ORAGENICS

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ORAGENICS, INC.

2003 Annual Report

ORAGENICS

BOARD OF DIRECTORS

Jeffrey D. Hillman
Chairman, Chief Scientific Officer

Mento A. Soponis
President, Chief Executive Officer

Brian Anderson
Former President and Chief Executive Officer
Cognetix, Inc.

David J. Gury
Founding CEO, Retired
Nabi Biopharmaceuticals

Brian McAlister
President
Cornet Capital Corporation

Robert T. Zahradnik
Chairman, Chief Executive Officer
Advanced Clinical Technologies, Inc.

CORPORATE OFFICERS

Mento A. Soponis
President, Chief Executive Officer

Jeffrey D. Hillman
Chairman, Chief Scientific Officer

Paul A. Hassie
Secretary, Treasurer, Chief Financial Officer

CORPORATE INFORMATION

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12085 Research Drive
Alachua, FL 32615
Tel: (386) 418-4018
Fax: (386) 462-0875
Email: info@oragenics.com
www.oragenics.com

General Counsel
Shumaker, Loop & Kendrick LLP
Tampa, Florida

Independent Auditors
Ernst & Young LLP
Tampa, Florida

Transfer Agent
Computershare
510 Burrard Street
Vancouver, BC V6C 3B9 Canada

Stock Listings
Toronto Stock Venture Exchange under the symbol ORA.U
Over the Counter Bulletin Board under the symbol OGEN

Visit our website at www.oragenics for additional copies of these reports or more information about Oragenics, Inc.

April 22, 2004

To our Shareholders:

It is my pleasure to welcome you to the Oragenics family. The past fifteen months have seen the beginning transformation of our company into a strong and vibrant biotechnology development organization. With your support, we completed our initial public offering in June and secured additional working capital through the exercise of our Series A warrants in December and our Series B warrants in March of 2004. Your investments in Oragenics are an expression of confidence and support that everyone in the company genuinely appreciates.

This funding has provided us with a foundation upon which to build and strengthen our company. Our founder and Chief Scientific Officer, Dr. Jeffrey Hillman, has committed his full-time services to the company. We have expanded our staff to fourteen people, including a seasoned Vice President of Product Development. Construction on our new facility has begun; we eagerly anticipate moving into our new home in August of this year.

We all remain focused and firmly committed to the implementation of our business strategy, which is to capture value with each product opportunity by advancing development into human trials and then considering strategic partnerships. Our development pathways are being clearly defined for each of our technologies. We will also continue to look at opportunistic situations for in-licensing that can increase our pipeline of product opportunities.

Replacement Therapy

Our goal is to begin a Phase I human clinical trial in 2004. The FDA has our IND on clinical hold pending additional safety studies. We completed a number of these studies during 2003 and submitted them to the FDA for their review. We presented our proposed protocol to the NIH Recombinant Advisory Committee at a public hearing last month and received a unanimous recommendation to go forward with the clinical trial. We have been granted a face-to-face meeting with the FDA later this month to discuss any remaining concerns the FDA may have concerning safety issues. We remain convinced that this technology has the potential to revolutionize dental care and create opportunity for long-term value.

Probiotic for Oral Health

Last August we determined that Dr. Hillman's idea for a probiotic product aimed at maintaining dental and periodontal health had encouraging commercial potential. We immediately filed a patent application to protect the idea. Initial pilot studies confirmed that the anticipated healthful effect of the proposed product could be achieved. In 2004 our goals are to complete final animal safety studies, develop a final product delivery form and initiate one human study to validate the product's performance.

The current probiotics market is targeted largely at digestive or immune system health. We expect our probiotic to be one of the first products designed for oral health and to have the potential to become a significant future revenue generator for Oragenics. The probiotics market is substantial in Japan and Europe. The North American market is beginning to accept the probiotic concept in growing numbers, and this market is expected to be a high-growth opportunity for our product in the years to come. We will look first for Asian and European partners to work with us to capture market share in their markets.

Mutacin 1140 Antibiotic

We are working on the production of our antibiotic molecule with the goal of designing a production method sufficient to produce at commercial scale. We will then undertake extensive pre-clinical studies in preparation for an IND submission. We will need to establish the route of administration for the drug. Given that our studies to date have shown no resistance to our drug by the pathogenic bacteria against which it has been tested, we believe our drug has the potential to meet a large and critical need in healthcare in combating drug-resistant bacterial infections. We are targeting our efforts to make that potential a reality.

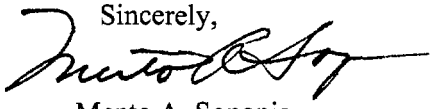
IVIAT-CMAT

IVIAT is a proprietary, novel approach called *In Vivo* Induced Antigen Technology for gene target identification for therapeutics and diagnostics. Change Mediated Antigen Technology (CMAT) is a revolutionary approach for identifying gene targets associated with the onset and progression of cancerous processes. Dr. Hillman is a co-inventor of these technologies, and he co-founded iviGene Corporation to develop them. Oragenics succeeded in licensing these technologies from iviGene for certain fields of use, including cancer, non-human applications and *mycobacterium tuberculosis*. The National Institute for Allergies and Infectious Diseases granted a $100,000 Phase I SBIR to Oragenics to fund initial research looking for gene targets leading to diagnostics and treatments for TB infections.

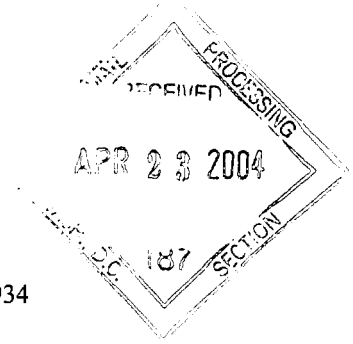
IVIAT and CMAT provide us with a potential platform to develop new diagnostics and therapies, particularly for cancer. It is important to appreciate that therapeutic products arising from these technologies are longer term developments; diagnostic products may, however, offer shorter-term potential for revenue generation.

Ultimately, success for any company depends on its personnel and their performance. We are indeed fortunate to have first-rate talent, and we will continue to recruit superior people as we grow. I must express my appreciation for the dedication and enthusiasm of our people I witness every day. We will continue to move forward in the years ahead to execute our strategy and realize the potential successes we see before us.

Sincerely,



Mento A. Soponis



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

FORM 10-KSB

[X] Annual report under Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended December 31, 2003

[ ] 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	59-3410522
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
12085 Research Drive, Alachua, Florida	**32615**
(Address of Principal Executive Offices)	(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act: None

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. [X] 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 revenues of registrant for the fiscal year ended December 31, 2003 were $0.00.

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of March 12, 2004 was approximately $18,619,564 based upon a last sales price of $3.45 as reported by TSX Venture Exchange.

As of March 12, 2004 there were 13,407,530 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Registrant's Definitive Proxy Statement for its 2004 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_

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PART I

PART II

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PART I

Item 1. Description of Business.

This description contains certain forward-looking statements that involve risks and uncertainties. The Company's 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. The Company assumes no obligation to update any forward-looking statements contained herein.

Overview

Oragenics, Inc. was incorporated under the laws of Florida on November 6, 1996. We commenced operations in 1999.

We, Oragenics, Inc., are a 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 aim is to in-license and develop products through human proof-of-concept (Phase I or II of the FDA's regulatory process discussed below) prior to partnering with major pharmaceutical, biotechnology or healthcare product firms for advanced clinical development and commercialization. We have generated no revenues from operations during the last two years. All of our revenues have been from a sponsored research agreement which has expired; none have been from sales.

We are currently developing the following products, each of which addresses potential market opportunities:

- **Replacement Therapy** is a single, painless topical treatment that has the potential to offer life-long protection from most tooth decay. We expect to initiate Phase I safety studies with this product during 2004.

- ***Mutacin* 1140** is a novel antibiotic with activity against essentially all Gram-positive bacteria including vancomycin-resistant *Staphylococcus aureus*. Researchers have not succeeded to-date in demonstrating bacterial resistance to this antibiotic. We are currently in early preclinical stages of development for *Mutacin* 1140.

- **"Probiotic" technology** employs naturally occurring beneficial bacteria to promote oral and periodontal health. Probiotics are widely employed in Japan and Europe and acceptance in the United States is growing. Such products may be marketed as "health supplements" without the need for regulatory filings, offering the opportunity for near-term commercialization.

- **"Other" technologies** include other technologies that we may develop from our research and development activities or that we may license, including our recently licensed technology called *in vivo* induced antigen technology that enables 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.

We amended our articles of incorporation on May 8, 2002, in order to change our name from Oragen, Inc. to Oragenics, Inc. and to increase our authorized capital from 100,000 shares of common stock to 100,000,000 shares of common stock and 20,000,000 shares of preferred stock. Our registered office is located at 4730 S.W. 103rd Way, Gainesville, Florida 36208, and our headquarters are located at 12085 Research Drive, Alachua, Florida 32615.

Our Business Strategy

For our business to become profitable and competitive, our technologies must be approved for production and sale by the Federal Food and Drug Administration ("FDA"). Our present strategy for financing the clinical trials which will be necessary as part of the FDA approval process involves conducting the research and development

work in respect of our technologies through Phase I clinical trials. Assuming we complete Phase I clinical trials successfully, we intend to consider the sublicense of our licensed, patented technologies to pharmaceutical companies, which would be responsible for completing Phase II and III clinical trials and for undertaking the new drug applications. We anticipate that such sublicenses would provide for payment of fees to us, a portion of which would be payable upon execution and the balance of which would be payable upon achievement of product development milestones, and for payment to us of royalties from sales. This strategy would serve to avoid the high costs of Phase II and III trials we would otherwise have to pay, and generate revenues from our technologies sooner than if we conducted those trials ourselves. There can be no assurance that we will be able to enter into such sublicenses on terms favorable to us, or at all.

If we are successful in sublicensing one or more of our technologies, we intend to seek to license promising new technologies in our fields of expertise. We hope to be able to obtain licenses of other technologies firstly from the University of Florida, with which a number of our directors and officers have a strong relationship, and secondly from other universities.

Our Technologies

Replacement Therapy

Background. Our licensed, patented replacement therapy technology is the fruit of 25 years of research by our founder and chief scientific officer, Dr. Jeffrey Hillman. In the course of his research at Forsyth Dental Center and the University of Florida, Dr. Hillman isolated a strain of a species of bacteria naturally resident on teeth with the ability to out-compete and displace other strains of that species. The strains of that species typically found on teeth produce lactic acid, which causes tooth decay. Dr. Hillman, through recombinant DNA technology, succeeded in replacing a gene in the strain of bacteria with the ability to out-compete. That gene is responsible for producing lactic acid. Dr. Hillman replaced it with a gene that causes that strain to produce other harmless, non-decay-causing substances. The University of Florida has obtained a patent in respect of that genetically altered strain, and we have obtained an exclusive license of that patent from the University of Florida. Our replacement therapy technology may prove to be a new treatment for human tooth decay.

In 2000, we entered into a sponsored research agreement with respect to our replacement therapy technology. Under that agreement, we were paid $357,787 in respect of research and development costs. The agreement allowed our sponsor the exclusive option to negotiate a sublicense of our replacement therapy technology. Our sponsor did not exercise the option, and it has expired. We have had no further discussions or negotiations with the sponsor since the agreement expired.

Market Opportunity. The dental care market in the United States is estimated to be $58 billion annually. Of this sum, a considerable portion is related to tooth decay. Since the introduction of fluoride, no significant technology has been introduced to prevent tooth decay. Our licensed, patented replacement therapy technology may prove to be the first new treatment for human tooth decay in many years.

Technical Background. Many different types of bacteria reside in everyone's mouth. *Streptococcus mutans* (S. *mutans*) is a bacteria that resides on nearly everyone's teeth. This bacteria converts sugar that we eat into lactic acid. Lactic acid erodes the tooth's enamel and causes the great majority of tooth decay. Our replacement therapy technology consists of a genetically modified strain of *S. mutans* that does not produce lactic acid. Our strain of S. *mutans* produces tiny quantities of a substance known as *mutacin* 1140, which allows our strain to out-compete the strain of S. *mutans* which is naturally resident on a person's teeth. Our strain eliminates the resident strain of S. *mutans* and replaces it in the mouth. It will be administered as a pharmaceutical composition by dentists during office visits. Because our strain out-competes resident strains on teeth, one treatment may last for a long time. Preliminary studies conducted by our Chief Scientific Officer, Dr. Jeffrey Hillman have shown our Replacement

Therapy technology to be effective and non toxic in animals.[1] We hope that further testing will confirm these results. We have not yet conducted human clinical trials.

Animal Studies. Dr. Jeffrey Hillman, our Chief Scientific Officer, and others have conducted animal studies of the effectiveness of our replacement therapy technology in rats at the Forsyth Institute, the University of Florida and our company from 1976 to 2002.[2] In the most recent of these studies, our strain of S. *mutans* and wild-type strains of *S. mutans* were grown in culture in the presence of sugar. After careful analysis of the culture, it was found that the wild strain made lactic acid almost exclusively from the metabolism of sugar. It also made very small amounts of other acids and the non-acidic compounds, ethanol and acetoin. By contrast, our strain made mostly the non-acidic compounds, ethanol and acetoin, from metabolism of the sugar. Our strain produced absolutely no detectable lactic acid. We then infected 2 identical groups of conventional rats with either the wild strain or our strain. A third identical group of rats was not infected and served as a control group. After feeding the rats a diet containing sugar for 8 weeks, the teeth of the rats were carefully inspected to determine their incidence and severity of tooth decay. It was found that animals infected with our strain had no more tooth decay than did the control group animals. Both the group infected with our strain and the control group had only half the tooth decay experienced by the wild strain.

Dr. Hillman and others also conducted a 6 month toxicity study in rats. They infected a group of rats with our licensed, patented strain of *S. mutans*. No gross or histological side effects were found during colonization of the rats over this prolonged period.

These studies provide scientific evidence of the effectiveness of our licensed, patented strain of *S. mutans* in preventing tooth decay, and of its non-toxicity, in animals.

Manufacturing. The manufacturing methods for producing our strain of *S. mutans* to be used in our replacement therapy technology will be standard fermentation methods. These involve culturing bacteria in large vessels, and harvesting them when mature by centrifuge or filtration. The cells will then be suspended in a pharmaceutical medium appropriate for application in the human mouth. These methods are commonplace and readily available within the pharmaceutical industry. We intend to consider sublicensing our replacement therapy technology to a pharmaceutical company. If we are successful in doing so, the sublicensee company will manufacture and market our replacement therapy technology.

Method of Administration. We expect, if we are successful in obtaining the necessary regulatory approvals, that the product based on our replacement therapy technology will be a liquid rinse which will be applied to a patient's teeth by a dentist. We expect that it will be available by prescription only.

Competition. We do not know of any direct competitors with our licensed, patented replacement therapy technology. We understand that certain companies have been researching vaccines to inhibit the growth of *S. mutans*. However, every vaccine has drawbacks, including induced-heart-reactive antibodies in animals. Major studies would be required to establish that elimination of naturally occurring bacteria such as *S. mutans* from the mouth will not create serious, unintended consequences. 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 in these areas 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 tooth sealants and fluoride treatments administered by dentists, and fluoride based toothpastes. Some of our competitors will include Colgate, Procter & Gamble, Unilever,

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[1] Hillman et al, Construction and Characterization of an Effector Strain of *Streptococcus mutans* for Replacement Therapy of Dental Caries, *Infection and Immunity (2000)* Vol.68, No. 2.

[2] Hillman et al, Construction and Characterization of an Effector Strain of *Streptococcus mutans* for Replacement Therapy of Dental Caries, *Infection and Immunity (2000)* Vol.68, No. 2.

GlaxoSmithKline and Dentsply. All of these companies are much larger and have far greater technical and financial resources than us. It is our intention to compete in the market for dental care products by obtaining a strategic partner with a dedicated sales force in the dental office market. There can be no assurance we will be able to obtain any such partner. If we are unable to secure such a strategic partner, we will seek to enter into a contract manufacturing arrangement with a pharmaceutical manufacturing company, and to enter into distribution agreements with dental product distributing companies. There can be no assurance we will be able to enter into any such arrangement.

License. We hold our patented replacement therapy technology under license from the University of Florida Research Foundation, Inc. The license is dated August 4, 1998. It was amended on September 15, 2000, July 10, 2002, September 25, 2002 and March 17, 2003. It provides us with an exclusive world wide license to make, use and sell products and processes covered by Patent No. 5,607,672. This patent covers the genetically altered strain of *S. mutans* which does not produce lactic acid, a pharmaceutical composition for administering the genetically altered strain, and the method of preventing tooth decay by administering the strain. 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 we make to the products and processes covered by the patent. Our license is for the period of the patent, subject to the performance of terms and conditions contained therein. The patent is dated March 4, 1997, and will expire on March 3, 2014.

Under the license, we have entered into an Equity Agreement with the University of Florida Research Foundation, Inc. under which we have issued as partial consideration for our license 599,940 shares of our common stock which is 4.5% of our total outstanding shares as of December 31, 2003. We are obligated to pay 5% of the selling price of our products to the University of Florida Research Foundation, Inc. If we sublicense the license, we are obligated to pay 20% of all amounts we receive from the sublicensee to the University of Florida Research Foundation, Inc. On December 31, 2005 and each year thereafter we are obligated to make a minimum royalty payment of $50,000. We spent at least an aggregate of $600,000 in 2003 and are obligated to spend or cause to be spent an aggregate of $1,000,000 in each calendar year following 2003 on the research, development and regulatory prosecution of our replacement therapy and *mutacin* 1140 technologies together, 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 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 patents beyond $105,000. We have paid $100,000 to UFRF for the patent expenses already incurred.

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. We have obtained liability insurance in the amount of $1,000,000. This policy expires on June 24, 2004. There is no assurance that we can obtain continued coverage on reasonable terms.

Intellectual Property Matters. We do not hold any patents on our replacement therapy technology. Our rights to this technology flow from our license with the University of Florida Research Foundation, Inc.

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. Their notification did not state that they intended to pursue legal remedies. Management of our company does not believe the gene in question infringes that patent. We have sent them correspondence setting out our position. We have heard nothing further from them.

Regulatory Status. We submitted an investigational new drug application for our replacement therapy technology in 1998. The FDA placed our application on clinical hold on December 3, 1998 pending resolution of concerns related to transmission of our genetically modified strain of *S. mutans* by those treated with it to others who have not been treated with it, possible reversion of our strain to an acid-producing strain, and the possibility of genetic transfer of the ability to produce *mutacin* 1140 from our strain to other forms of bacteria which occur naturally in human beings. The clinical hold order was issued because the FDA believed our application did not contain sufficient information to allow it to assess the risks to the subjects in our proposed human clinical studies. We may not commence Phase I human clinical studies of our replacement therapy technology until the clinical hold is lifted. We have amended our first investigational new drug application three times to respond to the FDA's concerns. We filed a new investigational new drug application in March of 2003. This investigational new drug application has also been placed on hold until we satisfy the FDA's safety concerns. As a result of the research and development work we have done to respond to the FDA's concerns, we have gained valuable knowledge about the use and administration of our replacement therapy technology.

On October 23, 2000, we met with representatives of the FDA's Center for Biological Evaluation and Research ("Center") to discuss their concerns. At that meeting, we and the Center's representatives discussed design of the preclinical experiments which the FDA would require in response to the clinical hold. In order to address the FDA's concerns, we developed a modification of our licensed, patented strain of *S. mutans*. The modified strain has a nutritional requirement for a substance known as D-alanine. If D-alanine is withdrawn from its diet, it will die. Conceptually, because of the nutritional requirement of our modified strain, if it is transmitted to those who have not been treated with it, it will die, unless D-alanine is administered regularly. D-alanine will be supplied to the trial subjects with mouth rinse. D-alanine is not normally found in the human diet, which is why it has been selected for our study as a potential recall mechanism. The maintenance system will be by regular mouth rinse, the amount and frequency of which will be determined in the clinical trials. In the rat animal model used, total eradication was not achieved even when D-alanine was removed from the diet. We hypothesize this occurred because the rats were able to feed our strain with D-alanine obtained through cross-feeding from bacteria in their feces, which the rats consumed. We commenced these studies in 2001. The results of the studies can be summarized as follows. The modifications to produce D-alanine dependence had no effect on the modified strain's production of lactic acid or *mutacin* 1140, which suggests that the modified strain compares identically to our original strain with respect to its ability to out-compete natural strains and non-production of tooth decay. No adverse side effects were observed in laboratory rats infected with the modified strain, and exposed to D-alanine in their drinking water, for five months. The potential for reversion of the modified strain to lactic acid production and for transmission of the modified strain to those not treated with it were demonstrated to be very low. Transfer of DNA from our strain to other strains was shown to be statistically extremely low because of the genetic modification made to prevent any DNA transfer.

On March 19, 2003, we submitted a new investigational new drug ("IND") application to the FDA in respect of our newly modified strain of our licensed, patented strain of *S. mutans*. It incorporates our previous investigational new drug application by reference. Our new investigational drug application refers to an ongoing eradication animal study and indicates that results from that study will be submitted as an amendment when it is complete. On April 18, 2003, the FDA notified us by telephone that it was placing our new investigational new drug application on clinical hold. We spoke again by telephone with the FDA on April 30, 2003. The FDA has indicated that, in order to lift the clinical hold, it wants certain of the experimental protocols for our human clinical trials described in our new investigational new drug application redesigned to include a full physical examination of subjects' spouses, and to include more extensive testing of subjects' spouses, including six months post-trial follow-up. The FDA also required additional preclinical animal toxicity studies in which our newly modified strain of *S. mutans* and D-alanine were ingested by rats together and separately, and studies demonstrating total eradication of our newly modified strain of *S. mutans* from test animals. The FDA issued a formal letter outlining its requests on May 15, 2003 and the requested studies were completed in December 2003. We filed an amendment to our IND with the results of those studies in January 2004. The FDA's primary safety concern is the theoretical risk of our strain reverting to acid production or of our strain's DNA being transferred to other naturally occurring organisms. Until the FDA is satisfied this theoretical risk is not a safety threat, the FDA will want to see total eradication of the strain from animals and from clinical subjects following the first human studies. Before allowing our clinical study to proceed, the FDA will submit our application and protocol to the FDA's Vaccines and Related Biological Product Advisory Committee and/or the National Institute of Health's Recombinant DNA Advisory Committee ("NIH

RAC") for their recommendations regarding concerns of release of the bacteria into the environment. We are scheduled to appear before the NIH RAC on March 10, 2004.

The D-alanine dependent strain was designed to meet the FDA's requirement for total eradication of the strain in the unlikely event that either of two adverse events is observed during clinical trials. In particular, if the strain somehow reacquired the ability to make lactic acid, this would qualify as a reason to eradicate it from the test subjects. Also, if it is observed that the strain can be transmitted from treated subjects to untreated subjects, this would also qualify as a reason to eradicate it. In several rat studies performed to test if eliminating D-alanine from the diet resulted in eradication, the strain was reduced significantly in numbers but not totally eradicated. We hypothesize that the rats continued to supply the strain with D-alanine by eating their feces. Many bacteria found in feces produce D-alanine naturally. This route of D-alanine supplementation is not a concern in human subjects. We expect that the absence of D-alanine in the human diet will enable us to achieve total eradication of the strain in human subjects by stopping the twice-daily rinses with D-alanine. The FDA has acknowledged the likelihood of our hypothesis, but would like us to devise a method that will assure eradication of the strain in animals. We conducted a study in which animals infected with the strain have been taken off their D-alanine supplementation and are also being treated twice daily by topical application of a commercially available chlorhexidine mouth rinse. The measured levels of the strain fell steadily over the course of the study to non-detectable levels. On February 5, 2004, the FDA informed the Company that our IND remained on clinical hold since the FDA still wants to see total eradication of our strain and has suggested the use of antibiotic treatments to accomplish total eradication. On February 24, 2004 we requested a face-to-face meeting with the FDA in early April 2004 to discuss and resolve their concerns and allow us to proceed with the Phase I clinical trial. If the FDA removes the clinical hold on our investigational new drug application, we will be permitted to commence human clinical trials of our licensed, patented replacement therapy technology. The cost per patient is estimated at $10,000.

Our patient estimate for each phase of the clinical trial process for the replacement therapy technology is:

Phase I	Combined Phase II/III
24-30	**3,000**

***Mutacin* 1140**

Background. Our second licensed, patented technology is *mutacin* 1140, an antibiotic peptide which is produced by our strain of *S. mutans*. It was discovered by Dr. Hillman in the course of his research into our replacement therapy technology. It is a broad spectrum antibiotic which has demonstrated potency, in laboratory studies against all Gram-positive bacteria against which it has been tested.[3] The testing was conducted by Dr. Jeffrey Hillman, our Chief Scientific Officer and a significant shareholder of our company, together with others at the University of Florida and at our laboratories in 1998 and 1999.

Introduction to Antibiotics. Before the development of effective modern antibiotics, serious bacterial infections were as feared as AIDS is today. Since development of antibiotics, they have been less feared. However, society may soon be faced once again with the prospect of bacterial and fungal diseases becoming major causes of death. Resistance to drugs which are effective against bacterial and fungi is increasing, and at a faster pace than development of drugs which are effective against them.

Market Opportunity. Since the initial discovery and introduction of antibiotics some 50 years ago, doctors and researchers have found that bacteria are efficient at developing or acquiring mechanisms of defense. Until recently, antibiotic resistance appeared to be a relatively minor nuisance. Drug manufacturers were confident they could modify the structure of existing drugs such as penicillins, cephalosporins and tetracyclines faster than bacteria are able to develop drug resistance. Unfortunately, this has not proved to be the case. The numbers of drug resistant bacteria are on the rise, and the development of new treatment options has not kept pace. The single greatest

[3] Hillman et al, Constructin and Characterization of an Effector Strain of *Streptococcus mutans* for Replacement Therapy of Dental Caries, *Infection and Immunity (2000)* Vol.68, No. 2.

problem in the use of antibiotics today is resistance by the disease causing organisms they are targeted against. The Center for Disease Control estimates that bacteria resistant to known antibiotics cause 44% of hospital infections. Drug resistant bacterial infections affect approximately 9 million people annually in the United States, resulting in some 60,000 deaths. Vancomycin, introduced in 1956, today serves as the last line of defense against certain life-threatening infections. Unfortunately, certain bacteria have developed strains which resist even vancomycin. Many experts caution we may soon see the return of the pre- antibiotic era.

Technical Background. Preliminary *in vitro*[4] laboratory studies conducted by Dr. Jeffrey Hillman have demonstrated *mutacin* 1140's effectiveness against all tested Gram-positive bacteria.[5] Gram-positive bacteria are a class of bacteria that cause a large variety of human infections. We hope further testing will confirm these results. *mutacin* 1140 belongs to a small class of antibiotics called lantibiotics. Lantibiotics differ from other antibiotics because they contain an unusual amino acid. They are able to kill a wide variety of bacteria by punching holes in their cellular membranes.

Nisin is a lantibiotic that has been widely used for decades as a food preservative. We will study *mutacin* 1140 first for its potential application in the clinical treatment of various infectious diseases. In laboratory studies it has been effective at killing a broad spectrum of bacteria, including the streptococci that cause pharyngitis (strep throat) and pneumonia. It is also effective against Staphylococci, which cause various sorts of infection.[6] At a later time, we may undertake the further study of *mutacin* 1140 for use as a food preservative.

Mutacin 1140 has other properties that indicate its potential usefulness and acceptance as an antibiotic. The most striking of these is the observation that these pathogenic bacteria based on testing to date seem to have great difficulty in becoming resistant to it.[7] It is a small, modified peptide that is expected to be absorbed by an oral route of administration. Preliminary animal testing conducted by Dr. Hillman indicates that it does not readily provoke an immune response, indicating that it may not be very allergenic.[8]

Laboratory Testing. Dr. Hillman and others have conducted laboratory studies at the Forsyth Institute, the University of Florida and our company to test the efficacy of *mutacin* 1140 as an antibacterial agent from 1984 to the present.[9] To test the ability of *mutacin* 1140 to kill bacteria, standard microbiological testing methods were employed. *Mutacin* 1140 was purified and incorporated into growth medium at different concentrations. This 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 that was observed to inhibit growth of the test bacterium, was recorded.

Purified *mutacin* 1140 was found to have a very broad spectrum of activity. It was found to kill all Gram-positive bacteria tested at concentrations comparable to many therapeutically effective antibiotics. The bacteria

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[4] Studies carried out in isolation from a living organism.

[5] Wojciehowski, Byers and Hillman, Regulation of Expression of the Structural Gene for *Mutacin* 1140 and Characterization of its Antibacterial Properties (2002), submitted for publication.

[6] Wojciehowski, Byers and Hillman, Regulation of Expression of the Structural Gene for *Mutacin* 1140 and Characterization of its Antibacterial Properties (2002), submitted for publication.

[7] Wojciehowski, Byers and Hillman, Regulation of Expression of the Structural Gene for Mutacin 1140 and Characterization of its Antibacterial Properties (2002), submitted for publication and Hillman et al, Isolation of a *Streptococcus mutans* Strain Producing a Novel Bacterium, *Infection and Immunity* (1984) Vol. 44, No. 1, pp. 141-144.

[8] Wojciehowski, Byers and Hillman, Regulation of Expression of the Structural Gene for Mutacin 1140 and Characterization of its Antibacterial Properties (2002), submitted for publication and Hillman el al, Isolation of a *Streptococcus mutans* Strain Producing a Novel Bacterium, *Infection and Immunity* (1984) Vol. 44, No. 1, pp. 141-144.

[9] Wojciehowski, Byers and Hillman, Regulation of Expression of the Structural Gene for Mutacin 1140 and Characterization of its Antibacterial Properties (2002), submitted for publication and Hillman el al, Isolation of a *Streptococcus mutans* Strain Producing a Novel Bacterium, *Infection and Immunity* (1984) Vol. 44, No. 1, pp. 141-144.

found to be sensitive included those responsible for human infections such as streptococcal pharyngitis ("strep throat"), the predominant type of human pneumonia, and bacterial endocarditis.

A particularly interesting feature of *mutacin* 1140 is that none of the sensitive species of bacteria tested were able to acquire genetically stable resistance to purified *mutacin* 1140. Acquired resistance to antimicrobial agents by strains of bacteria which cause illness in humans has become a major problem in the recent past.

Manufacturing. We have not yet identified the production method for *mutacin* 1140.

Method of Administration. We expect that, if we are successful in identifying a production method for *mutacin* 1140 and obtaining the necessary regulatory approvals, any products based on our *mutacin* 1140 technology will be antibiotic drugs, available only by prescription. We do not yet know the method by which products based on *mutacin* 1140 will be administered to patients. They may be administered orally, topically or by injection.

Competition. We believe that the current direct competitors with our *mutacin* 1140 technology are antibiotic drugs such as vancomycin and others. There are strains of bacteria which have developed resistance even to vancomycin. We believe that there is ample room in the marketplace for new antibiotic drugs.

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 potential competitors of ours are taking approaches quite different from ours to the development of antibiotic drugs. These include traditional natural products screening, genomics to identify new antibiotic 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. The commercial success of our *mutacin* 1140 technology will depend on our ability and the ability of our sublicensees to compete effectively in all these areas. There can be no assurance our competitors will not succeed in developing products which are more effective than *mutacin* 1140, or which would render *mutacin* 1140 obsolete and non competitive.

If we are able to find a suitable method for producing *mutacin* 1140 and to obtain the necessary regulatory approvals, any products based on our *mutacin* 1140 technology will compete against a large number of prescription antibiotics currently on the market, and against new antibiotic products which 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. It is our intention 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 we will be able to obtain any such partner. If we are not, we will be obliged to develop our own channels of distribution for products based on *mutacin* 1140. There can be no assurance we will be able to do so.

License. We hold our patented *mutacin* 1140 technology under license from the University of Florida Research Foundation, Inc. dated June 22, 2000. It was amended on September 15, 2000, July 10, 2002, September 25, 2002 and March 17, 2003. It provides us with an exclusive world wide license to make, use and sell products and processes covered by patents no. 5,932,469 and 6,391,285. These patents together cover *mutacin* 1140, a pharmaceutical preparation containing *mutacin* 1140, and the method of controlling growth of bacteria by use of *mutacin* 1140. Our license is for a period of the patent, subject to the performance of terms and conditions contained therein. 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 we make to the products and processes covered by the patent. Patent No. 5,932,469 is dated August 3, 1999 and expires August 2, 2016, and Patent No. 6,391,285 is dated May 21, 2002 and expires May 20, 2019. Under the terms of the license, we are obligated to pay 5% of the selling price of our products to the University of Florida Research Foundation, Inc. If we sublicense the license, we are obligated to pay 20% of the amounts we receive from the sublicensee to the University of Florida Research Foundation, Inc. In calendar year 2005 and each year thereafter we are obligated to make a minimum royalty payment of $50,000. We spent at least an aggregate of $600,000 in 2003 and are obligated

to spend or cause to be spent an aggregate of $1,000,000 in each calendar year following 2003 on the research, development and regulatory prosecution of our replacement therapy and *mutacin* 1140 technologies together, 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 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. We have obtained liability insurance in the amount of $1,000,000. This policy expires on June 24, 2004.

Intellectual Property Matters. We do not hold any patents on our *mutacin* 1140 technology. Our rights to this technology flow from our license with the University of Florida Research Foundation, Inc.

We are aware that the University of Laval has obtained a patent in respect of a mutacin antibiotic similar to *mutacin* 1140. It is our view that this patent and our licensed patent do not infringe on each other. The University of Florida Research Foundation, Inc. obtained its patent in respect of *mutacin* 1140 before the University of Laval obtained its patent. Nevertheless, it is possible our licensed patent may infringe on the University of Laval's patent. If so, we may have to incur substantial costs related to sublicensing the University of Laval's patent, or if we are unable to negotiate a sublicense, we may be exposed to litigation from the University of Laval.

Regulatory Status. We have not yet submitted an investigational new drug application to the FDA for our *mutacin* 1140 technology, because we have not yet found a method to produce it in quantities necessary to undertake such studies. We have hired two senior scientists dedicated to creating a satisfactory production method. We hope to complete development of such a method within 6 to 9 months.

Our patient estimate for each phase of the clinical trial process for our *mutacin* 1140 technology is:

Phase I	**Phase II/III**
24-30	500 - 1,000

Probiotic Technology

Background. Probiotics employ naturally occurring bacteria to confer a health benefit when administered in adequate amounts. Probiotics are widely accepted in Japan and Europe and acceptance in the United States is growing. The uses of yogurt containing live *Lactobacillus* cultures to improve digestion, immune system support or vaginal and urinary tract health are examples of common probiotic applications. Dr. Hillman has capitalized on his extensive research to create a probiotic product that is intended to maintain dental and periodontal health.

Market Opportunity. Probiotics have been targeted at improving the digestive system for many years, and they have broad acceptance in Japan and Europe. The world market has been estimated at greater than $3 billion in annual sales. If successfully developed, our probiotic treatment will be one of the first probiotic products marketed for the maintenance of oral health.

Technical Background. We have identified three natural strains of bacteria that can be employed as a probiotic product. Our laboratory and animal studies have demonstrated the ability of these organisms to maintain a healthy oral environment by creating a healthful balance of total bacteria, including a reduction in the numbers of bacteria that are the causative agents of periodontal disease and tooth decay.

Laboratory Testing. Research by Dr. Hillman 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 (gum) disease. The beneficial bacteria are called *Streptococcus oralis* and *Streptococcus uberis.* These bacteria have been shown to inhibit the growth of disease-causing bacteria both in the laboratory and in animal models of infection.[1,2] Analysis of data from a number of laboratories indicated that the presence of *S. oralis* and *S. uberis* provided a good indication of the health of the gums.[3] When these bacteria are absent from sites in the gums, the sites are much more prone to disease. In order to maintain a healthy balance of bacteria in the gums, Oragenics will provide a probiotic product that contains a mixture of *S. oralis* and *S. uberis.*

Most human tooth decay has been shown to be caused by *Streptococcus mutans,* which lives on nearly everyone's tooth surfaces and converts sugar in their diet to lactic acid. The lactic acid erodes the mineral in enamel and dentine, weakening the tooth and ultimately resulting in decay. Research by Dr. Hillman has led to the discovery of a particular strain of *Streptococcus rattus* that is naturally deficient in its ability to produce lactic acid. Therefore, this strain of *S. rattus* was shown to be unable to cause tooth decay.[4] Because *S. rattus* is very closely related to *S. mutans,* we believe that daily treatment with this beneficial strain could significantly reduce the numbers of tooth decay-causing *S. mutans* by competing for nutrients and attachment sites on the tooth surface. This belief has been tested in laboratory animals and was confirmed. Therefore, the Oragenics probiotic will contain a mixture of three natural bacteria that includes lactic acid-deficient *S. rattus* strain for the maintenance of dental health, in addition to the *S. oralis and S. uberis* strains for the maintenance of periodontal health.

Oragenics is currently performing acute and 3 month chronic toxicity testing in laboratory rats. Further work will involve studies to determine an appropriate and stable delivery system, and to determine the optimum dosage levels in human clinical trials.

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[1] Socransky et al., Associations Between Microbial Species in Subgingival Plaque Samples. Oral Microbiology and Immunology *(1987)* Vol.3:1-7.

[2] Hillman et al., Interaction Between Wild-type, Mutant and Revertant Forms of the Bacterium *Streptococcus sanguis* and the Bacterium *Actinobacillus actinomycetemcomitans In Vitro* and in the Gnotobiotic Rat. Archives of Oral Biology *(1988)* Vol.33:395-401.

[3] Socransky et al., Associations Between Microbial Species in Subgingival Plaque Samples. Oral Microbiology and Immunology *(1987)* Vol.3:1-7.

[4] Johnson et al., Cariogenic Potential I*n Vitro* in Man and *In Vivo* in the Rat of Lactate Dehydrogenase Mutants of *Streptococcus mutans*. Archives of Oral Biology Vol.25:707-713.

Manufacturing. The manufacturing methods for producing our probiotic strains will be standard fermentation methods. These involve culturing bacteria in large vessels and harvesting them when mature by centrifuge or filtration. These methods are commonplace and readily available within the pharmaceutical industry.

Method of Administration. We expect that the product will be self-administered by consumers as a mouth rinse.

Competition. Many companies sell probiotics that are principally designed for digestive health, vaginal health and immune system support. Our product will not compete directly with these companies. Recently researchers at the University of Hiroshima have published studies that indicate the *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.

Intellectual Property Matters. We filed a patent application for this technology in August of 2003. The Company owns the patent rights to this technology.

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 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.

Other Licensed Technology

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.

This technology platform was developed by our founder, chairman 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.

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. To support the research for this technology, we have 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 will support initial research to help us identify genes of *Mycobacterium tuberculosis* that are specifically induced during human infections with that pathogen.

Directors and officers of Oragenics have a significant ownership interest in IviGene Corporation. 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.

This licensed technology is in its early stages and will require further development which will require additional capital.

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.

Our Regulatory Consultants

We have engaged Health Decisions to provide us with consulting services relating to our regulatory affairs, and strategic and scientific advice related to our projects, under an agreement dated October 24, 2003. We have agreed to pay Health Decisions fees ranging from $550 to $2,200 per day. We will also pay Health Decisions out-of-pocket and other expenses incurred as a result of performing their services. Either party may terminate the agreement without cause at any time.

Marketing. We presently intend to seek to sublicense our replacement therapy and *mutacin* 1140 *technologies* to pharmaceutical companies for manufacturing and marketing. Assuming the new drug applications are successful, the sublicensees would be responsible for marketing products derived from our licensed, patented technologies. We intend to select sublicensees on the basis of their experience and financial success. We can offer you no assurances that we will obtain FDA approval for our technologies or that we will be successful in entering into sublicenses with established multinational companies.

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 and the performance of your investment.

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 and Mento Soponis. 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

In our last two fiscal years, we have spent $1,239,362 on research and development of our technologies.

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 our 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 eleven full time employees other than our three officers and directors.

Available Information

Our website is 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").

Item 2. Description of Property.

Our administrative office and laboratory facilities are located at 12085 Research Drive, Alachua, Florida 32615. This is also our mailing address. Our telephone number is (386) 418-4018. We lease this property from the University of Florida Research Foundation, Inc. pursuant to an operating lease from March 15, 2003 to March 14, 2004 that was amended on January 26, 2004 allowing us to continue occupancy on a month-to-month basis. The annual rental is $43,352.

In January 2004, we entered into an agreement with a real estate developer to have a facility built that we will lease from the developer. The agreement requires us to pay a deposit of $6,400 and provides for monthly lease payments of $6,400, exclusive of utilities, insurance and real estate taxes. We also anticipate paying approximately $250,000 for equipment to outfit the facility. We anticipate moving to the new facility in July 2004 or shortly thereafter.

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.

Oragenics, Inc. common stock is traded on the TSX Venture Exchange Tier 2 under the symbol ORA.U. The following sets forth the high and low closing bid prices for the common stock on the TSX Venture Exchange for the periods indicated. Such prices represent prices between dealers without adjustment for retail mark ups, mark downs, or commissions and may not necessarily represent actual transactions.

	2003	
	High	Low
COMMON STOCK		
Second quarter (commencing June 24, 2003)	$ 2.30	$ 1.80
Third quarter	$ 4.45	$ 2.62
Fourth quarter	$ 4.40	$ 3.50

On March 12, 2004, the closing bid prices of the common stock, as reported by TSX Venture Exchange, was $3.45. As of December 31, 2003, there were approximately 16 record owners of our common stock. 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. Based on information requests received from representatives of such beneficial owners, management believes that as of March 12, 2004, there were approximately 548 beneficial holders of the common stock.

On January 16, 2004, the National Association of Securities Dealers, Inc. ("NASD") cleared our common stock for eligibility for quotation on the OTC Bulletin Board. Our symbol on the OTC Bulletin Board is "OGEN."

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

There were no sales of unregistered securities during 2003.

Use of Proceeds

On June 24, 2003, we completed an initial public offering. The managing underwriter for our initial public offering was Haywood Securities, Inc. Under the registration statement, we registered 2,400,000 units at a price of $1.25 per unit. 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. The shares of common stock sold in the offering and eligible for issuance upon exercise of the warrants 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. One whole Series A warrant may be exercised on or before December 24, 2003 to acquire one share of common stock at a price of $2.00 per share. One whole Series B warrant may be exercised on or before March 24, 2004 to acquire one share of common stock at a price of $3.00 per share. All 2,400,000 units were sold in the offering that provided gross proceeds of $3,000,000

and net proceeds to us of approximately $2,300,000 after deducting $717,388 in commissions paid to the underwriter and other expenses incurred in connection with the offering. In addition, the underwriter received warrants to purchase 500,000 shares at $1.25 per share on or before June 24, 2005. Through December 31, 2003, 1,200,000 of the Series A Warrants, 9,750 of the Series B Warrants and 160,750 of the underwriter's warrants were exercised for total cash proceeds of $2,630,188 and 1,370,500 shares of the Company's common stock were issued.

Through December 31, 2003 we have applied a total of $1,344,211 in net proceeds from the offering as follows:

Reduction of notes payable and accrued interest thereon to directors and officers:	
Brian McAlister (Cornet Capital Corp.)	$ 179,757
Robert Zahradknik	72,418
Jeffrey Hillman	13,036
Deferred compensation payable to officers	137,500
Patent expenses paid to University of Florida	100,000
Regulatory consulting fees	112,000
Mutacin 1140 production research	143,000
Preclinical research	262,500
General and administration costs	299,500
Purchase of computer and laboratory equipment	24,500
	$ 1,344,211

Other than normal and recurring compensation 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. Unexpended proceeds are held in one financial institution and invested overnight in obligations of the U. S. Government or its agencies. Actual commissions and other expenses associated with the offering were $717,388, as compared to estimated commissions and expenses described in the prospectus of $575,000. The difference of $142,388 was essentially caused by additional fees incurred by underwriter's legal counsel of $54,284, by our legal counsel of $60,812 and by our auditors of $37,000 due to the length of time involved in finalizing our initial public offering.

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. The Company's 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, Oragenics, Inc., are a 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 aim is to in-license and develop products through human proof-of-concept (Phase I or II) prior to partnering with major pharmaceutical, biotechnology or healthcare product firms for advanced clinical development and commercialization. We have generated no revenues from operations during the last two years. All of our revenues have been from a sponsored research agreement which has expired; none have been from sales.

We are currently developing the following products, each of which addresses potential market opportunities:

- **Replacement Therapy** is a single, painless topical treatment that has the potential to offer life-long protection from most tooth decay. We expect to initiate Phase I safety studies with this product during 2004.

- ***Mutacin* 1140** is a novel antibiotic with activity against essentially all Gram-positive bacteria including vancomycin-resistant *Staphylococcus aureus*. Researchers have not succeeded to-date in demonstrating bacterial resistance to this antibiotic. We are currently in early preclinical stages of development for *Mutacin* 1140.

- **"Probiotic" technology** employs naturally occurring beneficial bacteria to promote oral and periodontal health. Probiotics are widely employed in Japan and Europe and acceptance in the United States is growing. Such products may be marketed as "health supplements" without the need for regulatory filings, offering the opportunity for near-term commercialization.

- **"Other" technologies** include other technologies that we may develop from our research and development activities or that we may license, including our recently licensed technology called *in vivo* induced antigen technology that enables 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.

A more detailed discussion of each technology follows:

Replacement Therapy

Streptococcus mutans (*S. mutans*) is a strain of bacteria residing on everyone's teeth. The activity of this bacterium in converting sugar to lactic acid is the principal cause of tooth decay. Our Replacement Therapy employs a patented, genetically modified strain of *S. mutans* that does not produce this decay-producing acid. When applied to a person's teeth via a painless mouthwash, this organism will displace the resident acid-producing *S. mutans* providing potentially life-long protection against most dental decay. Replacement therapy is the result of 25 years of research by our founder and chief scientific officer, Jeffrey Hillman, DMD, PhD, a world-renowned molecular geneticist and expert on oral microbiology. Our plans are to initiate Phase I trials of this treatment during 2004.

***Mutacin* 1140**

Research has shown that the effective oral colonization by our Replacement Therapy bacterial strain is due to its production of a highly potent bactericidal substance with a broad antimicrobial spectrum of activity. Research

has characterized this substance, called *mutacin* 1140, as a novel lantibiotic – a peptide containing the unusual amino acid lanthionine. 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 vitro studies show *mutacin* 1140 to have highly effective antibiotic activity against all Gram-positive bacteria tested to date including vancomycin-resistant *Staphylococcus Aureus and Enterococcus faecalis*, both of which are rapidly growing healthcare problems. Moreover, to date, bacteria exposed to *mutacin* 1140 have not acquired resistance to *mutacin* 1140's bactericidal effects. We are currently conducting preclinical development and developing a method for the commercial production of *mutacin* 1140. The company expects to complete this effort and file an Investigational New Drug application to begin clinical testing of *mutacin* 1140 in 2005.

"Probiotic" Technology

Probiotics are live microorganisms that confer a health benefit to their host when administered in adequate amounts; the use of yogurt containing live *Lactobacillus* cultures to improve vaginal and urinary tract health is an example of a common probiotic application. Our research suggests that probiotics can reduce the levels of "bad" bacteria that contribute to poor oral health. We have identified three natural strains of bacteria and have demonstrated inlaboratory tests and animal studies the ability of these organisms to provide significant protection against the causative organisms of periodontal disease and tooth decay. We plan to conduct human studies of our probiotic treatment during 2004. Because probiotic treatments are not generally subject to regulatory oversight, we believe we may achieve commercialization of this product in certain markets by early 2005. Probiotics have been targeted at improving the digestive system for many years, and they have broad market acceptance for this use in Japan and growing market appeal in Europe and the United States. If successfully developed, our probiotic treatment will be one of the first probiotic products marketed for the maintenance of oral health.

Other Technology

From time to time we may develop or license additional technologies that we believe would have market potential. For example we recently licensed technology that 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. This technology platform was developed by our founder, chairman 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.

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 present strategy involves undertaking the animal studies necessary for approval of an investigational new drug application for each technology. If successful, we will then undertake and complete Phase I human clinical trials. We intend at that point to consider a sublicense of each of our technologies to one or more pharmaceutical companies, who will be responsible for funding the completion of the Phase II and III clinical trials for the technologies, the cost of the new drug application (see "Federal Food and Drug Administration Regulations"), and for the manufacture and distribution of products based on our technologies. In order to accomplish these objectives, we must take the following actions:

Replacement Therapy

1. Obtain FDA approval to begin human clinical studies.
2. Complete Phase I clinical trials.

Mutacin 1140

1. Develop a suitable production method for *mutacin* 1140.
2. Complete preclinical studies, including animal toxicity and efficacy, required for an investigational new drug application submission.
3. Submit an investigational new drug application to the FDA. .

Probiotic Technology

1. Conduct pre-market safety studies in animals.
2. Develop appropriate manufacturing and packaging systems.
3. Complete one human study.

Other Technology

1. Complete research on TB targets as described in the NIAID Grant.
2. Begin program with CMAT on cancer targets.

These actions, both individually and in the aggregate, are expected to be costly and will require additional capital to complete.

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 and Canada. The preparation of financial statements in accordance with Accounting Principles Generally Accepted in the United States and Canada 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 significant estimates that have a material impact on our results of operations or financial condition.

New Accounting Pronouncements

In January 2003, the FASB issued Interpretation No. 46, *Consolidation of Variable Interest Entities* ("FIN 46") that requires the consolidation of variable interest entities, as defined. FIN 46, as revised, is applicable to financial statements of companies that have interests in "special purpose entities," as defined, during 2003. FIN 46 is applicable to financial statements of companies that have interests in all other types of entities, in first quarter 2004. However, disclosures are required currently if the Company expects to consolidate any variable interest entities. The Company does not currently believe that any material entities will be consolidated with it as a result of FIN 46.

The Company adopted SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* ("SFAS 150") on July 1, 2003. SFAS 150 establishes standards for classifying and measuring as liabilities certain financial instruments that embody obligations of the issuer and have characteristics of both liabilities and equity, such as redeemable preferred stock and certain equity derivatives that frequently are used in connection with share repurchase programs. The Company's adoption of SFAS 150 did not have a material impact on its results of operation or financial position. On October 29, 2003, the FASB voted to defer for an indefinite period the application of SFAS 150 to classification of non-controlling interests of limited-life subsidiaries. The deferral did not have a material impact on the Company's results of operations or financial position.

Results of Operations

Operating Results Summary

	Three Months Ended December 31	
	2003	**2002**
Revenue	**$ –**	$ –
Operating expenses:		
Research and development	**333,150**	97,971
General and administration	**296,036**	104,156
Total operating expenses	**629,186**	202,127
Loss from operations	**(629,186)**	(202,127)
Other income (expense):		
Interest income	**3,599**	277
Interest expense	**(1,884)**	(2,095)
Total other income (expense), net	**1,715**	(1,818)
Loss before income taxes	**(627,471)**	(203,945)
Income tax benefit	**–**	16,000
Net loss	**$ (627,471)**	$ (187,945)

	Years ended December 31	
	2003	**2002**
Revenue	**$ –**	$ –
Operating expenses:		
Research and development	**929,355**	310,007
General and administration	**738,596**	399,693
Total operating expenses	**1,667,951**	709,700
Loss from operations	**(1,667,951)**	(709,700)
Other income (expense):		
Interest income	**7,874**	2,169
Interest expense	**(12,877)**	(8,072)
Total other expense, net	**(5,003)**	(5,903)
Loss before income taxes	**(1,672,954)**	(715,603)
Income tax benefit	**–**	16,000
Net loss	**$ (1,672,954)**	$ (699,603)

For the Quarters Ended December 31, 2003 and 2002

We had no revenues in the three months ended December 31, 2003 and 2002. Our operating expenses increased 211% to $629,186 in the three months ended December 31, 2003 from $202,127 in same period in 2002. Research and development expenses increased 240% to $333,150 in the three months ended December 31, 2003 from $97,971 in the same period in 2002, reflecting the expensing of stock option compensation, hiring of additional research staff, increased consumption of laboratory supplies, an increase in occupied laboratory facilities and the costs associated with regulatory filings. General and administration expenses increased 184% to $296,036 in the three months ended December 31, 2003 from $104,156 in same period in 2002. This increase reflects the expensing of stock option compensation, increased costs relating to legal, accounting and financial consulting, travel and liability insurance.

Interest income increased to $3,599 in the three months ended December 31, 2003 from $277 in the same period in 2002. This significant increase was a result of higher cash balances in 2003 due to the sale of common stock. Interest expense decreased 10% to $1,884 in the three months ended December 31, 2003 from $2,095 during the same period in 2002, reflecting the pay-off of shareholder notes in December 2003.

We incurred net losses of $627,471 and $187,945 during the three months ended December 31, 2003 and 2002, respectively. The increase in our net loss was principally caused by the expensing of stock option compensation, hiring of additional personnel, increased consumption of supplies, increased fees paid to outside professionals, additional facilities leased and the cost of insurance in 2003.

For the Years Ended December 31, 2003 and 2002

We had no revenues in the years ended December 31, 2003 and 2002. Our operating expenses increased 135% to $1,667,951 in the year ended December 31, 2003 from $709,700 in 2002. Research and development expenses increased 200% to $929,355 in 2003 from $310,007 in 2002, reflecting the expensing of stock option compensation, the hiring of research staff, increased consumption of laboratory supplies, increase in occupied laboratory facilities and the costs associated with regulatory filings and patent protection. General and administration expenses increased 85% to $738,596 in 2003 from $399,693 in 2002, reflecting the expensing of stock option compensation, salary increases, increased costs relating to legal, accounting and financial consulting, travel and liability insurance.

Interest income increased 263% to $7,874 in 2003 from $2,169 in 2002, which was a result of the higher average cash balances maintained in 2003 due to the sales of common stock through the initial public offering in June 2003 and the exercise of Series A common stock warrants in December 2003. Interest expense increased 60% to $12,877 in 2003 from $8,072 in 2002 as a result of short-term borrowings from a director and shareholder during the first and second quarter of 2003.

We incurred net losses of $1,672,954 and $699,603 during the years ended December 31, 2003 and 2002, respectively. The increase in our net loss was principally caused by the expensing of stock option compensation, hiring of additional personnel, increased consumption of supplies, increased fees paid to outside professionals, additional facilities leased and the cost of insurance in 2003.

Liquidity and Capital Resources

From inception through December 31, 2003, we have financed our operations primarily through the issuance of common stock for $6,138,188 of which $4,912,799 was received in 2003 in connection with the initial public offering ("IPO") of our common stock and common stock warrant exercises associated with the IPO offering.

On February 14, 2003, we obtained a loan of $100,000 from Cornet Capital Corp., and issued an uncollateralized promissory note in the principal amount of $100,000 that pays interest at 10% per annum to Cornet Capital Corp. Principal and interest are payable on demand and in any event before February 14, 2004. On April 29, 2003, we obtained a further loan of $75,000 from Cornet Capital Corp., and issued an uncollateralized promissory note in the amount of $75,000 that pays interest at 10% per annum to Cornet Capital Corp. Principal and interest are payable on April 29, 2004. These borrowings were not made under the loan facility with Cornet Capital Corp. described under "Certain Relationships and Related Transactions." No shares were issued to Cornet Capital Corp. in connection with these borrowings. These loans were repaid during 2003 from the proceeds of our IPO.

We lease our laboratory and office facilities, as well as certain equipment, under a 12-month cancelable operating lease with annual renewal options. In January 2004, we entered into an agreement with a real estate developer to have a facility built that we will lease from the developer. The agreement requires us to pay a deposit of $6,400 and provides for monthly lease payments of $6,400, exclusive of utilities, insurance and real estate taxes. We also anticipate paying approximately $250,000 for equipment to outfit the facility. It is anticipated we will begin occupancy in June 2004, however, we have arranged to remain in our current location until the new facility is complete.

We had cash and cash equivalents of $3,583,757 at December 31, 2003 that are held in one financial institution and invested overnight in US government securities. We anticipate that our current funds will be adequate to satisfy our operating expenses and capital requirements as planned into 2005.

We expect to incur significant research and development expenses including continued increases in personnel and costs related to research, preclinical testing and clinical trials. 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. Our future capital requirements will depend on many factors, including continued scientific progress in our research and development programs, the magnitude of these programs, the scope and results of preclinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, competing technological and market developments and our ability to establish development, manufacturing and marketing arrangements. We intend to seek additional funding through sublicensing arrangements or through public or private financings, but there can be no assurance that additional financing will be available on acceptable terms or at all.

Risk Factors Affecting Our Business

Investors should carefully consider the following risk factors, in addition to the other information concerning the factors affecting forward-looking statements. Each of the risk factors could adversely affect our business, operating results and financial condition as well as adversely affect the value of an investment in us.

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 and, because such statements involve risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. The terms "Oragenics," "company," "we," "our," and "us" refer to Oragenics, Inc. The words "expect," "believe," "goal," "plan," "intend," "anticipate," "estimate," "will" and similar expressions and variations thereof if used, are intended to specifically identify forward-looking statements. Forward-looking statements are statements regarding the intent, belief or current expectations, estimates or projections of Oragenics, our directors or our officers about Oragenics and the industry in which we operate, and

assumptions made by management, and include among other items, (i) our strategies regarding growth, including our intention to develop and market our products; (ii) our financing plans; (iii) trends affecting our financial condition or results of operations; (iv) our ability to continue to control costs and to meet our liquidity and other financing needs; (v) our ability to respond to and meet regulatory demands. Although we believe our expectations are based on reasonable assumptions, we can give no assurance that the anticipated results will occur. We disclaim any intention or obligation to update or revise forward-looking statements, whether as a result of new information, future events or otherwise.

Investors and prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those in the forward-looking statements as a result of various factors which include, among others, (i) general economic conditions, particularly those affecting our ability to raise additional capital; (ii) conditions in the capital markets, including the interest rate environment and the availability of capital, which could affect our internal growth and possibilities for licensing and/or strategic alliances; (iii) changes in the competitive marketplace that could affect our expected revenue and/or costs of product development; (iv) our rights to the use of intellectual property and the potential for others to challenge and otherwise adversely affect or impair such rights; and (v) other factors including those identified in our filings from time to time with the SEC and the following risk factors:

We have experienced a history of losses and expect to incur future losses. We have generated extremely limited revenue from our operations, and no revenue from sales. Therefore, we must continue to raise money from investors and seek partners with whom to collaborate our research and development efforts so as to fund our operations. If we are unable to fund our operations, we may cease doing business.

We have recorded minimal revenue to date and we have incurred a cumulative operating loss of approximately $2,387,000 through December 31, 2003. Our losses have resulted principally from costs incurred in research and development activities related to our efforts to develop our technologies and from the associated administrative costs. We expect to incur significant operating losses and negative cash flows over the next several years due to the costs of expanded research and development efforts and preclinical and clinical trials and hiring additional personnel. We will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Even if we do achieve profitability, we may not be able to sustain or increase profitability. We have limited capital resources and it is likely that we will require additional capital to meet our future capital requirements. There is no assurance that such capital will be available to us or, if available, be on terms acceptable to us. To the extent we are unable to raise additional capital and our operating losses continue, we will need to take actions to reduce our costs of operations, which may adversely impact future operations, employee morale, business relations and other aspects of our business. An increase in capital resulting from a capital raising transaction under adverse business circumstances could result in substantial dilution to existing holders of our common stock and adversely impact our stock price.

The FDA has put our investigational new drug application for our replacement therapy technology on clinical hold. If we are unable to obtain or maintain regulatory clearance or approval for our technologies, we will be unable to generate revenues and may have to cease operations.

Our technologies have not been cleared for marketing by the FDA or foreign regulatory authorities and cannot be commercially distributed in the United States or any international markets until such clearance is 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 replacement therapy and mutacin 1140 technologies may be found to be unsafe or ineffective or otherwise fail to satisfy regulatory requirements. The FDA has put our investigational new drug application for our replacement therapy technology on clinical hold. This means that we may not begin human clinical trials under our application until the FDA gives us permission to do so. We have amended our first investigational new drug application three times to respond to the FDA's concerns. We filed a new investigational new drug application in March of 2003. This investigational new drug application has also been placed on hold until we satisfy the FDA's safety concerns. 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 obtain or maintain FDA clearance for one or all of our 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.

Our three 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 will 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 is 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 will 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 obtaining regulatory approval to produce and market them. Research and development activities, by their nature, preclude definitive statements as to the time required and costs involved in reaching certain objectives. Actual costs may exceed the amounts we have budgeted and actual time may exceed our expectations. If research and development requires more funding than we anticipate, then we may have to reduce technological development efforts or seek additional financing. There can be no assurance that we will be able to secure any necessary additional financing or that such financing would be available on favorable terms. Additional financings could result in substantial dilution to existing shareholders. We anticipate we will remain engaged in research and development for a considerable period of time.

It is possible that our replacement therapy technology will be less effective in humans than it has been shown to be in animals. It is possible our mutacin 1140 technology will be shown to be ineffective or harmful in humans. If either 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. 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 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 we conduct these studies, 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 either technology, 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 preclinical and clinical trials that are required in order to obtain FDA permission to sell it, and we will be unable to generate revenues from it, 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 order for us to conduct the preclinical and Phase I clinical studies that we must complete in order to find a partner who will sub-license this technology from us and finance the Phase II and III clinical studies we must complete in order to obtain FDA approvals necessary to sell products based on this technology, we must demonstrate a method of producing commercial quantities of this substance economically. To date we have not found such a method and it is possible we will be unable to find one.

If we are not able to find such a method, we will be unable to generate revenues from this technology and we may have to cease operations.

Beginning in 2004, we must spend at least $1 million annually on development of the technologies 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 our 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 licenses, we must spend at least $1 million per year beginning in 2004 and thereafter on development of those technologies before the first commercial sale of products derived from those technologies. If we do not, our licenses could be terminated. Until commercial sales of such 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 our 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 agreement. There is no assurance that we will be able to comply with these conditions. If we cannot, and if our license is terminated, our investment in development of our replacement therapy technology will become valueless and we may have to cease operations.

If clinical trials for our products are unsuccessful or delayed, we will be unable to meet our anticipated development and commercialization timelines, which could cause our stock price to decline.

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 or more. Our 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.

The 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.

We intend to consider relying on third parties to pay the majority of the costs of 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 them 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 licensed, patented technologies to pharmaceutical companies after completion of Phase I clinical studies. If we do so, our sublicensees will pay the costs of Phase II and III clinical trials, and manufacturing and marketing 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 are not, 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. 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, others could compete against us more directly, which would 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.

If third parties claim we are infringing their intellectual property rights, we could suffer significant litigation or licensing expenses or be prevented from marketing our products.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of others. However, regardless of our intent, our technologies may infringe the patents or violate other proprietary rights of third parties. In the event of such 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. Their notification did not state that they intended to pursue legal remedies. Management of our Company 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 them. If necessary, we are prepared to assert our rights vigorously with respect to such matter. 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. If we become involved in any claims, litigation, interference or other administrative proceedings, we may incur substantial expense and the efforts of our technical and management personnel may be significantly diverted. Any future claims or adverse determinations with respect to our intellectual property rights may subject us to loss of our proprietary position or to significant liabilities, may require us to seek licenses from third parties, cause delays in the development and release of new products or services and/or may restrict or prevent us from manufacturing and selling certain of our products. If we are required to seek licenses from third parties, costs associated with these arrangements may be substantial and may include ongoing royalties. Furthermore, we may not be able to obtain the necessary licenses on satisfactory terms, if at all.

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

The production and marketing of our products 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 devices 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 our products to market, and we cannot guarantee that any of our 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 new products 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 U.S. In the U.S. 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 our current products for broader or different applications or to market updated products that represent extensions of our basic technology. In addition, we may not receive FDA export approval to export our products 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 products. 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 products could make it more difficult and costly to obtain approval for new products, 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 and *mutacin* 1140 licensed technologies, that have been developed through biotechnology, 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 produced with 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 $1,000,000 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, we may have to cease operations.

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 fail to present such clinical data that will adversely affect our ability to obtain favorable third party reimbursement, we will earn less revenue and we may have to cease operations.

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

The trading price of our common stock has been, and may be, subject to wide fluctuations in response to a number of factors, many of which are beyond our control. These factors include:

- quarter-to-quarter variations in our operating results;
- the results of testing, technological innovations, or new commercial products by us or our competitors;
- governmental regulations, rules, and orders;
- general conditions in the healthcare, dentistry, or biotechnology industries;
- comments and/or earnings estimates by securities analysts;
- developments concerning patents or other intellectual property rights;
- litigation or public concern about the safety of our products;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel;
- release of lock-up 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 March 12, 2004, our stock price has fluctuated from a high of $4.50 to a low of $1.69 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 12, 2004, there were 13,407,530 shares of our common stock outstanding, with another 1,111,700 shares of common stock issuable upon exercise of our Series B warrants, 306,474 shares of common stock issuable upon exercise of our underwriter warrants and 740,000 shares issuable upon exercise of options issued or available for issuance under our stock option plans. The stock underlying these options has been registered for resale with the SEC, including approximately 1.2 million shares underlying currently unexercised but "in-the-money" warrants held by certain investors. We currently have approximately 6,913,028 shares of our 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 released from escrow periodically in three and six month increments and are subject to the limitations of the respective escrow agreements. Of these shares, 6,150,573 are held by principals of the Company, 449,955 are held by the University of Florida Research Foundation, Inc. and 312,500 are held by other non-principal shareholders.

We may be unable to maintain the listing of our common stock on the TSX Venture Exchange Tier 2 and penny stock rules may apply to the sale of our common stock that, in each case, would make it more difficult for shareholders to dispose of their common stock.

Our common stock is listed on the TSX Venture Exchange Tier 2 in Canada. We cannot guarantee that it will always be listed. The TSX Venture Exchange Tier 2 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 delisted from the TSX Venture Exchange Tier 2, trading in our common stock would be conducted, if at all, on the NEX Board of the TSX Venture Exchange in Canada and 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.

There are separate rules regulating United States broker-dealers who trade on behalf of customers in unlisted stocks. These rules require broker-dealers to:

- sell common stock only to purchasers for which transactions in penny stocks are suitable unless such purchasers are established customers as defined in Rule 15g-9 of the Securities Exchange Act of 1934;
- sell common stock only to purchasers that have sufficient knowledge and experience in financial matters that the person reasonably may be expected to be capable of evaluating the risks of transactions in penny stock; and
- receive the purchaser's written consent to the transaction prior to sale.

The United States Securities and Exchange Commission has adopted regulations that define "penny stock" to include common stock that has a market price of less than $5.00 per share, subject to certain exceptions. Our shares of common stock are covered by the penny stock rules under Section 15(g) of the Securities Exchange Act of 1934, as amended, and the related rules of the SEC. They impose additional sales practice requirements on United States broker/dealers who sell our securities. Broker-dealers engaging in the sale of penny stocks must comply with, among other things, the following requirements:

- delivery to purchasers, prior to the transaction, of a risk disclosure statement prepared by the Securities and Exchange Commission relating to the penny stock market;
- disclosure to purchasers of the commissions payable to the broker-dealer and its registered representative;
- disclosure to purchasers of current quotations for the securities; and
- delivery to customers with monthly statements disclosing recent price information for all penny stock held in the customer's account and information on the limited market in penny stocks.

The broker must provide the bid and offer quotations and compensation information before effecting the transaction. This information must be contained in the customer's confirmation. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for a stock that is subject to the penny stock rules because of the lack of ability or incentive of broker-dealers to sell our common stock.

Our shares are subject to the foregoing rules in the United States. The foregoing rules apply to broker/dealers. The application of the penny stock rules may affect your ability to resell your shares in the United States because some broker/dealers may not be willing to make a market in our securities because of the burdens imposed upon them by the penny stock rules. Also, the broker prepares the information provided to the broker's customers. Because we do not prepare the information, we cannot assure you such information is current or complete.

Our common stock is defined as a penny stock under the Securities and Exchange Act of 1934, and its rules. Because our common stock is a penny stock, you may not be able to resell your shares in the United States. This is because the Exchange Act and the penny stock rules impose additional sales practice and disclosure requirements on broker/dealers who sell our securities to persons other than accredited investors. As a result, fewer broker/dealers are willing to make a market in our stock.

We must maintain a current prospectus and registration statement in order for our outstanding warrants to be exercised by their holders.

We must maintain an effective registration statement on file with the Securities and Exchange Commission before the holder of any of our warrants may be redeemed or exercised. It is possible that we may be unable to cause a registration statement covering the common stock underlying the warrants to be effective. We anticipate that we may need to meet state registration requirements for sales of securities in states where an exemption from registration is not otherwise available. The warrants may expire unexercised, which would result in the holders losing all the value of their investment in the warrants. There can be no assurance that we will be able to maintain an effective registration statement covering the issuance of common stock upon redemption or exercise of the warrants. If we are unable to maintain an effective registration for the issuance of common stock upon exercise of the warrants, we may be subject to claims by the warrant holders.

Item 7. Financial Statements.

Incorporated by reference to pages F-1 to F-14 at the end of this report.

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

None.

Item 8A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Within 90 days prior to the date of this report, we carried out an evaluation (the "Evaluation"), under the supervision and with the participation of our President and 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"). Based on the Evaluation, our CEO and CFO concluded that, subject to the limitations noted below, our Disclosure Controls are effective in timely alerting them to material information required to be included in our periodic SEC reports.

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.

PART III

Certain information required by Part III is omitted from this Report in that the Company expects to file a definitive proxy statement with the Securities and Exchange Commission (the "Commission") within 120 days after the end of its fiscal year pursuant to Regulation 14A, as promulgated by the Commission, for its 2004 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 the Company's Proxy Statement.

Item 10. Executive Compensation.

The information required by this Item 10 with respect to management remuneration and transactions is incorporated herein by reference to the Company's 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 the Company's 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 the Company's Proxy Statement under the heading "Certain Relationships and Related Transactions."

Item 13. Exhibits and Reports on Form 8-K.

(a) Exhibits.

		Incorporated by Reference				
Exhibit Number	Exhibit Description	Form	File No	Exhibit	Filing Date	Filed Herewith
3.1	Articles of Incorporation	SB-2	333-100568	3.1	10/16/02	
3.2	Bylaws	SB-2	333-100568	3.2	10/16/02	
3.3	Amended Articles of Incorporation	SB-2	333-100568	3.3	10/16/02	
3.4	Amended Articles of Incorporation	SB-2	333-100568	3.4	10/16/02	
4.1	Specimen Stock Certificate	SB-2	333-100568	4.1	10/16/02	
4.3	Specimen Series B warrant certificate	SB-2	333-100568	4.3	10/16/02	
4.4	Specimen underwriter's warrant certificate	SB-2	333-100568	4.4	10/16/02	
10.1	License Agreement	SB-2	333-100568	10.1	10/16/02	
10.2	Amendment to License Agreement	SB-2	333-100568	10.2	10/16/02	
10.3	Second Amendment to License Agreement	SB-2	333-100568	10.3	10/16/02	
10.4	Third Amendment to License Agreement	SB-2	333-100568	10.4	10/16/02	
10.5	License Agreement	SB-2	333-100568	10.5	10/16/02	
10.6	Amendment to License Agreement	SB-2	333-100568	10.6	10/16/02	
10.7	Second Amendment to License Agreement	SB-2	333-100568	10.7	10/16/02	

Exhibit Number	Exhibit Description	Form	File No	Exhibit	Filing Date	Filed Herewith
10.8	Equity Agreement	SB-2/A-2	333-100568	10.8	2/10/03	
10.11	First Amendment to Employment Agreement with Jeffrey D. Hillman	SB-2	333-100568	99.3	10/16/02	
10.14	Incubator License Agreement – Office Lease	SB-2	333-100568	99.5	10/16/02	
10.15	First Amendment to Incubator License Agreement	SB-2	333-100568	99.6	10/16/02	
10.16	Second Amendment to Incubator License Agreement	SB-2	333-100568	99.7	10/16/02	
10.17	Series A and B Warrant Indenture	SB-2/A-5	333-100568	10.17	12/23/02	
10.18	Renewal Term for Incubator License Agreement	SB-2	333-100568	99.8	10/16/02	
10.19	Escrow Agreement between our principals, ourselves and Computershare Trust Company	SB-2	333-100568	99.10	10/16/02	
10.20	Value Escrow Agreement between ourselves, the University of Florida Research Foundation, Inc. and Computershare Trust Company	SB-2	333-100568	99.11	10/16/02	
10.21	Pooling Agreement between our non-Principal shareholders and Haywood Securities Inc.	SB-2/A-3	333-100568	10.21	4/9/03	
10.22	Financing Agreement between ourselves and Cornet Capital Corp.	SB-2	333-100568	99.13	10/16/02	
10.23	First Amendment to Financing Agreement between ourselves and Cornet Capital Corp.	SB-2	333-100568	99.15	10/16/02	
10.24	Escrow Agreement between ourselves, Brian McAlister and Sutherland, Asbill and Brennan	SB-2	333-100568	99.14	10/16/02	
10.25	First Amendment to Escrow Agreement between ourselves, Brian McAlister and Sutherland, Asbill and Brennan	SB-2/A-1	333-100568	10.25	12/23/02	
10.26	Stock Option Plan	SB-2	333-100568	99.16	10/16/02	
10.27	Transfer Agent, Registrar and Dividend Disbursing Agent Agreement for Common Stock	SB-2/A-3	333-100568	10.27	4/9/03	
10.28	Warrant Agreement and Registrar Agreement	SB-2/A-1	333-100568	10.28	12/23/02	
10.29	Registration Rights Agreements between ourselves and Cleo Christine Allan, James Butler, Quickswood Ltd., Ernest Mario, Amelia Investments Ltd. and Angel Investment Company Ltd.	SB-2/A-3	333-100568	10.29	4/9/03	
10.31	Proprietary Information Agreements between ourselves and Brian Anderson, Brian McAlister, Robert Zahradnik, Howard Kuramitsu, and Steven Projan	SB-2	333-100568	99.23	10/16/02	
10.32	Confidential Information Agreement between us and Paul Hassie	SB-2	333-100568	99.24	10/16/02	

Exhibit Number	Exhibit Description	Form	File No	Exhibit	Filing Date	Filed Herewith
10.34	Second Amendment to Financing Agreement between ourselves and Cornet Capital Corp.	SB-2/A-5	333-100568	10.34	5/5/03	
10.36	Fourth Amendment to License Agreements	SB-2/A-3	333-100568	10.36	4/9/03	
10.37	Agreement between Dr. Robert Zahradnik and ourselves under which Dr. Zahradnik has agreed not to seek repayment of certain loans from the proceeds of the initial public offering	SB-2/A-3	333-100568	10.37	4/9/03	
10.38	Agreement between Dr. Jeffrey Hillman and ourselves under which Dr. Hillman has agreed not to seek repayment of certain loans from the proceeds of the initial public offering	SB-2/A-3	333-100568	10.38	4/9/03	
10.39	Promissory Note with principal amount of $100,000 payable to Cornet Capital Corp.	SB-2/A-3	333-100568	10.39	4/9/03	
10.40	Second Amendment to Escrow Agreement	SB-2/A-3	333-100568	10.40	4/9/03	
10.41	Promissory Note with principal amount of $75,000 payable to Cornet Capital Corp.	SB-2/A-5	333-100568	10.41	5/5/03	
10.42	Employment agreement of Mento Soponis					X
10.43	Employment agreement of Jeffrey Hillman					X
10.44	Employment agreement of Paul Hassie					X
10.45	Consultancy Agreement between us and Health Decisions, Inc.					X
23.1	Consent of Ernst & Young LLP					X
31.1	Rule 13a-14(a)/15d-14(a) Certification					X
31.2	Rule 13a-14(a)/15d-14(a) Certification					X
32.1	Section 1350 Certifications					X
32.2	Section 1350 Certifications					X

(b) Reports on Form 8-K:

The Company filed Form 8-K's on October 2, 2003, October 24, 2003 and November 3, 2003, relating to (i) the press release announcing the appointment of David J. Gury, to the board of directors; (ii) the press release for the quarterly results filed pursuant to Regulation FD; and, (iii) the press release announcing the grant of stock options to Paul Hassie and Brian Anderson, respectively.

Item 14. Principal Accountant Fees and Services.

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

Oragenics, Inc.

Financial Statements

Years ended December 31, 2003 and 2002

Contents

Report of Independent Certified Public Accountants

Board of Directors
Oragenics, Inc.

We have audited the accompanying balance sheet of Oragenics, Inc. as of December 31, 2003, and the related statements of operations, changes in stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the 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 audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Oragenics, Inc. at December 31, 2003, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States.

January 30, 2004
Tampa, Florida

Oragenics, Inc.

Balance Sheet
December 31, 2003
(In US Dollars)

Assets		
Current assets:		
Cash and cash equivalents	$	3,583,757
Prepaid expenses		24,637
Total current assets		3,608,394
Equipment		42,371
Total assets	$	3,650,765
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$	140,614
Accrued interest		25,582
Deferred compensation		44,672
Total current liabilities		210,868
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; 13,296,204 shares issued and outstanding		13,296
Additional paid in capital		5,820,697
Accumulated deficit		(2,394,096)
Total stockholders' equity		3,439,897
Total liabilities and stockholders' equity	$	3,650,765

See accompanying notes.

Oragenics, Inc.

Statements of Operations
(In US Dollars)

	Year ended December 31	
	2003	**2002**
Revenue	**$ –**	$ –
Operating expenses:		
Research and development	**929,355**	310,007
General and administration	**738,596**	399,693
Total operating expenses	**1,667,951**	709,700
Loss from operations	**(1,667,951)**	(709,700)
Other income (expense):		
Interest income	**7,874**	2,169
Interest expense	**(12,877)**	(8,072)
Total other expense, net	**(5,003)**	(5,903)
Loss before income taxes	**(1,672,954)**	(715,603)
Income tax benefit	**–**	16,000
Net loss	**$ (1,672,954)**	$ (699,603)
Basic and diluted net loss per share	**$ (0.15)**	$ (0.08)
Shares used to compute basic and diluted net loss per share	**10,814,198**	8,884,239

See accompanying notes.

Oragenics, Inc.

Statements of Changes in Stockholders' Equity (Deficit)
(In US Dollars)

	Common Stock		Additional Paid In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance at January 1, 2002	7,512,048	$ 7,512	–	$ (21,539)	$ (14,027)
Issuance of common stock	1,913,656	1,914	628,234	–	630,148
Net loss	–	–	–	(699,603)	(699,603)
Balance at December 31, 2002	9,425,704	9,426	628,234	(721,142)	(83,482)
Net loss	–	–	–	(1,672,954)	(1,672,954)
Issuance of common stock and warrants	2,500,000	2,500	2,280,112	–	2,282,612
Exercise of common stock warrants	1,370,500	1,370	2,628,817	–	2,630,187
Compensation expense relating to option issuances	–	–	283,534	–	283,534
Balance at December 31, 2003	13,296,204	$ 13,296	$ 5,820,697	$ (2,394,096)	$ 3,439,897

See accompanying notes.

Oragenics, Inc.

Statements of Cash Flows
(In US Dollars)

	Year ended December 31 2003	2002
Operating activities		
Net loss	**$ (1,672,954)**	$ (699,603)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	**12,545**	1,585
Non-cash issuance of common stock and common stock options	**54,000**	122,148
Stock-based compensation expense	**229,534**	–
Changes in operating assets and liabilities:		
Costs associated with initial public offering	**271,937**	(271,937)
Prepaid expenses	**(15,896)**	(8,741)
Accounts payable and accrued expenses	**(92,197)**	162,772
Accrued interest	**8,120**	8,072
Income tax payable	**–**	(16,000)
Deferred compensation	**(13,999)**	24,262
Net cash used in operating activities	**(1,218,910)**	(677,442)
Investing activity		
Purchases of equipment	**(50,258)**	(5,458)
Net cash used in investing activity	**(50,258)**	(5,458)
Financing activities		
Proceeds from notes payable to stockholders	**175,000**	–
Payment of notes payable to stockholders	**(260,454)**	–
Net proceeds from issuance of common stock	**4,912,799**	508,000
Net cash provided by financing activities	**4,827,345**	508,000
Net increase (decrease) in cash and cash equivalents	**3,558,177**	(174,900)
Cash and cash equivalents at beginning of period	**25,580**	200,480
Cash and cash equivalents at end of period	**$ 3,583,757**	$ 25,580
Non-cash financing activities		
Common stock issued in connection with amendment to officer employment agreement	**$ –**	$ 122,148
Common stock and common stock options issued in connection with investment bank and related financing services	**$ 54,000**	$ 192,016
Interest paid	**$ 4,757**	$ –

See accompanying notes.

1. Organization and Significant Accounting Policies

Oragenics, Inc. (the Company) (formerly known as Oragen, Inc.) was incorporated in November 1996 and operating activity commenced in 1999. The Company is dedicated to developing technologies associated with oral health, broad spectrum antibiotics and other general health benefits.

Basis of Presentation

The financial statements of the Company, which have been prepared in accordance with accounting principles generally accepted in the United States, conform in all material respects with accounting principles generally accepted in Canada.

Concentrations of Credit Risk and Significant Customer

The Company's cash and cash equivalents are deposited in one financial institution and consist of demand deposits and overnight repurchase agreement investments.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

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.

1. Organization and Significant Accounting Policies (continued)

Cash Equivalents

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

Equipment

Equipment is recorded at its acquisition cost. Depreciation is computed utilizing the declining balance and straight-line methods over the estimated useful lives (three years) of the related assets.

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.

1. Organization and Significant Accounting Policies (continued)

	Years ended December 31	
	2003	**2002**
	(in US Dollars)	
Net loss, as reported	$ (1,672,954)	$ (699,603)
Add: Total stock-based employee compensation expense reported in net loss	229,534	
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(44,371)	(2,925)
Pro forma net loss	$ (1,487,791)	$ (702,528)
Earnings per share:		
Basic and diluted – as reported	$ (0.15)	$ (0.08)
Basic and diluted – pro forma	$ (0.14)	$ (0.08)

Common Stock Split

On March 25, 2002, the Board of Directors approved a 108 to 1 stock split of all outstanding shares. All share and per share information included in the financial statements has been retroactively adjusted to reflect this split. The Board of Directors approved an increase to the authorized shares of the preferred stock to 20,000,000 and to increase the authorized shares of common stock to 100,000,000.

Net Loss Per Share

The weighted-average shares outstanding include all common stock issued. In computing diluted loss per share, outstanding common stock options and warrants representing 2,279,500 and 315,000 common shares for the year ended December 31, 2003 and 2002, respectively, were excluded from the diluted loss per share computation because their effects would have been anti-dilutive.

Research and Development Expenses

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

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating 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 to be realized by the use of a valuation allowance.

1. Organization and Significant Accounting Policies (continued)

Recently Issued Accounting Pronouncements

In January 2003, the FASB issued Interpretation No. 46, *Consolidation of Variable Interest Entities* ("FIN 46") that requires the consolidation of variable interest entities, as defined. FIN 46, as revised, is applicable to financial statements of companies that have interests in "special purpose entities," as defined, during 2003. FIN 46 is applicable to financial statements of companies that have interests in all other types of entities, in first quarter 2004. However, disclosures are required currently if the Company expects to consolidate any variable interest entities. The Company does not currently believe that any material entities will be consolidated with it as a result of FIN 46.

The Company adopted SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* ("SFAS 150") on July 1, 2003. SFAS 150 establishes standards for classifying and measuring as liabilities certain financial instruments that embody obligations of the issuer and have characteristics of both liabilities and equity, such as redeemable preferred stock and certain equity derivatives that frequently are used in connection with share repurchase programs. The Company's adoption of SFAS 150 did not have a material impact on its results of operation or financial position. On October 29, 2003, the FASB voted to defer for an indefinite period the application of SFAS 150 to classification of non-controlling interests of limited-life subsidiaries. The deferral did not have a material impact on the Company's results of operations or financial position.

2. Equipment

Equipment consists of the following as of December 31, 2003 *(in US Dollars)*:

Computer equipment	$	**58,976**
Accumulated depreciation		**(16,605)**
	$	**42,371**

Depreciation expense for 2003 and 2002 was $12,545 and $1,585, respectively.

3. Notes Payable to Stockholders

The Company issued promissory notes for cash to two stockholders in the amounts of $69,604 and $15,000 in 2001 and 1999, respectively. These notes were payable upon demand and accrued interest at 7% per year. The principal portion of the notes was repaid in December 2003 and related accrued interest totaling $18,452 was paid in January 2004.

In 2003 the Company issued two demand promissory notes to a stockholder in the amounts of $100,000 and $75,000 bearing interest at 10% per annum. Both notes and interest totaling $4,757 were repaid in June 2003.

4. Deferred Compensation

During 2000, the Company entered into a two-year employment agreement with an officer and shareholder. The agreement provided for the deferral of compensation until a certain level of investment funding is received and requires the Company to accrue interest on the deferred balance at 7% per year. Beginning July 1, 2001, the agreement was amended whereby the deferral of compensation ceased. At December 31, 2003, deferred compensation plus accrued interest totaled $41,539. No compensation expense was recognized in 2003 or 2002 and interest expense relating to the employment agreement for the years ended December 31, 2003 and 2002 was $2,409 and $2,530, respectively. In January 2004, payments totaling $41,539 were made in settlement of this obligation.

Between December 2002 and June 2003, compensation payments totaling $149,263 to three officers of the Company were deferred due to limited cash flow of the Company. As of December 31, 2003, payments of $139,000 were made and the balance of $10,263 was paid in January 2004. There is no provision to pay interest on these deferred compensation payments.

5. Stock Options

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, 2003, the Company had not awarded stock appreciation rights or restricted stock under the Plan. The Company has reserved an aggregate of 1,000,000 shares of common stock for grants under the Plan, of which 250,000 shares are available for future grants as of December 31, 2003. The exercise price of each option shall be determined by the Board and an option's maximum term is five years.

In September 2002, the Company issued 195,000 options that were re-priced upon the change in the initial public offering (See Note 10) 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 2003, the Company recognized $229,534 of compensation expense.

5. Stock Options (continued)

A summary of the status of the Company's outstanding stock options, including employee stock options discussed above, as of December 31, 2003 and 2002 and changes during the periods ending on those dates is presented below:

	Options	Option Price Per Share	Weighted Average Exercise Price
Outstanding at January 1, 2002	–		–
Granted	315,000	$ 1.25	$ 1.25
Outstanding at December 31, 2002	315,000	1.25	1.25
Granted	285,000	2.65 – 4.00	3.29
Outstanding at December 31, 2003	600,000		$ 2.22
Exercisable at end of year	155,000	$ 1.25 – 4.00	$ 2.14

The range of exercise price is $1.25 to $4.00 per share. The weighted-average per option fair value of options granted during 2003 and 2002 was $1.26 and $.12, 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. Retirement Plan

During 2001, the Company established a defined contribution retirement plan that covers substantially all of the employees of the Company. The plan generally allows for employer contributions up to 15% of each employee's salary, limited to $30,000 per year. Employees may also contribute up to $2,000 to the plan annually. Employees are fully vested in all contributions made to the plan. There was no expense related to the plan in 2003 and 2002.

In January 2004, the Company established a new defined contribution retirement plan covering all employees and providing for a Company match of up to 3% of all employee contributions to the plan. During 2004, employee contributions are limited to $9,000 except for individuals 50 years or older for which the contribution limitation is $10,500.

7. Income Taxes

The components of income tax benefit are as follows:

	Year ended December 31	
	2003	**2002**
	(In US Dollars)	
Current – federal	$ –	$ (14,000)
Current – state	–	(2,000)
Total	$ –	$ (16,000)

At December 31, 2003, 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 (*In US Dollars*):

Deferred tax assets:	
Net operating loss carryforward	$ 753,911
Consulting services	28,223
Non qualified stock options	46,897
Tax credit	48,724
Total deferred tax assets	877,755
Less valuation allowance	(877,755)
Total net deferred taxes	$ –

The following is a reconciliation of tax computed at the statutory federal rate to the income tax benefit in the statements of operations for the years ended December 31, 2003 and 2002:

	Year ended December 31	
	2003	**2002**
	(In US Dollars)	
Income tax benefit computed at statutory federal rate of 34%	$ (568,804)	$ (243,305)
State income tax benefits, net of federal expense/benefit	(60,728)	(25,947)
Change in valuation allowance	596,049	263,604
Non-deductible expenses	60,303	274
Research and development credit	(32,512)	16,212
Other	5,692	(26,838)
Total	$ –	$ (16,000)

7. Income Taxes (continued)

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 $877,755 at December 31, 2003 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, 2003 was $596,049. At December 31, 2003, the Company has available net operating loss carryforwards of $2,003,484, which begin to expire in 2022.

In connection with the initial public offering, it is possible that the Company 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.

8. Lease of Facilities

The Company leases its laboratory and office space, as well certain equipment, under a 12-month cancelable operating lease with annual renewal options. Total rent expense under this lease was $33,583 and $18,506 for the years ended December 31, 2003 and 2002, respectively. The lease agreement ends in March 2004. The minimum lease payments that are due through the formal lease termination date in 2004 are $11,000.

In January 2004, the Company entered into an agreement with a real estate developer to have a facility built that the Company will lease from the developer for a term of five years. The expected completion date is in July 2004. The agreement requires the Company to pay a deposit of $6,400 and provides for monthly lease payments of $6,400, exclusive of utilities, insurance and real estate taxes.

9. Transactions with Related Parties

Costs incurred for consulting services provided by a stockholder of the Company during 2002 were approximately $15,000. At December 31, 2003 and 2002, $75,000 was owed and included in accounts payable and accrued expenses. No interest is being accrued on this outstanding debt.

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. The license agreements provide for, among other things, the Company to make minimum annual research expenditures of $600,000 in 2003 and $1,000,000 thereafter, to adhere to specific milestones and pay royalties on product sales, which beginning December 31, 2005 will be a minimum of $50,000 annually per agreement. The agreement also required the Company to pay $100,000 to UFRF as reimbursement for patent filing costs upon the closing of any financing in excess of $1,000,000. If the Company fails to perform certain of its obligations, UFRF may terminate the license agreements. Upon completion of the initial public offering in June 2003 (See Note 10), the Company paid UFRF $100,000.

10. Initial Public Offering

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 allows the holder to purchase a share of the Company's stock at $3.00 per share until March 24, 2004. As of December 31, 2003, 9,750 Series B warrants were exercised providing proceeds to the Company of $29,250. 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. As of December 31, 2003, 160,750 underwriter warrants were exercised providing proceeds to the Company of $200,937. The cost of the IPO was $717,388 including the agent's commission.

11. 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 (*In US Dollars*).

	2003			
	First	**Second**	**Third**	**Fourth**
Total operating expenses	$ 207,899	$ 432,440	$ 398,426	$ 629,186
Net loss	(211,442)	(437,319)	(396,722)	(627,471)
Loss per share:				
Basic	$ 0.02	$ 0.05	$ 0.03	$ 0.05
Diluted	$ 0.02	$ 0.05	$ 0.03	$ 0.05

	2002			
	First	**Second**	**Third**	**Fourth**
Total operating expenses	$ 206,037	$ 130,784	$ 170,752	$ 202,127
Net loss	(207,773)	(131,943)	(171,942)	(187,945)
Loss per share:				
Basic	$ 0.03	$ 0.01	$ 0.02	$ 0.02
Diluted	$ 0.03	$ 0.01	$ 0.02	$ 0.02

SIGNATURES

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

Dated: March 17, 2004

ORAGENICS, INC.
(Registrant)

By: /s/ Mento A. Soponis
Mento A. Soponis, Chief Executive Officer and President

By: /s/ Paul A. Hassie
Paul A. Hassie, Chief Financial Officer, Secretary and Treasurer (Principal Accounting Officer)

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

Signature	Title	Date
/s/ Mento A. Soponis Mento A. Soponis	Chief Executive Officer and President	March 17, 2004
/s/ Paul A. Hassie Paul A. Hassie	Chief Financial Officer	March 17, 2004
/s/ Robert T. Zahradnik Robert T. Zahradnik	Director	March 17, 2004
/s/ Jeffrey D. Hillman Jeffrey D. Hillman	Director	March 17, 2004
/s/ Brian McAlister Brian McAlister	Director	March 17, 2004
/s/ Brian Anderson Brian Anderson	Director	March 17, 2004
/s David J. Gury David J. Gury	Director	March 17, 2004

Exhibit 23.1

Consent of Independent Certified Public Accountants

We consent to the incorporation by reference in the Registration Statement (Form S-8, No. 333-110646) pertaining to the Oragenics, Inc. 2002 Stock Incentive Plan of our report dated January 30, 2004 with respect to the financial statements of Oragenics, Inc. incorporated by reference in its Annual Report (Form 10-KSB) for the year ended December 31, 2003.

/s/ Ernst & Young LLP

Tampa, Florida
March 15, 2004

Exhibit 31.1

CERTIFICATION

I, Mento A. Soponis, certify that:

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

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

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

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

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

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

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

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

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

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

Date: _____

/s/ Mento A. Soponis

Mento A. Soponis
President
(principal executive officer)

Exhibit 31.2

CERTIFICATION

I, Paul A. Hassie, certify that:

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

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

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

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

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

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

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

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

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

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

Date: _____

/s/ Paul A. Hassie

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

Exhibit 32.1

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

In connection with the Annual Report of Oragenics, Inc. (the "Company") on Form 10-KSB for the period ended December 31, 2003 as filed with the Securities and Exchange Commission on the date here of (the "report"), I, Mento A. Soponis, 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 day of , 2004.

/s/ Mento A. Soponis
Mento A. Soponis
Chief Executive Officer

Exhibit 32.2

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

In connection with theAnnual Report of Oragenics, Inc. (the "Company") on Form 10-KSB for the period ended December 31, 2003 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 day of , 2004.

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