapy and mutacin 1140 technologies combined, until a product which is covered wholly or partially by the claims of the patent, or is manufactured using a process which is covered wholly or partially by the claims of the patent, is sold commercially. If we fail to make these minimum expenditures, the University of Florida Research Foundation, Inc. may terminate our license.



We must also pay all patent costs and expenses incurred by the University of Florida Research Foundation, Inc. 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. During 2004 and 2005, we paid the university an additional \$83,000 as reimbursement for patent prosecutions. We have agreed to indemnify and hold the University of Florida Research Foundation, Inc. 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 in the amount of \$2,000,000 that expires in August, 2006. There is no assurance that we can obtain continued coverage on reasonable terms.

We received notification from B.C. International Corporation on July 29, 2002 that a gene utilized in its licensed, patented strain of *Streptococcus mutans* infringes a patent which it holds under a license. B.C. International Corporation's notification did not state that they intended to pursue legal remedies. We do not believe that the gene in question infringes that patent and we sent them correspondence setting out our position. We have received no further communication from B.C. International Corporation.

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

The manufacturing methods for producing our genetically engineered strain of *Streptococcus mutans* are standard fermentation methods. These methods involve culturing bacteria in large vessels and harvesting them when mature by centrifuge 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, by 2005 consumers will drink 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. Teeth lose density with age and become more susceptible to decay. 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 *Streptococcus mutans*. We know that certain companies and several academic and research institutions are developing and testing caries vaccines aimed at eradicating *Streptococcus mutans*. An alternative approach involves topical application of adhesion-blocking synthetic peptides that prevent *Streptococcus mutans* from attaching to the tooth surface. Products that result in the elimination of *Streptococcus mutans* from the natural ecosystem would require major studies to determine whether such eradication of a naturally occurring bacteria might not create serious, unintended consequences. The problem with eradicating *Streptococcus mutans* is that it disrupts the natural ecosystem leaving a void for another pathogen potentially more harmful than *Streptococcus 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 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.

## **Mutacin 1140**

Most clinical isolates of *Streptococcus mutans* secrete peptides, called mutacins, which exhibit antimicrobial activity against closely related streptococcal species and other Gram-positive bacteria. Research suggests that these mutacins play a key role in enabling *Streptococcus mutans* to effectively colonize the oral cavity.

Two types of mutacins have been characterized at the molecular level: lantibiotics and non-lantibiotics. Scientists have identified approximately 20 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***

Mutacin 1140 was discovered by our researchers in the course of their research on our core replacement therapy technology; it is the mutacin produced by our genetically engineered effector strain of *Streptococcus mutans*. Mutacin 1140 is a lantibiotic, a class of lanthionine-containing antibiotic, which we believe has the potential to treat a wide variety of infectious diseases. Extensive in vitro studies we have conducted demonstrate its effectiveness against all tested Gram-positive bacteria, including such commercially relevant pathogens as *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Enterococcus faecalis* and *Listeria monocytogenes*. To date, our research has not identified any pathogen resistance to mutacin 1140.

### ***Preclinical Studies***

Our researchers and others have conducted laboratory studies on mutacin 1140 to determine its efficacy as an antibacterial agent. To test mutacin 1140's ability to kill bacteria, standard microbiological testing methods were employed. Mutacin 1140 was purified and incorporated into growth medium at different concentrations. The medium was then inoculated with the bacterium under study, and its ability to grow in the presence of mutacin 1140 was observed. The minimal inhibitory concentration (MIC), which is defined as the lowest concentration of mutacin 1140 observed to inhibit growth of the test bacterium, was recorded.

We believe the results of our laboratory studies demonstrate that mutacin 1140 is effective at killing a broad spectrum of bacteria, including the streptococci that cause pharyngitis ("strep throat"), 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* infections, both of which are rapidly growing problems within the medical community. Mutacin 1140 was found to kill all Gram-positive bacteria tested at concentrations comparable to many therapeutically effective antibiotics. A particularly interesting feature of mutacin 1140 is that none of the sensitive species of bacteria tested was able to acquire genetically stable resistance to purified mutacin 1140.

During the next two months, we plan to conduct two preclinical studies with MU 1140™, utilizing independent testing labs, that will provide information on Tier 2 spectrum of activity against clinically important Gram-positive bacteria and the effectiveness in a drug resistant *Staphylococcus aureus* infected animal model system.

### ***Regulatory Status***

Currently, mutacin 1140 is in the early stages of preclinical development and we have not yet filed an Investigational New Drug application with the FDA, however, such filing is expected after successful completion of animal studies that are currently expected to begin in 2006.

### ***Intellectual Property***

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

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

Upon successful completion of animal studies, we will file an IND application for mutacin 1140 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 for further clinical development and commercialization, including establishing large-scale manufacturing and production capabilities.

### ***Market Opportunity***

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. Vancomycin, introduced in 1956, serves as the last line of defense against certain life-threatening infections. Unfortunately, certain bacteria have developed strains which resist even vancomycin.

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

### ***Competition***

Mutacin 1140 competes directly with antibiotic drugs such as vancomycin. Given the growing resistance of target pathogens to many antibiotics, even vancomycin, we believe that there is ample room in the marketplace for new antibiotics. We are aware of a mutacin peptide similar to mutacin 1140 patented by the University of Laval. Successful development of that technology would constitute major competition for mutacin 1140.

Many of our competitors are taking approaches to drug development differing from our approach. These approaches include traditional screening of natural products, genomics to identify new targets and combinatorial chemistry to generate new chemical structures. Competition in the pharmaceutical industry is based on drug safety, efficacy, ease of use, patient compliance, price, marketing and distribution. Commercial success of mutacin 1140 technology will depend on our ability and the ability of our sublicensees to compete effectively in all of these areas. There can be no assurance that competitors will not succeed in developing products that are more effective than mutacin 1140 or would render mutacin 1140 obsolete and non-competitive.

Any products based on the mutacin 1140 technology will compete against a large number of prescription antibiotics currently on the market, and against new antibiotic products that will enter the market over the next several years. Producers of antibiotic products include many large, international pharmaceutical companies, all of which have much greater financial and technical resources than us. We intend to compete in the market for antibiotic products by obtaining a strategic partner with an established sales force calling on doctors and hospitals. There can be no assurance that we will be able to obtain any such partner. If not, we will be obliged to develop our own channels of distribution for products based on the mutacin 1140 technology. There can be no assurance that we will be able to do so.

## **Probiotics**

Probiotics are live microorganisms that confer a health benefit to their host when administered in adequate amounts. In probiotic therapy, beneficial microorganisms are colonized in areas normally colonized by pathogens. By being better adapted to their ecosystem than the pathogens, these beneficial bacteria crowd out harmful bacteria and inhibit colonization and growth of the disease-causing pathogens. Examples of common probiotic applications are the use of yogurt containing live cultures to improve digestion, immune system response, and vaginal and urinary tract health.

The oral cavity provides an ecological niche for 400 -500 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. Our oral rinse probiotics' technology employs three natural strains of beneficial bacteria which promote oral health and inhibit the growth of harmful bacteria that cause periodontal disease and tooth decay.

### ***Technical Background***

Through our research, we have developed a probiotic product containing three natural strains of beneficial bacteria that promote oral health. The three bacterial strains are *Streptococcus oralis* and *Streptococcus uberis* for the maintenance of periodontal health and *Streptococcus rattus* for the maintenance of dental health.

*Streptococcus oralis* and *Streptococcus uberis* are among several hundred bacterial species of bacteria 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. These bacteria have demonstrated an ability to inhibit bacteria implicated in periodontal disease in both laboratory and animal studies. Human studies have correlated presence of these bacteria with the absence of periodontal pathogens. Probiotics containing these bacteria applied frequently can provide significant protection against causative organisms of periodontal disease.

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. 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 protection against tooth decay.

### ***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 bacteria that are causative agents of periodontal disease and dental caries.

*Periodontal disease.* 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 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 levels of the pathogenic bacteria are usually low. In diseased periodontal sites, the opposite situation prevails; *Streptococcus oralis* and *Streptococcus uberis* are usually undetectable. When these bacteria are absent from sites in the periodontium, the sites are much more prone to disease.

*Dental caries.* 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 and thus unable to cause tooth decay. Because *Streptococcus rattus* is very closely related to *Streptococcus mutans*, *Streptococcus rattus* reduces the number of *Streptococcus mutans* by competing for nutrients, attachment sites, and other important colonization factors. As animal studies have revealed, daily treatment with this beneficial strain can promote dental health by significantly reducing the numbers of dental caries-causing *Streptococcus mutans*.

We are currently performing studies to determine an appropriate and stable delivery system. We expect to initiate a human trial within the next two months to support product claims for Probiora 3™. While there can be no assurances, this study should be completed by early in the third quarter of 2006.

#### ***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 any drug claims. In the European Union regulatory approval is not required for commercialization of the 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 centrifuge or filtration. These methods are relatively commonplace and readily available within the pharmaceutical industry. We intend to seek one or more strategic partners for the manufacturing, marketing and distribution of our oral probiotic technology in Asia and Europe. European and Asian companies have signaled their intent to establish a licensing agreement with us, while another potential partner is completing a laboratory evaluation of the product before moving forward with possible licensing discussions. Product launch in select markets is currently expected to occur in 2007.

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

Probiotics are relatively common in Japan and are being adopted with increasing frequency in Europe. The probiotics market in the U.S. is still emerging and we expect the U.S. market will develop slowly. 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 not aware of any product on the market today that is targeted to maintain periodontal health.

## **IVIAT and CMAT**

In March 2004, we licensed from iviGene Corporation, applications of a novel technology that enables the simple, fast identification of novel and potentially important gene targets associated with the natural onset and progression of cancers and other diseases in humans and other living organisms, including plants. This licensed technology will offer us the potential to generate and develop a number of product candidates for future out-licensing to corporate partners, particularly in the area of cancer. Two of our directors own an aggregate 19.1% interest in iviGene Corporation.

To support the research for this technology 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 grant supported initial research to help us identify genes of *Mycobacterium tuberculosis* that are specifically induced during human infections with that pathogen. This licensed technology is in its early stages and will require further development which will require additional capital.

### ***Technical Background***

This 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 easily identify *in vivo* induced genes in human infections without the use of animal models, facilitating the discovery of new targets for the development of vaccines, antimicrobials and diagnostics. Dr. Hillman and his collaborators have further developed methods based on this approach to create 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 disease.

### ***Intellectual Property***

Our license provides us with exclusive worldwide rights to this broad platform technology in the areas of cancer and tuberculosis, as well as agricultural and other non-human uses. In return, we will pay royalties on revenues we are able to generate from any products developed using the technology, including royalties on sublicense fees, milestone payments and future product sales. Under the terms of our license with iviGene we are not obligated to make any payments to iviGene until we have achieved certain milestone or royalty payments. We are required to pay all patent-related expenses and commit two full-time staff or spend at least \$200,000 toward product development annually to maintain our license. In 2005 we did not meet the requirements of committing two full-time staff or spending at least \$200,000, however, we obtained a waiver of these provisions from iviGene Corporation, thus maintaining our license arrangement with them. We have applied for SBIR grant funding from the National Institutes of Health and with these funds expect to be able to meet the requirements of the license agreement in 2006.

## **Federal Food and Drug Administration (FDA) Regulation**

The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, manufacture and marketing of drugs. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, record-keeping, approval, advertising and protection of most products we may develop.

### **General**

The steps required before a new drug may be produced and marketed in the United States are:

1. Preclinical laboratory and animal tests
2. Investigational new drug application
3. Clinical trials (Phases I, II and III)
4. New drug application (review and approval)
5. Post-marketing surveys

The testing and approval procedures require substantial time, effort and financial resources and we cannot assure you that any approval will be timely granted, or at all.

### **Preclinical Trials and Investigational New Drug Application**

Preclinical tests are conducted in the laboratory, and usually involve animals. They are done to evaluate the safety and efficacy of the potential product. The results of the preclinical tests are submitted as part of the investigational new drug application and are fully reviewed by the FDA prior to granting the applicant permission to commence clinical trials in humans. Submission of an investigational new drug application may not result in FDA approval to commence clinical trials.

### **Clinical Trials**

Clinical trials are conducted in three phases, normally involving progressively larger numbers of patients.

#### ***Phase I***

Phase I clinical trials consist of administering the drug and testing for safety and tolerated dosages as well as preliminary evidence of efficacy in humans. They are concerned primarily with learning more about the safety of the drug, though they may also provide some information about effectiveness. Phase I testing is normally performed on healthy volunteers. The test subjects are paid to submit to a variety of tests to learn what happens to a drug in the human body; how it is absorbed, metabolized and excreted, what effect it has on various organs and tissues; and what side effects occur as the dosages are increased. The principal objective is to determine the drug's toxicity.

#### ***Phase II***

Assuming the results of Phase I testing present no toxicity or unacceptable safety problems, Phase II trials may begin. In many cases Phase II trials may commence before all the Phase I trials are completely evaluated if the disease is life threatening and preliminary toxicity data in Phase I shows no toxic side effects. In life threatening disease, Phase I and Phase II trials are sometimes combined to show initial toxicity and efficacy in a shorter period of time. Phase II trials involve a study to evaluate the effectiveness of the drug for a particular indication and to determine optimal dosages and dose interval and to identify possible adverse side effects and risks in a larger patient group. The primary objective of this stage of clinical testing is to show whether the drug is effective in treating the disease or condition for which it is intended. Phase II studies may take several months or longer and involve a few hundred patients in randomized controlled trials that also attempt to disclose short-term side effects and risks in people whose health is impaired. A number of patients with the disease or illness will receive the treatment while a control group will receive a placebo. At the conclusion of Phase II trials, we and the FDA will have a clear understanding of the short-term safety and effectiveness of our technologies and their optimal dosage levels.



### ***Phase III***

Phase III clinical trials will generally begin after the results of Phase II are evaluated. If a product is found to be effective in Phase II, it is then evaluated in Phase III clinical trials. The objective of Phase III is to develop information that will allow the drug to be marketed and used safely. Phase III trials consist of expanded multi-location testing for efficacy and safety to evaluate the overall benefit or risk index of the investigational drug in relation to the disease treated. Phase III trials will involve thousands of people with the objective of expanding on the clinical evidence.

Some objectives of Phase III trials are to discover optimum dose rates and schedules, less common or even rare side effects, adverse reactions, and to generate information that will be incorporated into the drug's professional labeling and the FDA-approved guidelines to physicians and others about how to properly use the drug.

### **Pharmaceutical Development**

The method of formulation and manufacture may affect the efficacy and safety of a drug. Therefore, information on manufacturing methods and standards and the stability of the drug substance and dosage form must be presented to the FDA and other regulatory authorities. This is to ensure that a product that may eventually be sold to the public has the same composition as that determined to be effective and safe in the clinical studies. Production methods and quality control procedures must be in place to ensure a relatively pure compound, essentially free of contamination and uniform with respect to all quality aspects.

### **New Drug Application**

The fourth step that is necessary prior to marketing a new drug is the new drug application submission and approval. In this step, all the information generated by the preclinical and human clinical trials, as well as manufacturing information for the drug, will be submitted to the FDA and, if successful, the drug will be approved for marketing.

### **Post Marketing Surveys**

The final step is the random surveillance or surveys of patients being treated with the drug to determine its long-term effects. This has no effect on the marketing of the drug unless highly toxic conditions are found.

The required testing, data collection, analysis and compilation of an investigational new drug application and a new drug application are labor intensive and costly and may take a great deal of time. Tests may have to be redone or new tests performed in order to comply with FDA requirements. Therefore, we cannot estimate with any certainty the length or the costs of the approval process. We can offer no assurance that we will ever receive FDA approval of products derived from our licensed, patented technologies.

### **Competition**

*Industry.* The pharmaceutical and biotechnology industries are characterized by intense competition, rapid product development and technological change. Competition is intense among manufacturers of dental therapeutics and prescription pharmaceuticals. Most of our potential competitors are large, well established pharmaceutical, chemical or healthcare companies with considerably greater financial, marketing, sales and technological resources than are available to us. Academic institutions, government agencies and other public and private research organizations may also conduct research, seek patent protection and establish collaborative arrangements for discovery, research and clinical development of technologies and products similar to ours. Many of our 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. Products developed from our technologies could be rendered obsolete or made uneconomical by the development of new products to treat the conditions to be treated by products developed from our technologies, technological advances affecting the cost of production, or marketing or pricing actions by our potential competitors. This could materially affect our business, financial condition and results of operations. We cannot assure you that we will be able to compete successfully.

*Personnel.* Competition among biotechnology and biopharmaceutical companies for qualified employees is intense, and there can be no assurance we will be able to attract and retain qualified individuals. If we fail to do so, this would have a material, adverse effect on the results of our operations.

We do not maintain any life insurance on the lives of any of our officers and directors. We are highly dependent on the services of our directors and officers, particularly on those of Jeffrey Hillman. If one or all of our officers or directors die or otherwise become incapacitated, our operations could be interrupted or terminated.

### **Research and Development Costs**

We have spent \$2,097,223 and \$1,990,979 on research and development of our technologies in 2005 and 2004, respectively.

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

We have licenses to sell products made using the replacement therapy and *mutacin* 1140 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 10 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.

**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 2006 will be approximately \$79,500, net of insurance, taxes and utilities that are paid by us. Lease payments escalate by 3% annually. We paid approximately \$12,000 and \$469,000 in 2005 and 2004, respectively, for leasehold improvements to outfit this facility. Such improvements included equipping the building with sufficient air-handling and building laboratory stations. We also spent approximately \$653,000 and \$181,000 in 2005 and 2004, 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 2006.

**Item 3. Legal Proceedings.**

As of the date hereof, we are not a party to any material legal proceedings.

**Item 4. Submission of Matters to a Vote of Security Holders.**

None during the fourth quarter of the 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 it 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 closing bid prices for the common stock on the TSX Venture Exchange from the beginning of 2004 through May 19, 2004 and on the American Stock Exchange from May 20, 2004 through the end of 2005. Such prices represent prices between dealers without adjustment for retail mark ups, mark downs, or commissions and may not necessarily represent actual transactions.

	2005		2004	
	High	Low	High	Low
<b>COMMON STOCK</b>				
First quarter	\$ 4.00	\$ 1.59	\$ 4.35	\$ 3.20
Second quarter	\$ 2.40	\$ 1.59	\$ 4.40	\$ 2.80
Third quarter	\$ 1.85	\$ 1.15	\$ 3.75	\$ 2.00
Fourth quarter	\$ 1.00	\$ 0.40	\$ 4.45	\$ 2.65

On March 6, 2006, the closing bid price of the common stock, as reported by the American Stock Exchange, was \$0.48. As of March 6, 2006, there were approximately 31 record holders of our common stock according to our transfer agent. The number of record holders does not reflect the number of beneficial owners of the common stock for whom shares are held by banks, brokerage firms and others.

### Equity Compensation Plan Information

The Company has reserved an aggregate of 1,500,000 shares of the Company's common stock for issuance pursuant to its 2002 Stock Option and Incentive Plan. The per share exercise price of each stock option or similar award granted under these plans must be at least equal to the closing fair market value of the stock on the date of grant. The following table represents the number of shares issuable upon exercise and reserved for future issuance under these plans as of December 31, 2005.

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
<b>Equity compensation plans approved by security holders</b>	1,260,000	\$1.90	240,000
<b>Equity compensation plans not approved by security holders</b>	137,500 (1)	2.75	---
	25,000 (1)	2.25	---
	35,000 (2)	1.59	---
	3,032,500 (3)	0.60	---
	35,000 (3)	0.40	---
<b>Total</b>	4,525,000	\$1.04	240,000

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- (1) Represents 137,500 warrants with an exercise price of \$2.75 per share issued on November 30, 2004, and exercisable for period of four years to investors and the placement agent and 25,000 warrants with an exercise price of \$2.25 per share issued to the placement agent in connection with the private placement of 250,000 shares of common stock for gross proceeds of \$687,500.
  - (2) Represents warrants issued to a consultant having provided investor relations services for us during 2005. Such warrants are exercisable for a period of three years.
  - (3) Represents (i) 2,937,500 warrants with an exercise price of \$0.60 per share issued to investors in connection with the private placement of 2,937,500 shares of common stock for gross proceeds of \$1,175,000, and (ii) warrants issued to Westrock Advisors, Inc. in connection with the termination of an investment advisor agreement, 95,000 warrants with an exercise price of \$0.60 per share and 35,000 warrants with an exercise price of \$0.40 per share. The warrants issued are exercisable for a two year period.

## **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 payment of dividends.

## **Recent Sales of Unregistered Securities**

On December 14, 2005, we issued a total of 2,937,500 shares of our common stock and warrants to purchase 2,937,500 shares of our common stock in a private placement to accredited investors. We received gross proceeds of \$1,175,000 in the private placement and incurred estimated costs of approximately \$70,000 resulting in net proceeds of approximately \$1,105,000. 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. 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 between us and Westrock Advisors, Inc. we issued warrants on similar terms as those issued in the private placement, representing the right to acquire 130,000 shares of common stock were issued to Westrock Advisors, Inc. Of the 130,000 shares covered by the warrants, 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 August 16, 2005, we entered into a consulting agreement for financial public relations services with Investor Awareness, Inc. The terms of that agreement provided that we pay \$10,000 per month plus out-of-pocket expenses and that we issue a common stock purchase warrant for 35,000 shares that has an exercise price of \$1.59 for three years. In November 2005, we suspended the continuance of the consulting agreement. As of December 31, 2005, no warrants had been exercised.

The issuance of the shares of common stock and warrants described above were made pursuant to exemptions from registration provided by Section 4(2) of the Securities Act of 1933 and Regulation D promulgated thereunder.

## **Use of Proceeds**

On June 24, 2003, we completed an initial public offering (IPO) of our common stock. The managing underwriter for our initial public offering was Haywood Securities Inc. The shares of common stock sold in the offering were registered under the Securities Act of 1933 on a registration statement (File No. 333-100568) that was declared effective by the Securities and Exchange Commission on June 11, 2003. Under the registration statement, we registered 2,400,000 units at a price of \$1.25 per unit. All 2,400,000 units were sold in the offering that provided gross proceeds of \$3,000,000 and net proceeds to us of \$2,282,612 after deducting \$717,388 in commissions paid to the underwriter and other expenses incurred in connection with the offering.

Each unit consisted of one share of common stock, one half of one non-transferable Series A Common Stock Purchase Warrant and one half of one non-transferable Series B Common Stock Purchase Warrant. One whole Series A warrant was exercisable on or before December 24, 2003 to acquire one share of common stock at a price of \$2.00 per share. All Series A warrants were exercised on or prior to December 24, 2003 providing proceeds of \$2,400,000. One whole Series B warrant was exercisable on or before March 24, 2004 to acquire one share of common stock at a price of \$3.00 per share. 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 our common stock and warrants to purchase 500,000 shares of our common stock at \$1.25 per share until June 24, 2005. All underwriter warrants were exercised providing additional proceeds to us of \$625,000. The costs associated with maintaining this registration statement totaling \$62,421 through December 31, 2005 are netted against proceeds and recorded as a component of stockholders' equity.

Through December 31, 2005 we have applied all of the net proceeds of \$8,231,391 we received from our initial public offering as follows:

Payment of notes payable and accrued interest thereon to directors and officers:	
Brian McAlister (Cornet Capital Corp.)	\$ 179,757
Robert Zahradnik	88,477
Jeffrey Hillman	15,429
Deferred compensation payable to officers	189,302
Patent expenses paid to University of Florida	100,000
Regulatory consulting fees	743,018
Mutacin 1140 production research	758,878
Pre-clinical research	2,554,652
General and administration costs	2,741,877
Repayment of indebtedness incurred to purchase computer and laboratory equipment	860,001
	<u>\$ 8,231,391</u>

Other than normal and recurring compensation (included in general administration costs above), the deferred compensation payments and payments on notes payable, there were no other payments, directly or indirectly, to any of our officers or directors or any of their associates, or to any persons owning ten percent or more of our outstanding common stock from the proceeds of this offering. We believe we have used the net proceeds from the offering consistent with our business strategy.

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

The following discussion and analysis should be read in conjunction with the Financial Statements and 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.

### Overview

We are an emerging, early-stage biotechnology company aimed at adding value to novel technologies and products sourced from innovative research at the University of Florida and other academic centers. Our strategy is to in-license and to develop products through human proof-of-concept studies (Phase I and II clinical trials of the U.S. Food and Drug Administration's regulatory process) prior to partnering with major pharmaceutical, biotechnology or healthcare product firms for advanced clinical development and commercialization. Since 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 which have expired. We have not generated revenues from sales of products.

We are in need of immediate substantial additional funds in order to continue the development of our technologies. We continue to seek additional funding and evaluate various strategic alternatives that may be available to us. We currently do not have any commitments for funding sufficient to fully implement our plan of operation or other strategic options and there can be no assurances that we will be able to obtain sufficient funding or implement any strategic options in the future. We have curtailed our operations, deferred payments to our chief executive officer and president, chief scientific officer, former chief executive officer and president and our board of directors, reduced compensation by 35% to certain other executive officers and laid-off approximately one-third of our 16 employees such that further development of our technologies has been reduced to a minimum. Our remaining capital resources are expected to be utilized to sustain minimal operations while we continue to explore opportunities to raise additional capital. After the repayment of \$495,799 of the outstanding balance of our existing loan obligation in the fourth quarter of 2005, the payment of operating costs and the receipt of funds from our recent private placement, our remaining available working capital at the end of 2005 was \$675,006. Absent continued future funding, this remaining capital, together with \$600,000 in proceeds we received from another private placement which closed in March 2006, is not sufficient to enable us to continue to operate through the second quarter of 2006, at which time we will likely need to cease all operations until we are able to raise additional capital. There can be no assurance that such capital will be available to us. 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 replacement therapy and Mutacin 1140 technologies. If we are unable to make these payments, our license could be terminated which will substantially diminish the value of our company.

We hope to be in a position to continue to develop several products, each of which we believe addresses potentially large market opportunities:

**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, *Streptococcus 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. Replacement therapy permanently replaces resident acid-producing *Streptococcus mutans* with a patented, genetically engineered strain of *Streptococcus mutans* that does not produce lactic acid. Applied topically to tooth surfaces with a swab, the therapy requires 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 III clinical trials. To facilitate further patient recruitment in our Phase I clinical trial, we opened an additional clinical site in June 2005, however, we have 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 concluded 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 is expected to be filed with the FDA by the end of February 2006 and we anticipate instituting a second Phase I clinical study by the end of the second quarter of 2006. We remain committed to complete the human safety study of replacement therapy to the satisfaction of the FDA and we expect the cost in 2006 will be approximately \$350,000.

**Mutacin 1140** is a highly potent bactericidal peptide that is produced by our strain of *Streptococcus mutans*. Our proprietary mutacin was discovered by our researchers during the course of developing replacement therapy and is a novel antibiotic that has broad-spectrum antimicrobial activity against essentially all Gram-positive bacteria including vancomycin-resistant *Staphylococcus aureus*. The antibiotic currently is in preclinical stages of development. During the second quarter of 2005, we completed development of a proprietary manufacturing process for mutacin 1140, which overcame a previous hurdle to that molecule's development. We are now able to manufacture in sufficient quantities to allow us to conduct preclinical studies needed to enable the filing of an Investigational New Drug (IND) application. If we are able to secure adequate funding, we plan to continue to perform in vitro antimicrobial susceptibility and toxicity testing during the first half of 2006 before performing more detailed animal safety and efficacy studies using mutacin 1140. For example, in March and April 2006 we plan to conduct two preclinical studies with MU 1140™, utilizing independent testing labs, that will provide information on Tier 2 spectrum of activity against clinically important Gram-positive bacteria and the effectiveness in a drug resistant *Staphylococcus aureus* infected animal model system. Upon adequate funding and successful completion of this testing and the animal studies we would then be positioned to file an IND for mutacin 1140.

**Probiotics** are live microorganisms that confer health benefits to the host when administered in adequate amounts; the use of yogurt containing live *Lactobacillus* cultures is an example of a probiotic application. We have identified three natural strains of bacteria that provide significant protection against the causative organisms of periodontal disease and dental caries. 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 in these markets by late 2006. We are continuing our efforts to seek partners in Europe and Asia for market opportunities for our oral probiotic technology. European and Asian companies have signaled their intent to establish a licensing agreement with us, while another potential partner is completing a laboratory evaluation of the product before moving forward with possible licensing discussions. We expect to initiate a human trial within the next two months to support product claims for Probiora 3™. While there can be no assurances, this study should be completed by early in the third quarter of 2006. If successfully developed, our oral rinse product will be one of the first probiotics to be marketed for the maintenance of oral health.

**IVIAT and CMAT** are technologies we licensed from iviGene Corporation. Two of our directors own a total of 19.1% interest in iviGene Corporation. These technologies enable the simple, fast identification of novel and potentially important gene targets associated with the natural onset and progression of infections, cancers and other diseases in humans and other living organisms, including plants. These licensed technologies offer the potential to generate and develop a number of product candidates for future out-licensing to corporate partners, particularly in the area of cancer and tuberculosis, as well as agricultural and other non-human uses. We are required to pay all patent-related expenses and commit two full-time staff or spend at least \$200,000 toward product development annually to maintain our license. In 2005 we did not meet the requirements of committing two full-time staff or spending at least \$200,000, however, we obtained a waiver of these provisions from iviGene Corporation, thus maintaining our license arrangement with them. As a result of our current financial condition we currently do not have the resources to pursue our IVIAT and CMAT technologies at this time. However, we filed for funding under SBIR grants with the National Institutes of Health and, if such funding becomes available, we will pursue additional research and expect that we will maintain compliance with our license agreement requirements with iviGene Corporation. If additional funding is not available to us, we will need to obtain another waiver or renegotiate the terms of our license with iviGene Corporation in order to maintain our license.



## **Business Objectives and Milestones**

The specific goal of our business is to successfully develop, clinically test and obtain FDA approval for sales of products based on our licensed, patented technologies. Our strategy is to develop novel technologies through human proof-of-concept studies (Phase II clinical trials) prior to partnering with major pharmaceutical, biotechnology or health care product firms for advanced clinical development and commercialization. Upon successful completion of proof-of-concept studies, we intend to consider sublicensing our licensed, patented technologies to 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:

### **Replacement Therapy**

1. Initiate second Phase I safety trial.

### **Mutacin 1140**

1. Complete preclinical studies, including animal toxicity and efficacy, required for an investigational new drug application submission.
2. Submit an investigational new drug application to the FDA.

### **Probiotic Technology**

1. Develop appropriate manufacturing and packaging systems.
2. Complete one human study.

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 period for the development of our technologies could change depending on the progress of our ability to negotiate a partnering arrangement, as well as our efforts to raise additional capital.

## 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. The preparation of financial statements in accordance with Accounting Principles Generally Accepted in the United States 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

In December 2004, the Financial Accounting Standards Board (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 expect to adopt in the first quarter of 2006, is generally similar to Statement 123, however, it will require all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. Thus, pro forma disclosure will no longer be an alternative to financial statement recognition. We do not believe the adoption of Statement 123(R) will have a material impact on our results of operations or financial position.

## Results of Operations

### Operating Results Summary

	Three Months Ended December 31	
	2005	2004
Revenue	\$ -	\$ 33,333
Operating expenses:		
Research and development	452,853	742,557
General and administration	307,153	565,181
Total operating expenses	760,006	1,307,738
Loss from operations	(760,006)	(1,274,405)
Other income (expense):		
Interest income	5,221	15,831
Interest expense	(6,610)	(442)
Total other income, net	(1,389)	15,389
Loss before income taxes	(761,395)	(1,259,016)
Income tax benefit	-	-
Net loss	\$ (761,395)	\$ (1,259,016)

	Years ended December 31	
	2005	2004
Revenue	\$ -	\$ 196,210
Operating expenses:		
Research and development	2,097,223	1,990,979
General and administration	1,166,854	1,329,983
Total operating expenses	3,264,077	3,320,962
Loss from operations	(3,264,077)	(3,124,752)
Other income (expense):		
Interest income	41,874	47,306
Interest expense	(29,175)	(442)
Total other income (expense), net	12,699	46,864
Loss before income taxes	(3,251,378)	(3,077,888)
Income tax benefit	-	-
Net loss	\$ (3,251,378)	\$ (3,077,888)

#### ***For the Quarters Ended December 31, 2005 and 2004***

We had no revenues in the three months ended December 31, 2005 as compared to \$33,333 in the quarter ended December 31, 2004 that related to a portion of the revenues earned on an SBIR grant. Our operating expenses decreased 42% to \$760,006 in the three months ended December 31, 2005 from \$1,307,738 in same period in 2004. Research and development expenses decreased 39% to \$452,853 in the three months ended December 31, 2005 from \$742,557 in the same period in 2004, reflecting the lay-off of five R&D employees in October 2005 amounting to approximately \$150,000, the reduction in use of outside consultants amounting to approximately \$122,000, and the reduction of stock option compensation expense of approximately \$95,000, offset by increases in depreciation totaling \$45,000 associated with new equipment purchases in early 2005, minimum royalty payment to the University of Florida amounting to \$25,000 and increased utility costs of approximately \$9,000. General and administration expenses decreased 46% to \$307,153 in the three months ended December 31, 2005 from \$565,181 in same period in 2004. This lower amount in 2005 reflects fewer administrative personnel in 2005 amounting to approximately \$29,000, the reduction of stock option compensation expense of approximately \$152,000, the reduction in use of outside consultants amounting to approximately \$17,000, the reduction in travel and entertainment expenses of approximately \$19,000, the reduction in the premium cost of Directors' and Officers' Liability Insurance amounting to approximately \$9,000 and higher than normal supply costs in 2004 to outfit our new building amounting to approximately \$34,000.

Interest income decreased 67% to \$5,221 in the three months ended December 31, 2005 from \$15,831 in the same period in 2004 as a result of lower cash balances in 2005. Interest expense increased to \$6,610 in the three months ended December 31, 2005 from \$442 during the same period in 2004. This increase of \$6,168 reflects the interest paid on our equipment loan in 2005 that was not active in 2004 and was retired in December 2005.

Our net loss decreased 40% to \$761,395 during the three months ended December 31, 2005 from \$1,259,016 in the same period in 2004. The decrease in our net loss was principally caused by the lay-off of personnel, the reduction in stock option compensation expense and the reduced use of outside consultants.

#### ***For the Years Ended December 31, 2005 and 2004***

We had no revenues in the year ended December 31, 2005 as compared to \$196,210 in 2004. This is a result of having two Small Business Innovation Research Grants for our Mutacin 1140 and IVIAT technologies in 2004. Our operating expenses decreased 2% to \$3,264,077 for the year ended December 31, 2005 from \$3,320,962 in 2004. Research and development expenses increased 5% to \$2,097,223 in 2005 from \$1,990,979 in 2004, reflecting higher depreciation costs of approximately \$203,000 associated with new equipment purchases in early 2005, higher facility costs of approximately \$70,000 associated with the rent and utilities of the building we began renting in late 2004, the start of paying minimum royalty fees to the University of Florida amounting to \$100,000, higher personnel costs for the entire year of approximately \$46,000 and the payment of product liability insurance premiums of approximately \$19,000 associated with our clinical trials, offset by the reduction of stock option compensation expense of approximately \$208,000, higher recruiting and relocation costs in 2004 of approximately \$77,000, higher outside consulting costs in 2004 of approximately \$44,000 mostly caused by the manufacture of clinical trial materials and higher travel expenses in 2004 of approximately \$11,000. General and administration expenses decreased 12% to \$1,166,854 in 2005 from \$1,329,983 in 2004, reflecting the reduction of stock option compensation expense of approximately \$333,000, fees of approximately \$64,000 paid to the American Stock Exchange in 2004 for the initial listing of our shares, the reduction in the use of outside consultants amounting to approximately \$49,000, the reduction of travel and entertainment expenses in 2005 approximating \$47,000, higher than normal supply costs in 2004 to outfit the our new building amounting to approximately \$34,000 and staff lay-offs amounting to approximately \$9,000, offset by fees associated with attempted financings of approximately \$108,000, increased legal and accounting fees approximating \$114,000, the severance charges for our former CEO approximating \$90,000, costs associated with hiring a new CEO totaling approximately \$28,000, higher depreciation costs of approximately \$16,000 in 2005 and higher facility costs in 2005 of approximately \$14,000.

Interest income decreased 11% to \$41,874 in the year ended December 31, 2005 from \$47,306 in 2004, which was a result of higher average cash balances maintained in 2004 due to the exercise of Series A and Series B common stock warrants in December 2003 and March 2004, respectively. Interest expense increased to \$29,175 in 2005 from \$442 in 2004. This increase of \$28,733 reflects the payments on our equipment loan in 2005 that was not active in 2004 and was retired in December 2005.

Our net loss increased 6% to \$3,251,378 in the year ended December 31, 2005 from \$3,077,888 in 2004. The increase in our net loss was principally caused by having no revenues in 2005, incurring fees associated with attempted financings, increased fees paid for professional services, increased depreciation charges and minimum royalty fees paid to the University of Florida, offset by the reduction of stock option compensation expenses, and the significant cut-backs in the fourth quarter of 2005 for personnel, use of outside consultants and travel costs.

### **Liquidity and Capital Resources**

Our operating activities used cash of \$3,437,118 for the year ended December 31, 2005 and \$2,745,243 for the year ended December 31, 2004. Our working capital was \$675,006 as of December 31, 2005. Cash used by operations in the year ended December 31, 2005 resulted primarily from operating losses from operations of \$3,251,378.

Our investing activities used cash of \$663,268 for the year ended December 31, 2005 for the acquisition of laboratory equipment.

Our financing activities provided \$1,372,195 in cash for the year ended December 31, 2005, which came from four sources. In the first quarter of 2005, we entered into a loan agreement with a bank that provided funds of approximately \$615,000, however, the entire loan principal was repaid before year end. Common stock warrants issued in connection with our IPO in June 2003 were exercised during the first half of 2005 providing funds of approximately \$345,000. In the third quarter of 2005, we issued common stock under our agreement with Fusion Capital that provided funds of \$35,000. In the fourth quarter of 2005, we issued common stock and warrants in a private placement that provided gross proceeds of \$1,175,000. Additional details of these financings are provided below:

**Loan Agreement** - On February 24, 2005, we entered into a Business Loan Agreement with a bank that funded \$615,192 of laboratory equipment purchases. We made monthly payments of interest and principal, having also made an accelerated payment of \$200,000 in October 2005 and a final payment of approximately \$296,000 in December 2005. Thus, the entire loan balance had been repaid at December 31, 2005. The loan had a term of 37 months with the first month's payment of interest only and the remaining monthly payments of principal and interest of approximately \$19,000 per month. Interest was calculated at the prime rate as published in the Wall Street Journal (8.00% in December, 2005) plus 1.00%. The loan was collateralized by the equipment purchased, as well as all equipment owned by us at the time of the agreement. The original loan terms required us to maintain working capital and tangible net worth of at least \$750,000 and not allow debt to be greater than 50% of stockholders' equity. Effective September 30, 2005, the bank amended the working capital covenant to provide that working capital not be lower than \$350,000. The bank also amended the debt-to-equity covenant whereby debt could not be greater than 56% of stockholders' equity. Thus, we were in compliance with the loan covenants throughout the term of the loan. We incurred interest of \$29,176 during the year.

**Exercise of Warrants** - On June 24, 2003, we completed the filing of an IPO whereby the underwriting agent received 100,000 shares of our common stock and warrants to purchase 500,000 shares of our common stock at \$1.25 per share that were exercisable until June 24, 2005. All of these warrants have been exercised. During 2005, the remaining outstanding warrants to acquire 276,180 shares of common stock were exercised prior to their expiration and 276,180 shares of common stock were issued providing additional proceeds to the Company of \$345,225.

**Fusion Capital** - On May 23, 2005, we entered into a Common Stock Purchase Agreement ("Purchase Agreement") with Fusion Capital. Pursuant to the terms of the Purchase Agreement, Fusion Capital has agreed to purchase from us up to \$9,000,000 of our common stock over a 30 month period. On each trading day during the term of the Purchase Agreement, we have the right to sell to Fusion Capital \$15,000 of our common stock at a price based upon the market price of the common stock on the date of each sale without any fixed discount to the market price. At our option, Fusion Capital can be required to purchase fewer or greater amounts of common stock each month. Fusion Capital 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. Subject to the foregoing, we have the right to control the timing and the number of shares sold to Fusion Capital. This offering was made pursuant to an exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended. Pursuant to the terms of a registration rights agreement we entered into with Fusion Capital in connection with the Purchase Agreement, dated May 23, 2005, we agreed to file a registration statement with the Securities and Exchange Commission covering the resale of the shares which may be purchased by Fusion Capital under the Purchase Agreement. The registration statement was declared effective on June 23, 2005 and the American Stock Exchange approved the listing of the shares on July 7, 2005. We incurred costs of approximately \$150,000 for legal, accounting, stock exchange, and regulatory fees in connection with this financing arrangement. During the year, we sold 22,092 of our shares to Fusion Capital pursuant to the Purchase Agreement for total proceeds of \$35,000. Because our stock price has traded below the \$0.75 threshold since November 23, 2006, Fusion Capital is not obligated to purchase any shares of our common stock from us.

**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. We intend to use the net proceeds of the private placement, including any proceeds we may receive from exercise of the warrants, for working capital and general corporate purposes. 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. Pursuant to the terms of a registration rights agreement, dated December 14, 2005, the Company agreed to file a registration statement with the Securities and Exchange Commission covering the resale of the acquired shares and the shares able to be acquired upon exercise of the warrants. The Company filed a registration statement on January 13, 2006 and it was declared effective on January 27, 2006.

**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. 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 \$600,000 in the private placement and incurred estimated costs of approximately \$75,000 resulting in net proceeds of approximately \$525,000. We intend to use the net proceeds of the private placement, including any proceeds we may receive from exercise of the warrants, for working capital and general corporate purposes. There was no underwriter or placement agent associated with this transaction. Each warrant is exercisable on or before January 6, 2008 to acquire one share of common stock at a price of \$0.60 per share. Pursuant to the terms of a registration rights agreement, dated January 6, 2006, the Company agreed to file a registration statement with the Securities and Exchange Commission covering the resale of the acquired shares in the private placement and the shares able to be acquired upon exercise of the warrants within 45 days of the closing of the transaction.

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 two fiscal years and have an accumulated deficit of \$8,723,362 as of December 31, 2005. Cash used in operations for 2005 and 2004 was \$3,434,382 and \$2,745,243, respectively. At December 31, 2005, our principal source of liquidity was \$937,789 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 took steps during the second half of 2005 to reduce our expenditure of cash. We curtailed hiring, froze salaries, reduced our matching contributions for the employee retirement plan, appreciably reduced travel and other operating costs, decreased the use of outside consultants and delayed the production of additional supplies of our replacement therapy technology to be used in later clinical studies. These efforts resulted in reducing operating expenses to below \$200,000 per month. As of December 31, 2005, we also deferred, \$56,500 in compensation to certain officers and board members, consisting of \$26,250 each in payments to Jeffrey Hillman, our Chief Scientific Officer, and Robert Zahradnik, our President & Chief Executive Officer, and \$3,500 in Audit Committee meeting fees to directors. The officer compensation deferrals and meeting fee deferral amounts 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. As of December 31, 2005, we also orally agreed with our former chief executive officer to defer certain payments due pursuant to our separation agreement, which amounted to a deferral of \$40,500 of such payments due to our former chief executive officer. As part of the oral agreement with our former chief executive officer, we are currently paying \$7,500 per month which is one half of the monthly amount due of \$15,000 under the separation agreement. These payments were originally to be concluded in July of 2006, but due to the deferred amount and the current payment schedule these payments are expected to continue beyond that time period until paid. 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 2006 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, 2005 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 replacement therapy technology, conducting animal studies for our mutacin 1140 antibiotic technology and developing strategic partners for our probiotic technology, we do not have sufficient capital resources to complete these projects. With continued limits on spending, and considering the recent private placement financings, we believe we will have cash resources to continue minimum operations through the end of the second quarter of 2006. 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 will require additional financing to sustain our operations and without it we will not be able to continue operations.**

We have incurred annual operating losses of \$3,251,378, \$3,077,888 and \$1,672,954, respectively, during the past three fiscal years of operation. As a result, at December 31, 2005 we had an accumulated deficit of \$8,723,362. We have generated minimal revenues to date and our revenues have not been sufficient to sustain our operations. Although we recently completed two financings totaling \$1,775,000 for the private placement of equity securities, we do not currently expect to have sufficient capital to sustain our operations beyond the second quarter of 2006. 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 have to lay-off our personnel;
- We could be unable to continue to make public filings;
- We will be delisted from the American Stock Exchange; and
- Our licenses for our replacement technology and Mutacin 1140 technology could be terminated which would significantly harm our business.

At December 31, 2005, we had working capital of approximately \$675,000. The independent registered public accounting firm's report for the year ended December 31, 2005, 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 \$3,434,382 for the year ended December 31, 2005, and have sustained operating cash flow deficits of \$2,745,243 in 2004 and \$1,218,910 in 2003. 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 replacement therapy, probiotic and Mutacin 1140 technologies. No assurances can be given when this will occur or that we will ever be profitable.

***We must spend at least \$1 million annually on development of our replacement therapy and Mutacin 1140 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 technologies may be terminated, and we may have to cease operations.***



We hold our replacement therapy and Mutacin 1140 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. If we do not, our licenses on these technologies could be terminated. We also hold a license for our IVIAT and CMAT technologies from iviGene Corporation, which required us to either find two full time resources or invest \$200,000 annually toward development of these technologies. In 2005 we did not meet the requirements of committing two full-time staff or spending at least \$200,000, however, we obtained a waiver of these provisions from iviGene Corporation, thus maintaining our license arrangement with them. We have applied for SBIR grant funding from the National Institutes of Health and with these funds expect to be able to meet the requirements of the license agreement in 2006. 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.

The University of Florida Research Foundation, Inc. may terminate our licenses in respect of our replacement therapy technology and our Mutacin 1140 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 replacement therapy and Mutacin 1140 technologies will become valueless and we may have to cease operations. In addition, iviGene Corporation may terminate our license in respect of our IVIAT and CMAT technologies if we breach or are unable to meet our obligations under the terms of our license. There can be no assurance that we will be able to comply with the obligations of our license with iviGene Corporation. If our license is terminated we will be unable to develop these technologies.

***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 replacement therapy technology has been granted clearance to begin Phase 1 human clinical trials by the Food and Drug Administration (FDA). Clinical trials on our replacement therapy are expected to take 4-5 years to fully complete. Our other technologies have not been cleared for testing in humans. Our 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 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 technologies. There is a possibility that our technologies may be found to be unsafe or ineffective or otherwise fail to satisfy regulatory requirements. If we are unable to resolve the FDA's concerns, we will not be able to proceed further to obtain regulatory approval for that technology. If we fail to maintain regulatory clearance for our replacement therapy or fail to obtain FDA clearance for our other technologies, we may have to cease operations.

***Our product candidates are in the preliminary 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 preliminary development state. Although we have current data which indicates the promise of the concept of our replacement therapy and Mutacin 1140 technologies, we can offer you no assurance that the technologies will be effective at a level sufficient to support a profitable business venture. If they are not, we will be unable to create marketable products, we will not generate revenues from our operations, and we may have to cease operations. The science on which our replacement therapy and Mutacin 1140 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 or 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 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 revenue from operations.

***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 sublicensees 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 many years of experience and specialized expertise in our business. Our performance also depends on our ability to retain and motivate our other executive officers and key employees. The loss of the services of our Chief Executive Officer, Robert T. Zahradnik and our Chief Scientific Officer, Dr. Jeffrey D. Hillman, and any of our other executive officers or of our researchers could harm our ability to develop and commercialize our technologies. We have no "key man" life insurance policies. We have three year employment agreement with Dr. Hillman, which automatically renews for one-year term unless 90 days written notice is given by either party.

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

***It is possible that our replacement therapy and oral probiotic technologies will be less effective in humans than they have been shown to be in animals. It is possible our Mutacin 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 replacement therapy technology has been undertaken solely in animals. Those 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 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 our oral probiotic technology has been undertaken solely in animals. Those studies have shown our technology to be effective at helping to reduce certain bacteria that are believed to cause periodontal disease. It is possible that our probiotic technology will not be effective in reducing those bacteria and will not improve periodontal health. If our oral probiotic technology is shown to be ineffective or harmful to humans, we will be unable to commercialize it and generate revenues from sales. To date the testing of the antibiotic substance, Mutacin 1140, has been undertaken solely in the laboratory. We have not yet conducted animal or human studies of Mutacin 1140. It is possible that when these studies are conducted, they will show that Mutacin 1140 is ineffective or harmful. If Mutacin 1140 is shown to be ineffective or harmful, we will be unable to commercialize it and generate revenues from sales of Mutacin 1140. If we are unable to generate revenues from our technologies, we may have to cease operations.

***It is possible we will be unable to find a method to produce Mutacin 1140 in large-scale commercial quantities. If we cannot, we will be unable to undertake the clinical trials that are required in order to obtain FDA permission to sell it, we will be unable to generate revenues from product sales, and we may have to cease operations.***

Our antibiotic technology, Mutacin 1140, is a substance produced by our genetically altered strain of *S. mutans*. To date, it has been produced only in laboratory cultures. In March 2005 we successfully developed a methodology for manufacturing Mutacin 1140 in quantities sufficient to undertake the preclinical studies necessary to prepare an Investigational New Drug (IND) application to the FDA. We believe we will be able to optimize this methodology to allow large-scale commercial production of the antibiotic. However, this methodology may not be feasible for large-scale manufacture of the Mutacin 1140 antibiotic. If we are not able to optimize this methodology, 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 products, we must demonstrate through preclinical testing and clinical trials that our products are safe and effective for use in humans. Conducting clinical trials is a lengthy, time-consuming and expensive process.

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

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

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

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

We intend to consider sublicensing our technologies to strategic partners prior to commercialization. If we do so, our sublicensees 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 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 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. B.C. International Corporation's 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 and we have not heard anything further from B.C. International Corporation. 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 B.C. International Corporation and/or we could owe substantial damages.

***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.

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 replacement therapy, oral probiotics and Mutacin 1140 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 \$2,000,000 in 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 can't 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 demonstrates positive outcomes and reduced utilization of other products or services as well as cost data which shows 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.***

We are evaluating our internal controls in order to allow management to report on, and our independent registered public accounting firm to attest to, our internal controls, as required by Section 404 of the Sarbanes-Oxley Act of 2002. We may encounter unexpected delays in implementing the requirements relating to internal controls, therefore, we cannot be certain about the timing of completion of our evaluation, testing and 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 remediation required in order to comply with the management certification and auditor attestation requirements. We are a small company with limited resources that will make it difficult for us to timely comply with the requirements of Section 404. If we are not able to timely 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. The requirement to comply with Section 404 of the Sarbanes-Oxley Act of 2002 will be no earlier than our fiscal year ending December 31, 2006.

In addition, in our system of internal controls we may rely on the internal controls of third parties such as payroll service providers. In our evaluation of our internal controls, we will consider the implication of our reliance on the internal controls of third parties. Until we have completed our evaluation, we are unable to determine the extent of our reliance on those controls, the extent and nature of the testing of those controls, and remediation actions necessary where that reliance cannot be adequately evaluated and tested.

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

*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 and as of March 6, 2006 was trading below \$0.75, which prohibits 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 a registration statement will be freely tradable. Fusion Capital may sell none, some or all of the shares of common stock purchased from us at any time. We expect that the shares offered pursuant to the registration statement we filed in connection with our obligation under the Fusion Capital transaction will be sold over a period of up to 30 months from the date of the effectiveness of the registration statement. 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. As long as our stock price is 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 stockholders and by the Company, including Fusion Capital pursuant to this prospectus and subsequent sale of common stock by the holders of warrants and options could have an adverse effect on the market price of our shares.

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 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;
- adverse announcements by our competitors; and
- the additional sale of common stock by us in a capital raising transaction.

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 and through January 9, 2006 our stock price has fluctuated from \$4.45 to \$0.35 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 6, 2006, there were 19,646,117 shares of our common stock outstanding, with another 4,765,000 shares of common stock issuable upon exercise of warrants to investors and underwriters, 1,170,000 shares issuable upon exercise of options issued and an additional 330,000 shares available for issuance under our stock option plans. The issuance 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. As of March 6, 2006, we had 1,320,106 shares of common stock held in escrow pursuant to Canadian law and underwriter requirements in connection with our initial public offering pursuant to escrow agreements. These shares are subject to release from escrow on June 24, 2006 and until such time are subject to the limitations of the respective escrow agreements. Of these shares 1,230,115 are held by principals of the Company and two former Directors of the Company and 89,991 are held by the University of Florida Research Foundation, Inc. Through March 6, 2006, approximately 6,970,649 shares held by principals (including former directors) and 509,949 shares held by the University of Florida Research Foundation, Inc. have been released from escrow. The released shares held by the principals (excluding former directors) may be resold into the market under Rule 144. This could cause the market price of our common stock to drop significantly. The shares held by the University of Florida Research Foundation, Inc. are eligible for resale without restriction once released from escrow.

***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.



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 NASD'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 15g-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.

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.

#### **Forward-Looking Statements**

The terms “Oragenics,” “Company,” “we,” “our,” and “us” refer to Oragenics, Inc. Certain oral statements made by management from time to time and certain statements contained herein and in documents incorporated herein by reference that are not historical facts are “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements include statements regarding, among other things, (a) our projected sales and profitability, (b) our growth strategies, (c) anticipated trends in our industry, (d) trends affecting our financial condition or results of operations, (e) our ability to continue to control costs and to meet our liquidity and other financing needs, (f) our ability to respond to and meet regulatory demands, and (g) our anticipated needs for working capital. Because such statements involve risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. 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. These statements are not guarantees of future performance and are subject to a number of known and unknown risks, uncertainties, and other factors, including those discussed above and elsewhere in this report, that could cause actual results to differ materially from future results, performances, or achievements expressed or implied by such forward-looking statements. Consequently, undue reliance should not be placed on these forward-looking statements. Although we believe our expectations are based on reasonable assumptions, we can give no assurance that the anticipated results will occur. We undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

## **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.**

### Changes in Registrant's Certifying Accountants

#### (a) Dismissal of Previous Independent Registered Public Accounting Firm:

(i) On August 26, 2005 the Audit Committee of the Board of Directors of Orogenics, Inc. ("the Company"), dismissed Ernst & Young LLP as the Company's independent registered public accounting firm.

(ii) The reports of Ernst & Young LLP on the Company's financial statements as of and for the years ended December 31, 2003 and 2004, did not contain an adverse opinion or a disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles, except that the report of Ernst & Young LLP on the Company's financial statements as of and for the year ended December 31, 2004 was modified for a going concern uncertainty.

(iii) During the Company's fiscal years ended December 31, 2003 and 2004, and the subsequent interim period from January 1, 2005 through August 26, 2005, there were no disagreements with Ernst & Young LLP on any matters of accounting principles or practices, financial statement disclosure, or auditing scope and procedures which, if not resolved to the satisfaction of Ernst & Young LLP would have caused Ernst & Young LLP to make reference to the matter in their report.

(iv) The Company requested Ernst & Young LLP to furnish it with a letter addressed to the Commission stating whether it agrees with the above statements. A copy of that letter, dated August 29, 2005, was filed as Exhibit 16 to the Form 8-K originally filed on August 29, 2005 and amended on August 31, 2005.

#### (b) Engagement of New Independent Registered Public Accounting Firm:

On August 26, 2005, the Audit Committee of the Company's Board of Directors approved the engagement of Kirkland, Russ, Murphy and Tapp, PA as the Company's independent registered public accounting firm for the year ending December 31, 2005. Prior to the dismissal of Ernst & Young LLP, the Company did not consult with Kirkland, Russ, Murphy and Tapp, PA regarding:

- (i) the application of accounting principles to a specified transaction, either completed or proposed; or
- (ii) the type of audit opinion that might be rendered on the Company's financial statement.

## **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.

## **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.

## **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 2006 annual meeting of shareholders (the "Proxy Statement"), and certain information included in the Proxy Statement will be incorporated herein by reference.

#### **Item 9. Directors and Executive Officers of the Registrant.**

The information required by this Item 9 with respect to identification of our directors will be included under the captions "Proposal I Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" is incorporated herein by reference to our Proxy Statement. 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.**

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."

#### **Item 12. Certain Relationships and Related Transactions.**

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."

#### **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."

Oragenics, Inc.

Financial Statements

Years ended December 31, 2005 and 2004

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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, 2005, and the related statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2005. 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 audit.

We conducted our audit 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. An audit 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 audit provides 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, 2005, and the results of its operations and its cash flows for the year ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America.

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

February 15, 2006, except for Note 11  
as to which the date is March 6, 2006  
Clearwater, Florida

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

Report of Independent Registered Public Accounting Firm on Financial Statements

The Board of Directors and Shareholders of  
Oragenics, Inc.

We have audited the statements of operations, changes in stockholders' equity and cash flows of Oragenics, Inc for the year ended December 31, 2004. 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 audit.

We conducted our audit 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. An audit includes 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 on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the results of operations and cash flows of Oragenics, Inc. for the year ended December 31, 2004, in conformity with accounting principles generally accepted in the United States.

The accompanying financial statements have been prepared assuming that Oragenics, Inc. will continue as a going concern. As more fully described in Note 1, the Company has incurred 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.

/s/ Ernst & Young LLP  
Certified Public Accountants

January 28, 2005  
Tampa, Florida



Oragenics, Inc.

Balance Sheet  
December 31, 2005

<b>Assets</b>	
Current assets:	
Cash and cash equivalents	\$ 937,789
Prepaid expenses and other current assets	112,047
Total current assets	<u>1,049,836</u>
Property and equipment, net	1,096,564
Total assets	<u>\$ 2,146,400</u>
<b>Liabilities and stockholders' equity</b>	
Current liabilities:	
Accounts payable and accrued expenses	\$ 374,830
Total current liabilities	<u>374,830</u>
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; 18,146,117 shares issued and outstanding	18,146
Additional paid in capital	10,476,786
Accumulated deficit	<u>(8,723,362)</u>
Total stockholders' equity	<u>1,771,570</u>
Total liabilities and stockholders' equity	<u>\$ 2,146,400</u>

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

Oragenics, Inc.

Statements of Operations

	Year ended December 31	
	<u>2005</u>	<u>2004</u>
Revenue	\$ -	\$ 196,210
Operating expenses:		
Research and development	2,097,223	1,990,979
General and administration	1,166,854	1,329,983
Total operating expenses	<u>3,264,077</u>	<u>3,320,962</u>
Loss from operations	(3,264,077)	(3,124,752)
Other income (expense):		
Interest income	41,875	47,306
Interest expense	(29,176)	(442)
Total other income (expense), net	<u>12,699</u>	<u>46,864</u>
Loss before income taxes	(3,251,378)	(3,077,888)
Income tax benefit	-	-
Net loss	<u>\$ (3,251,378)</u>	<u>\$ (3,077,888)</u>
Basic and diluted net loss per share	<u>\$ (0.22)</u>	<u>\$ (0.22)</u>
Shares used to compute basic and diluted net loss per share	<u>15,082,098</u>	<u>14,118,129</u>

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

Oragenics, Inc.

Statements of Changes in Stockholders' Equity  
Years ended December 31, 2005 and 2004

	<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, 2003	13,296,204	13,296	5,820,697	(2,394,096)	3,439,897
Exercise of common stock warrants	1,048,720	1,049	3,034,724	-	3,035,773
Costs associated with filing initial public offering post effective amendment	-	-	(62,421)	-	(62,421)
Issuance of common stock and warrants	250,000	250	544,676	-	544,926
Compensation credit relating to option issuances	-	-	156,157	-	156,157
Net loss	-	-	-	(3,077,888)	(3,077,888)
Balance at December 31, 2004	14,594,924	14,595	9,493,833	(5,471,984)	4,036,444
Exercise of common stock warrants	276,180	276	344,949	-	345,225
Issuance of common stock and warrants	3,275,013	3,275	1,023,695	-	1,026,970
Compensation expense relating to option issuances	-	-	(385,691)	-	(385,691)
Net loss	-	-	-	(3,251,378)	(3,251,378)
Balance at December 31, 2005	<u>18,146,117</u>	<u>\$ 18,146</u>	<u>\$ 10,476,786</u>	<u>\$ (8,723,362)</u>	<u>\$ 1,771,570</u>

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

Oragenics, Inc.

Statements of Cash Flows

	Year ended December 31	
	<u>2005</u>	<u>2004</u>
<b>Operating activities</b>		
Net loss	\$ (3,251,378)	\$ (3,077,888)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	260,636	41,987
Stock-based compensation (credit) expense	(385,691)	156,157
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,151)	(84,258)
Accounts payable and accrued expenses	(54,798)	289,013
Accrued interest	-	(25,582)
Deferred compensation	-	(44,672)
Net cash used in operating activities	<u>(3,434,382)</u>	<u>(2,745,243)</u>
<b>Investing activity</b>		
Purchases of property and equipment	(666,268)	(690,548)
Net cash used in investing activity	<u>(666,268)</u>	<u>(690,548)</u>
<b>Financing activities</b>		
Net proceeds from issuance of common stock	1,372,195	3,518,278
Net proceeds from bank loan	615,192	-
Repayments of bank loan principal	(615,192)	-
Net cash provided by financing activities	<u>1,372,195</u>	<u>3,518,278</u>
Net (decrease) increase in cash and cash equivalents	(2,728,455)	82,487
Cash and cash equivalents at beginning of year	3,666,244	3,583,757
Cash and cash equivalents at end of year	<u>\$ 937,789</u>	<u>\$ 3,666,244</u>
<b>Supplemental disclosure of cash flow information</b>		
Interest paid	<u>\$ 29,176</u>	<u>\$ 26,024</u>

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

## **1. Organization and Significant Accounting Policies**

Oragenics, Inc. is dedicated to developing technologies associated with oral health, broad spectrum antibiotics and other general health benefits. The Company has licensed two unique technologies from the University of Florida: replacement therapy for the prevention of tooth decay and mutacin 1140, a novel antibiotic. The Company has also developed a probiotics technology to provide protection against the causative organisms of periodontal disease and has licensed two related platform technologies that enable the simple, fast identification of gene targets associated with the natural onset and progression of infections, cancers and other diseases.

### **Basis of Presentation**

The financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America 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 \$3,251,378 for the year ended December 31, 2005 and as of that date had an accumulated deficit of \$8,723,362. Cash used in operations for the years ended December 31, 2005 and 2004 was \$3,434,382 and \$2,745,243, respectively, and cash flow from operations was negative throughout 2005. The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes its working capital at December 31, 2005 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 2005 the Company conducted a private placement to raise capital. During 2006 the Company expects to raise additional capital through selling additional debt or equity securities on terms acceptable to the Company. There can be no assurance that additional financing will be available to the Company on acceptable terms, or at all. 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 its current development programs, cut operating costs and forego future development and other opportunities. Without sufficient capital to fund its 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.

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

### **Use of Estimates**

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

### **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, net**

Property and equipment, net 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**

The Company has a stock-based employee compensation plan, which is described more fully in Note 5. The Company accounts for the plan under the recognition and measurement principles of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related Interpretations. The following table illustrates the effect on net loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation.

## Notes to Financial Statements (continued)

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

	<b>Year ended December 31</b>	
	<b>2005</b>	<b>2004</b>
Net loss, as reported	\$ (3,251,378)	\$ (3,077,888)
Effect of stock-based employee compensation expense (credit) included in reported net loss	(385,691)	156,157
Total stock-based employee compensation expense determined under fair value based method for all awards	(200,233)	(152,545)
Pro forma net loss	<u>\$ (3,837,302)</u>	<u>\$ (3,074,276)</u>
Loss per share:		
Basic and diluted - as reported	\$ (0.22)	\$ (0.22)
Basic and diluted - pro forma	\$ (0.25)	\$ (0.22)
Shares used to compute basic and diluted net loss per share	15,082,098	14,118,129

**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.

**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, 2005 and 2004.

**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.

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

### 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.

### Recently Issued Accounting Pronouncements

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123 (revised 2004) "Share Based Payment" ("FAS 123(R)", which is a revision of FASB Statement No. 123 "Accounting for Stock Based Compensation" ("FAS 123"). This statement supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees" ("Opinion 25") which allowed companies to use the intrinsic value method of valuing share-based payment transactions and amends FAS Statement No. 95, "Statement of Cash Flows". FAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. The Company will adopt FAS 123 (R) on January 1, 2006.

FAS 123(R) permits public companies to adopt its requirements using one of two methods. A "modified prospective" method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of FAS 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of FAS 123 for all awards granted to employees prior to the effective date of FAS 123(R) that remain unvested on the effective date. A "modified retrospective" method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under FAS 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption. The Company will determine which method to adopt prior to the effective date of FAS 123(R).

The impact of adoption of FAS 123(R) cannot be accurately predicted at this time since it will depend on levels of share-based payments granted in the future. However, had the Company adopted FAS 123(R) in prior periods, the impact of the standard would have approximated the impact of FAS 123 as described in the disclosure of pro forma net loss and loss per share in Note 1 to the financial statements. FAS 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. While the Company cannot estimate what those amounts will be in the future (because they depend on, among other things, when employees exercise stock options), there were no amounts of operating cash flows recognized in prior periods for such excess tax deductions in 2005 and 2004.

As permitted by FAS 123, the Company currently accounts for share-based payments using Opinion 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options.



## Notes to Financial Statements (continued)

**2. Property and Equipment, net**

Property and equipment, net consists of the following as of December 31, 2005:

Laboratory equipment	\$ 876,343
Leasehold improvements	481,606
Office and computer equipment	<u>55,107</u>
	1,413,056
Accumulated depreciation and amortization	<u>(316,492)</u>
	<u>\$ 1,096,564</u>

Depreciation and amortization expense for 2005 and 2004 was \$260,636 and \$41,987, respectively.

**3. Related Party Transactions**

At December 31, 2005 and 2004, \$55,000 and \$75,000, respectively, was owed and included in accounts payable and accrued expenses for consulting services provided by a stockholder of the Company in prior years. No interest is being accrued on this outstanding debt.

In January 2004, payments were made to an officer totaling \$41,539 in settlement of deferred compensation and accrued interest thereon.

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. The agreement requires the former CEO to be available as a consultant to management. In the fourth quarter of 2005, \$40,500 of these payments were deferred and included in accounts payable and accrued expenses at December 31, 2005. Beginning January 1, 2006, the Company continued to defer 50% of the payments due to the former CEO. Interest is not being accrued on the deferred amounts.

In the fourth quarter of 2005, five members of management and the board of directors began deferring a portion of their compensation. In December 2005, three members of management were paid the amounts deferred, however, at December 31, 2005 two officers were owed \$52,500 and amounts due to directors totaled \$3,500. Interest is not being accrued on the deferred amounts.

#### 4. Business Loan Agreement

On February 24, 2005, the Company entered into a Business Loan Agreement with a bank that funded \$615,192 of laboratory equipment purchases. The Company made monthly payments of interest and principal, having also made an accelerated payment of \$200,000 in October 2005 and a final payment of approximately \$296,000 in December 2005. Thus, the entire loan balance had been repaid at December 31, 2005. The loan had a term of 37 months with the first month's payment of interest only and the remaining monthly payments of principal and interest of approximately \$19,000 per month. Interest was calculated at the prime rate as published in the Wall Street Journal (8.00% in December, 2005) plus 1.00%. The loan was collateralized by the equipment purchased, as well as all equipment owned by the Company at the time of the agreement. The original loan terms required the Company to maintain working capital and tangible net worth of at least \$750,000 and not allow debt to be greater than 50% of stockholders' equity. Effective September 30, 2005, the bank amended the working capital covenant to provide that working capital not be lower than \$350,000. The bank also amended the debt-to-equity covenant whereby debt could not be greater than 56% of stockholders' equity. Thus, the Company was in compliance with the loan covenants throughout the term of the loan. The Company incurred interest of \$29,176 during the year.

#### 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 regulatory fees in connection with this financing arrangement. During the year, the Company sold 22,092 of its common stock to the investor pursuant to the arrangement for total proceeds of \$35,000.

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

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.

**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, 2005, the Company had not awarded stock appreciation rights or restricted stock under the Plan. The Company has reserved an aggregate of 1,500,000 shares of common stock for grants under the Plan, of which 240,000 shares are available for future grants as of December 31, 2005. 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, after which time the compensation will be recognized immediately at each reporting period. During 2004, the Company recognized compensation expense of \$156,157. During 2005, the Company recognized a credit to compensation expense of \$385,691 as a result of the decline in the fair market value of the Company's common stock below the price of \$1.25 at the IPO.

## Notes to Financial Statements (continued)

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

A summary of the status of the Company's outstanding stock options as of December 31, 2005 and 2004 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, 2004	600,000	\$ 1.25 - 4.00	\$ 2.22
Forfeited	(20,000)	2.65	2.65
Granted	175,000	3.30 - 4.25	3.83
Granted	315,000	2.25 - 2.65	2.38
Outstanding at December 31, 2004	1,070,000	1.25 - 4.25	2.52
Forfeited	(392,000)	1.25 - 3.30	2.25
Granted	582,000	0.53 - 2.25	1.00
Outstanding at December 31, 2005	<u>1,260,000</u>	<u>0.53 - 4.25</u>	<u>\$ 1.90</u>
Exercisable at end of year	<u>686,664</u>	<u>\$ 0.53 - 4.25</u>	<u>\$ 1.80</u>

The range of exercise price is \$0.53 to \$4.25 per share. The weighted-average per option fair value of options granted during 2005 and 2004 was \$0.62 and \$1.48, respectively, and the weighted average remaining contractual life of those options is 4.3 years. Options vest over a period of three to four years from respective grant dates and the options expire 5 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 1.00-2.87%; dividend yields of 0%; weighted-average volatility factors of the expected market price of the Company's common stock of 55%; and an expected life of the option of four years.

**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.

## Notes to Financial Statements (continued)

**6. Licenses (continued)**

In March 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. The license provides the Company with exclusive worldwide rights to this broad platform technology in the areas of cancer and tuberculosis, as well as agricultural and other non-human uses. In return, the Company will pay royalties on revenues it is able to generate from any products developed using the technology, including royalties on sublicense fees, milestone payments and future product sales. Under the terms of the license with iviGene, the Company is not obligated to make any payments to iviGene until it has achieved certain milestone or royalty payments, however, Oragenics is required to spend up to \$200,000 annually on these technologies to maintain its license. To support the research for this technology in 2004, the Company received a Phase I Small Business Innovation Research Grant from the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) that paid to the Company \$96,210. In 2005 Oragenics did not meet the requirements of committing two full-time staff or spending at least \$200,000, however, the Company obtained a waiver of these provisions from iviGene, thus maintaining our license arrangement with them.

**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 2005 and 2004, employee contributions were limited to \$10,000 and \$9,000, respectively, except for individuals 50 years or older for which the contribution limitations were \$12,000 and \$10,500, respectively. Total matching contributions made by the Company in 2005 and 2004 were \$31,895 and \$28,315, respectively.

**8. Income Taxes**

At December 31, 2005, 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	\$ 3,170,707
Consulting services	57,010
Non qualified stock options	20,320
Tax credits	195,326
Total deferred tax assets	3,443,363
Less valuation allowance	(3,443,363)
Total net deferred taxes	<u>\$ -</u>

## 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, 2005 and 2004:

	<b>Year ended December 31</b>	
	<b>2005</b>	<b>2004</b>
Income tax benefit computed at statutory federal rate of 34%	\$ (1,105,469)	\$ (1,046,482)
State income tax benefits, net of federal expense/benefit	(118,025)	(111,727)
Change in valuation allowance	1,387,567	1,178,040
Non-deductible expenses	(98,021)	60,721
Research and development credit	(66,052)	(80,552)
Total	<u>\$ -</u>	<u>\$ -</u>

SFAS No. 109, *Accounting for Income Taxes*, requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all of the evidence, both positive and negative, management has determined that a valuation allowance of \$3,443,363 at December 31, 2005 is necessary to reduce the deferred tax assets to the amount that will more likely than not be realized. The change in the valuation allowance for the year ended December 31, 2005 was \$1,387,567. At December 31, 2005, the Company has available net operating loss carryforwards of approximately \$8,426,000 that begin to expire in 2021. The Company also has a research and development credit carryforward of \$195,326 that is available to reduce future tax liabilities through 2025.

In connection with the initial public offering and other equity financings undertaken, it is possible that the Company has experienced a change in control within the meaning of Section 382 of the Internal Revenue Code. If so, the ability of the Company to use its net operating losses may be limited and subject to annual limitation that could result in the expiration of some net operating losses prior to utilization.

## Notes to Financial Statements (continued)

**9. Commitments and Contingencies**

The Company leased its laboratory and office space, as well certain equipment, under a 12-month cancelable operating lease with annual renewal options. That lease agreement terminated in November 2004 when the Company moved into a new facility. The rent expense incurred through November 2004 was \$47,376.

The new 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 \$6,400, exclusive of utilities, insurance, sales taxes and real estate taxes. Total rent expense under this lease was \$81,653 and \$10,184 for the years ended December 31, 2005 and 2004, respectively. In addition, the Company has entered into certain operating leases for office equipment.

Future annual minimum payments under all noncancelable operating leases are approximately as follows:

Year ended:	
2006	\$ 86,600
2007	88,600
2008	87,800
2009	82,600
Thereafter	-
	<u>\$345,600</u>

**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.

	2005			
	First	Second	Third	Fourth
Total operating expenses	\$ 879,105	\$ 874,963	\$ 750,003	\$ 760,006
Net loss	(866,130)	(872,681)	(751,172)	(761,395)
Loss per share:				
Basic and Diluted	\$ (0.06)	\$ (0.06)	\$ (0.05)	\$ (0.05)

	2004			
	First	Second	Third	Fourth
Revenue	\$ -	\$ 44,235	\$ 118,642	\$ 33,333
Total operating expenses	544,461	723,202	745,561	1,307,738
Net loss	(537,440)	(667,662)	(613,770)	(1,259,016)
Loss per share:				
Basic and Diluted	\$ (0.04)	\$ (0.05)	\$ (0.04)	\$ (0.09)

**11. Subsequent Event**

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 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 January 6, 2008 to acquire one share of common stock at a price of \$0.60 per share.



## 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 23, 2006

ORAGENICS, INC.  
(Registrant)

By: /s/ Robert T. Zahradnik  
Robert T. Zahradnik, Chief Executive Officer and President

By: /s/ Paul A. Hassie  
Paul A. Hassie, Chief Financial Officer, Secretary and  
Treasurer (Principal Financial and 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/ Robert T. Zahradnik</u> Robert T. Zahradnik	Chief Executive Officer and President	March 23, 2006
<u>/s/ Paul A. Hassie</u> Paul A. Hassie	Chief Financial Officer	March 23, 2006
<u>/s David J. Gury</u> David J. Gury	Chairman	March 23, 2006
<u>/s/ Brian Anderson</u> Brian Anderson	Director	March 23, 2006
<u>/s/ George T. Hawes</u> George T. Hawes	Director	March 23, 2006
<u>/s/ Jeffrey D. Hillman</u> Jeffrey D. Hillman	Director	March 23, 2006

## Exhibit Index

### Incorporated by Reference

Exhibit Number	Exhibit Description	Form	File No	Exhibit	Filing Date	Filed Herewith
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	
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					
10.10	Equity Agreement between the Company and the University of Florida Research Foundation dated August 4, 1998 (including registration rights)	SB-2/A-2	333-100568	10.8	02/10/03	
10.11	Escrow Agreement between our principals, the Company and Computershare Trust Company	SB-2	333-100568	99.10	10/16/02	
10.12	Value Escrow Agreement between the Company, the University of Florida Research Foundation, Inc. and Computershare Trust Company	SB-2	333-100568	99.11	10/16/02	
10.20+	2002 Stock Option and Incentive Plan	SB-2	333-100568	99.16	10/16/02	
10.21+	Amendment No. 1 to the 2002 Stock Option and Incentive Plan	DEF 14A	333-100568	App. E	04/22/04	
10.31	Proprietary Information Agreements between the Company, Brian Anderson, Robert Zahradnik and Howard Kuramitsu,	SB-2	333-100568	99.23	10/16/02	
10.32*	Proprietary Information and Invention Agreement between the Company and Jeffrey D. Hillman	SB-2	333-100568	99.4	10/16/02	
10.43*	Employment agreement of Jeffrey Hillman	10-KSB	000-50614	10.43	03/17/04	
10.44*	Employment agreement of Paul Hassie	10-KSB	000-50614	10.44	03/17/04	
10.45	Memorandum of Agreement - License Agreement between iviGene Corporation and the Company	10-QSB	000-50614	10.1	08/11/04	
10.46	Letter dated February 3, 2006 waiving iviGene license requirements for 2005	10-KSB	000-50614	10.46	3/8/06	
10.47	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	03/14/05	
10.48	Termination Agreement between Westrock Advisors, Inc. and Oragenics, Inc.	S-3	333-131015	10.1	1/13/06	
10.49	Agreement of Separation and Release between the Company and Mento S. Soponis	10-QSB	001-32188	10.1	08/11/05	
10.50	Employment Agreement of Robert Zahradnik	10-QSB	001-32188	10.2	08/11/05	
16.0	Letter regarding change in certifying accountant	8-K	001-32188	16.0	08/29/05	
23.1	Consent of Kirkland Russ Murphy & Tapp, PA					X
23.2	Consent of Ernst & Young LLP					X



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31.1	Rule 13a-14(a)/15d-14(a) Certification	X
31.2	Rule 13a-14(a)/15d-14(a) Certification	X
32.1	Section 1350 Certifications	X
32.2	Section 1350 Certifications	X

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\* management contract

+ compensatory plan or arrangement

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**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 February 15, 2006, with respect to the 2005 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. 1 to the Registration Statement on Form S-3 to Form SB-2 (No. 333-100568) and related Prospectus of Oragenics, Inc. for the registration of 297,724 shares of its common stock issuable upon exercise of warrants; and
- (iii) Registration Statement (Form S-3 No. 333-131015) and related Prospectus of Oragenics, Inc. for the registration of 7,205,000 shares of its common stock.

of our report dated February 15, 2006, 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, PA

Certified Public Accountants  
Clearwater, Florida  
March 23, 2006

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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 January 28, 2005, with respect to the 2004 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. 1 to the Registration Statement on Form S-3 to Form SB-2 (No. 333-100568) and related Prospectus of Oragenics, Inc. for the registration of 297,724 shares of its common stock issuable upon exercise of warrants; and
- (iii) Registration Statement (Form S-3 No. 333-131015) and related Prospectus of Oragenics, Inc. for the registration of 7,205,000 shares of its common stock:

of our report dated January 28, 2005, with respect to the financial statements of Oragenics, Inc. included in this Annual Report (Form 10-KSB) of Oragenics, Inc.

/s/ Ernst & Young LLP

Certified Public Accountants  
Tampa, Florida  
March 23, 2006

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## CERTIFICATION

I, Robert T. Zahradnik, certify that:

1. I have reviewed this amended annual report on Form 10-KSB/A 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 23, 2006

By: /s/ Robert T. Zahradnik

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Robert T. Zahradnik  
(principal executive officer)

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## CERTIFICATION

I, Paul A. Hassie, certify that:

1. I have reviewed this amended annual report on Form 10-KSB/A 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 23, 2006

By: /s/ Paul A. Hassie

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Paul A. Hassie  
Chief Financial Officer  
(principal financial officer)

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

In connection with the Annual Report of Orogenics, Inc. (the "Company") on Form 10-KSB/A for the period ended December 31, 2005 as filed with the Securities and Exchange Commission on the date here of (the "Report"), I, Robert T. Zahradnik, 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 23, 2006.

/s/ Robert T. Zahradnik  
Robert T. Zahradnik  
Chief Executive Officer

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

In connection with the Annual Report of Oragenics, Inc. (the "Company") on Form 10-KSB/A for the period ended December 31, 2005 as filed with the Securities and Exchange Commission on the date here of (the "Report"), I, Paul A. Hassie, 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 23, 2006.

/s/ Paul A. Hassie  
Paul A. Hassie  
Chief Financial Officer

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