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

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2008

☐ **TRANSITION REPORT PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number 001-32188

ORAGENICS, INC.
(Exact name of registrant as specified in its charter)

Florida	**59-3410522**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
13700 Progress Blvd., Alachua, Florida (Address of Principal Executive Offices)	**32615** (Zip Code)

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

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

Title of each class	**Name of each exchange on which registered**
Common stock, par value $.001 per share	**NYSE Euronext Paris Exchange**

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☒

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of June 30, 2008 was approximately $12,043,419 based upon a last sales price of $0.55 as reported by the NYSE Alternext US (formerly known as the American Stock Exchange).

As of March 10, 2009 there were 38,316,585 shares of the registrant's Common Stock outstanding.

Documents Incorporated by Reference: Portions of the Proxy Statement for the registrant's 2009 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K.

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FORWARD LOOKING STATEMENTS AND CERTAIN CONSIDERATIONS

This report, along with other documents that are publicly disseminated by us, contains or might contain forward-looking statements within the meaning of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements included in this report and in any subsequent filings made by us with the SEC other than statements of historical fact, that address activities, events or developments that we or our management expect, believe or anticipate will or may occur in the future are forward-looking statements. These statements represent our reasonable judgment on the future based on various factors and using numerous assumptions and are subject to known and unknown risks, uncertainties and other factors that could cause our actual results and financial position to differ materially. We claim the protection of the safe harbor for forward-looking statements provided in the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act and Section 21E of the Exchange Act. Examples of forward-looking statements include: (i) projections of revenue, earnings, capital structure and other financial items, (ii) statements of our plans and objectives, (iii) statements of expected future economic performance, and (iv) assumptions underlying statements regarding us or our business. Forward-looking statements can be identified by, among other things, the use of forward-looking language, such as "believes," "expects," "estimates," "may," "will," "should," "could," "seeks," "plans," "intends," "anticipates" or "scheduled to" or the negatives of those terms, or other variations of those terms or comparable language, or by discussions of strategy or other intentions.

Forward-looking statements are subject to known and unknown risks, uncertainties and other factors that could cause the actual results to differ materially from those contemplated by the statements. The forward-looking information is based on various factors and was derived using numerous assumptions. Important factors that could cause our actual results to be materially different from the forward-looking statements include the following risks and other factors discussed under the Item -1A "Risk Factors" in this Annual Report on Form 10-K. These factors include:

- Our failure to raise capital,
- We have incurred significant operating losses since our inception and cannot assure you that we will generate revenue or profit,
- As a result of our lack of financial liquidity and negative shareholders' equity, our auditors have indicated there is uncertainty of our ability to continue as a "going concern,"
- If we fail to raise significant additional capital we may need to significantly curtail operations, marketing and development and it could cause us to be forced to cease operations or seek federal bankruptcy protection,
- If we raise capital it may be on terms that result in substantial dilution to our existing shareholders,
- We may be unable to achieve commercial viability and acceptance of our consumer products and our proposed products,
- Orders we receive for our consumer products may be subject to terms and conditions that could result in their cancellation or the return of products to us,
- We may become dependent on a few large retail customers for sales of our consumer products,
- If we are unable to raise sufficient capital our license for our SMaRT™ Replacement Therapy and M 1140 with the University of Florida Research Foundation could be terminated,
- We are subject to extensive and costly regulation by the FDA, applicable international regulators and other regulatory bodies, which must approve our product candidates in development and could restrict or delay the sales and marketing of such products in development,
- We may be unable to successfully operate internationally,
- We may be unable to improve upon, protect and/or enforce our intellectual property,

- We may be unable to enter into strategic collaborations or partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates or maintain strategic collaborations or partnerships,

- We may be adversely impacted by the current worldwide credit crisis and its impact on consumers and equity markets as well as our ability to obtain required additional funding to conduct our business,

- We are subject to significant competition,

- As a public company, we must implement additional and expensive finance and accounting systems, procedures and controls as we grow our business and organization to satisfy new reporting requirements, which will increase our costs and require additional management resources.

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

PART I

ITEM 1. BUSINESS.

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

Overview

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

Corporate History

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

Corporate Strategy

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

Our Technologies

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

(1) Consumer Healthcare
   a. Oral probiotics that contain our ProBiora3^{TM} technology (food additive);
   b. Products for weight loss that revolve around our LPT3-04^{TM} weight loss agent(food/nutritional supplement);

(2) Antibiotics
   a. DPOLT^{TM} lantibiotic synthesis platform (for generation of drug products);
   b. MU 1140, *mutacin* (drug)

(3) Diagnostics
   a. PIVIAT™ (diagnostics and drugs) and
   b. PCMAT™ (diagnostics and drugs)

(4) Replacement Therapy
   a. SMaRT Replacement Therapy™ (biological drug)

CONSUMER HEALTHCARE:

Consumer Healthcare has two product categories; (1) Oral Probiotics, and (2) Weight Loss.

Oral Probiotics:

Our oral probiotics revolve around the ProBiora3™ technology.

ProBiora3™ (Probiotics)

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

Oral Biology

The oral cavity provides an ecological niche for 400-700 bacterial species, some of which are responsible for periodontal disease (gum disease) and dental caries (tooth decay). Of all of the bacteria normally residing in a person's mouth, only about half a dozen are the primary cause of periodontal disease and dental caries.

Regulatory Status of Oral Probiotics

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

Market Opportunities

Oral Care: The oral care market is exceptionally large. It has been estimated by Packaged Facts that the over-the-counter ("OTC") global oral care market was in excess of $7.5 billion in retail in 2006. At present, ProBiora3™ is the only comprehensive oral probiotic technology in the market.

Companion Pets: According to the APPA ("American Pet Products Association"), in 2006, approximately 63% of US households owned a pet, with 38.4 and 44.8 million households owning cats and dogs respectively. The APPA also estimates that total pet industry expenditures in 2008 in the US was $43.2 billion with $10.2 billion being spent on Supplies/OTC Medicine.

Probiotics in general: Probiotics products are relatively common in Asia and Europe. The probiotics market in the U.S. is emerging, and products are available that address gastrointestinal problems and other uses, especially as nutritional supplements, food supplements, dietary aide, or other non-prescription products. If successfully developed, we expect our technology will be one of the first probiotics to be marketed for the promotion of oral health.

Marketing ProBiora3™

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

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

EvoraPlus™ was launched in December 2008. The next product we expect to take to market is Teddy's Pride™, which is expected to follow later this year.

EvoraPlus™ Description & Manufacturing

EvoraPlus™ is a probiotic mint packaged in a 60 unit box with four 15-dose blister packs. The intended use for EvoraPlus™ is for the consumer to take one mint twice per day after brushing. As such, one box equals approximately one-month's supply of the product. It is important to note that EvoraPlus™ is not a casual use product, but rather a repetitive use product. We believe this feature is highly attractive since it provides recurring revenues. We have completely outsourced the manufacturing process to a large, GMP certified manufacturer with the ability to scale production as needed.

Competition to the ProBiora3™ Technology

Many companies sell probiotics that are principally designed for digestive health, vaginal and urinary tract health, and immune system support. Our product will not compete directly with the products of these companies. Recently, researchers at the University of Hiroshima in Japan have published studies indicating that *Lactobacillus reuteri* aids in the prevention of tooth decay. *Lactobacillus reuteri* is widely used as a probiotic for other indications and may be used in the future for dental health. We are aware of a probiotic product from BioGaia AB, containing a strain of *lactobacillus reuteri*, which is on the market today and is targeted to maintain dental health. Another oral probiotic therapy commercially available from TheraBreath (known as AKTIV K12 probiotic), available in a mouthwash and tablets; it is stated to be used for bad breath and contains the bacterium, *Streptococcus salivarius* K12. This bacterium principally colonizes the cheek and tongue surfaces in oral cavity, and as such is promoted only for its activity as an aid for halitosis. As compared to all of these competitors, Probiora3™ potentially has greater beneficial actions for maintaining oral health.

Weight Loss:

The Company's weight loss products are based on the discovery of LPT3-04™.

LPT3-04™ Brief Description

LPT3-04™ is a naturally occurring compound, which is normally consumed in the human diet in small amounts. Our scientists discovered that consumption of significantly larger amounts results in dose dependent weight loss in experimental animal models. The mechanism of action appears to be induction of apoptosis, or programmed cell death specifically in white fat cells. LPT3-04™ consumption in the required amounts has been shown to be completely safe in humans.

The Weight Loss & Diet Control Market

According to Marketdata, Inc., the US Weight Loss & Diet Control market was approximately $59 billion in 2007. Obesity is at epidemic proportions and is a global problem.

Weight Loss Marketing Strategy

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

ANTIBIOTICS:

DPOLT™

The cornerstone of our antibiotics division is our Synthetic Chemistry Platform, DPOLT™ (Differentially Protected Orthogonal Lantionine Technology), which affords us the ability to synthesize a unique class of antibiotics known as lantibiotics.

DPOLT™ Brief Description

DPOLT™ is a patented, novel organic chemistry synthesis platform that will enable large scale, cost effective production of clinical grade MU 1140 and potentially 50 other known lantibiotics. Over the past 80 years, efforts to devise methods to investigate the usefulness of this class of antibiotics have met with uniform failure. We believe DPOLT™ can to lead to 6-10 new antibiotics with novel mechanisms of action. This represents a substantial pipeline of antibiotics to replace ones that are currently failing due to the development of bacterial resistance.

MU 1140

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

Market Opportunity

Two million hospital acquired infections occur each year according to the Center for Disease Control, and about 100,000 patients die each year. The critical care market for antibiotics is about $7 billion in U.S.A. Cubicin®, a newer gram positive lipopeptide antibiotic, had 2008 sales of $415 million in the US. The need for novel antibiotics is increasing as a result of the growing resistance of target pathogens. The Center for Disease Control estimates that bacteria resistant to known antibiotics cause 44% of hospital infections; individual hospitals have resistant rates as high as 70% for many important gram positive infections. Vancomycin, introduced in 1956, serves as the last line of defense against certain life-threatening infections, but certain bacteria have developed strains which resist even vancomycin.

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

Preclinical Studies

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

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

Intellectual Property

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

Progress

On October 14, 2008, we announced the successful synthesis of an antibiotic using our proprietary DPOLT™ technology. The molecule belongs to a class of antibiotics called Lantibiotics that were first discovered over 80 years ago. Although there are now over 50 different Lantibiotics known, this is the first report of a cost-effective method for making one in sufficient amounts and with sufficient purity to enable comprehensive testing and commercial viability. As a first step in further development, we have retained Almac Sciences, a leading contract manufacturer and a division of the Almac Group, to refine and scale-up GMP production of the synthetic MU1140™ analogue to achieve sufficient quantities for it to be fully tested for regulatory approval. We currently estimate that, once commenced, the regulatory process will take at least four years of clinical testing and the application and approval of an NDA by the FDA before this drug could be commercially available. Other synthetic Lantibiotics are expected to follow as they are developed and tested.

Competition

MU 1140 would compete directly with antibiotic drugs such as vancomycin and newer drugs, Cubicin (daptomycin) and Zyvox (linezolid). Given the growing resistance of target pathogens to even new antibiotics, we believe that there is ample room in the marketplace for additional antibiotics.

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

Many of our competitors are taking approaches to drug development differing from our approach, including traditional screening of natural products; e.g., genomics to identify new targets, and combinatorial chemistry to generate new chemical structures. Competition in the pharmaceutical industry is based on drug safety, efficacy, ease of use, patient compliance, price, marketing, and distribution. Commercial success of MU 1140 technology will depend on our ability and the ability of our sub-licensees to compete effectively in all of these areas, against other companies with existing and pipeline antibiotics to be commercialized in the future. There can be no assurance that competitors will not succeed in developing products that are more effective than MU 1140 or would render MU 1140 obsolete and non-competitive.

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

DIAGNOSTICS:

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

Developing a Diagnostic Test Using Gene Targets

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

(1) **Identification of Gene Targets.** We use our proprietary platforms to identify gene targets for specific disease states.

(2) **Validation.** Once targets have been identified, they then need to be validated. This can be done internally or by a third-party.

(3) **Incorporation into a Diagnostic Test.** Validated targets can then be incorporated into a diagnostic test. We could license the targets to a third-party diagnostics company.

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

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

PIVIAT™ Brief Description

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

PCMAT™ Brief Description

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

The In Vitro Diagnostics ("IVD") Market

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

Progress

On September 29, 2008, we entered into a Collaboration Agreement with a major, global diagnostics company regarding our gene targets for various stages of colorectal cancer that we discovered using the PCMAT™ platform. We have also initiated a new internal program for both the PIVIAT™ and PCMAT™ platforms. Under this initiative we expect to augment our development work by including the validation of gene targets we have discovered through the use of the platforms. We anticipate that this will in turn make our gene targets more valuable and decrease time to market for any test that utilizes them.

REPLACEMENT THERAPY:

SMaRT Replacement Therapy™

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

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

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

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

Regulatory Status

We have conducted a FDA Phase I clinical trial and we have been approved for a FDA Phase I(b) clinical trial. We anticipate initiating this second Phase I safety trial. We also believe that SMaRT Replacement Therapy will be an appealing technology for developing countries. As such, we intend on pursuing regulatory approval in Mexico as soon as our capital resources permit.

Manufacturing, Marketing and Distribution

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

Market Opportunity

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

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

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

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

Competition

We are not aware of any direct competitors with respect to our licensed, patented replacement therapy technology. However, there may be several ways to disable or eradicate *S. mutans*. We know that certain companies and several academic and research institutions are developing and testing caries vaccines aimed at eradicating *S. mutans*. An alternative approach involves topical application of adhesion-blocking synthetic peptides that prevent *S. mutans* from attaching to the tooth surface. Products that result in the elimination of *S. mutans* from the natural ecosystem would require major studies to determine whether such eradication of naturally occurring bacteria might not create serious, unintended consequences. The problem with eradicating *S. mutans* is that it disrupts the natural ecosystem leaving a void for another pathogen potentially more harmful than *S. mutans* to dominate.

Any product based on our replacement therapy technology will compete against traditional oral care products used to combat tooth decay. These products include fluoride-based toothpastes as well as fluoride treatments and tooth sealants administered by dentists. These competitors could include, among others, Colgate; Procter & Gamble; Unilever; GlaxoSmithKline; and Dentsply. All of these companies are much larger and have far greater technical and financial resources than us.

Our In-Licensed Technology Agreements

Replacement Therapy

We have exclusively licensed the intellectual property for our replacement therapy technology from the University of Florida Research Foundation, Inc., a non profit Florida corporation (the "Florida Research Foundation"). The original license agreement was dated August 4, 1998 and was subsequently amended on September 15, 2000, July 10, 2002, September 25, 2002 and March 17, 2003. The amended license agreement provides us with an exclusive worldwide license to make, use and sell products and processes covered by Patent No. 5,607,672, entitled "Replacement Therapy for Dental Caries", which was filed in the United States Patent Office on June 7, 1995 and made effective on March 4, 1997. The patent will expire on June 7, 2015. Our license is for the period of the patent, subject to the performance of terms and conditions contained therein. The patent covers the genetically altered strain of *Streptococcus mutans* which does not produce lactic acid, a pharmaceutical composition for administering the genetically altered strain and the method of preventing tooth decay by administering the strain. See "-Our Intellectual Property".

We issued 599,940 shares of our common stock to the Florida Research Foundation as partial consideration for the initial license.

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

MU 1140.

We have exclusively licensed the intellectual property for our MU 1140 lantibiotic technology from the Florida Research Foundation. The original license agreement was dated June 22, 2002, 1998 and was subsequently amended on September 15, 2000, July 10, 2002, September 25, 2002 and March 17, 2003. The amended license agreement provides us with an exclusive worldwide license to make, use and sell products and processes covered by Patent No. 5,932,469 entitled "Antimicrobial Polypeptide and Methods of Use". Our license is for the period of the patent, subject to the performance of terms and conditions contained therein. See "-Our Intellectual Property."

Common Terms

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

We are obligated to pay 5% of the selling price of any products developed from the licensed technologies that we may sell as royalty to the Florida Research Foundation. In addition, if we sublicense any rights granted by the amended license agreements, we are obligated to pay the Florida Research Foundation twenty percent (20%) of all revenues received from the sublicenses (excluding monies received solely for development costs).

We are also obligated to make minimum annual royalty payments to the Florida Research Foundation for the term of the amended license agreement in the amount of $50,000 by the end of each year for each license agreement. The minimum royalty payments are required to be paid in advance on a quarterly basis. For the replacement therapy and Mutacin 1140 minimum royalty payments, we must pay the Florida Research Foundation an aggregate of $100,000 which is required to be paid in equal quarterly installments of $25,000.

Under the terms of the amended license agreements, in each calendar year and in addition to the royalty payment obligations, we are obligated to spend, or cause to be spent, an aggregate of $1,000,000 on the research, development, and regulatory prosecution of our replacement therapy and Mutacin 1140 technologies combined, until a product which is covered wholly or partially by the claims of the patent, or is manufactured using a process which is covered wholly or partially by the claims of the patent, is sold commercially. If we fail to make these minimum research and development expenditures, the Florida Research Foundation may terminate our license agreement.

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

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

We are required to maintain liability insurance coverage appropriate to the risk involved in marketing the products, for which we obtained liability insurance that expired in August, 2008 and renewed through March, 2010. There is no assurance that we can obtain continued coverage on reasonable terms.

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

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

Technical Background Of Our Products And Platform Technologies

Consumer Healthcare

Oral Care Probiotic Products. ProBiora3™ is a blend of three naturally occurring oral bacteria for use in the promotion of oral health. The human body is host to hundreds of species of microorganisms that are normally non-pathogenic and in some cases are even required for good health. The concept of supplementing the diet with certain microorganisms to promote health is well established for the gastrointestinal tract, and these probiotic products are today a leading growth segment in the nutrition industry. We have applied this same concept to oral health and demonstrated that the regular introduction of select species of naturally occurring oral bacteria can promote oral health by reducing the number of pathogenic bacteria responsible for dental caries (tooth decay) and periodontal (gum) disease. Our probiotic system utilizes three separate, natural species of bacteria, each with a specific function for maintaining a healthy oral environment. These strains may be administered together or separately.

Through our research we discovered a very strong inverse relationship between the presence of certain species of viridans streptococci and the bacteria that are thought to cause most types of periodontal disease. In a healthy periodontal site, *Streptococcus oralis* (previously called *S. sanguis* type II) and *Streptococcus uberis* are commonly found in significant amounts, while the levels of periodontal pathogens including *Tannerella forsythensis* (Tf)*, Aggregatibacter actinomycetemcomitans* (Aa)*, Porpyromonas gingivalis* (Pg)*, Prevatella intermedia* (Pi)*, Peptostreptococcus micros* (Pm), *Campylobacter rectus* (Cr), and *Prevotella melaninogenica* (Pmel) are usually quite low. The opposite situation prevails in disease sites where, in fact, *S. oralis* and *S. uberis* are usually undetectable. Our scientists have demonstrated that the observed negative interactions between *S. oralis* and *S. uberis* and the various periodontal pathogens is dose dependent. Furthermore, our scientists have demonstrated that *S. oralis* and *S. uberis* inhibit the growth of periodontal pathogens by producing hydrogen peroxide.

Our research revealed that Probiora3 has also demonstrated other features. One feature of our Probiora3™ is that the production of hydrogen peroxide by these microorganisms was demonstrated in pilot laboratory experiments to be sufficient to produce a substantial whitening effect on tea and chlorhexidine stained ceramic disks and, in separate experiments, to oxidize volatile sulfur compounds (VSC) responsible for bad breath. Another feature of our ProBiora3™ technology is that it expressed the ability to suppress the levels of *Streptococcus mutans,* the principle etiologic agent of tooth decay. *Streptococcus rattus* is a very close relative of *S. mutans.* In fact, until fairly recently, *S. rattus* was considered to be one of several subspecies of *S. mutans.* We have isolated a particular, completely natural strain of *S. rattus*, called JH145, which does not make lactic acid from metabolism of sugar. The genetic defect in JH145 has been identified as a spontaneous deletion mutation in the middle of the structural gene for the enzyme lactate dehydrogenase. Since JH145 does not make lactic acid, it is virtually incapable of causing tooth decay.

We have discovered, developed, filed for international patent protection, and completed a "proof-of-principle" clinical trial for our ProBiora3™ oral probiotic product intended for maintenance of oral health. See "—Our Intellectual Property". A twice-daily administration of our proprietary blend of naturally occurring oral bacteria, in a mouthwash format, was well tolerated by the subjects and no safety issues were observed during the trial. The mouthwash was able to produce substantial decreases in the numbers of key pathogenic bacteria in the saliva and periodontal sulci of young healthy adults, most likely through the mechanisms of direct interaction and competitive exclusion. Probiora3 should be administered daily for maximum benefit. The stable product format allows incorporation into many different types of deliveryvehicles such as mouthwash, chewing gum, lozenges, and fast-dissolve tablets.

Weight Loss Product LPT3-04™. Through our research we have identified a naturally occurring dietary ingredient, LPT3-04™, which, when added in sufficient amounts to the diet of laboratory animals, has the effect of causing a dose-dependent loss in weight. This effect has been observed in double blind studies in a number of rodent strains and in dogs, and anecdotally in humans. At optimal doses, and indeed at super-optimal doses, no deleterious side-effects were observed during prolonged administration. Our laboratory and animal data provide intriguing evidence that LPT3-04™ can be used to induce weight loss without observable adverse side-effects. Our data further indicate that LPT3-04™ acts to induce apoptosis (programmed cell death) specifically in white adipose cells, probably using an unrecognized pathway.

While we believe LPT3-04™ can be marketed as a nutritional supplement for weight management it would not be a suitable candidate for drug development, primarily because the size of a daily dose is in grams and not milligram quantities. Upon completion of an ingredient dossier to satisfy the safety requirements, we believe it can also be used as a food additive for weight loss and weight management. We expect that this same regulatory path can be followed in other key geographic areas.

Blinded animal studies demonstrated a dose dependent effect of LPT3-04™ on both weight loss and fat content. In both Sprague-Dawley and Fisher rats, statistically significant weight loss was observed in treated animals within weeks. The size of an animal's mesenteric fat pad was inversely proportional to the amount of LPT3-04™ in its diet. The weight loss was reversed by elimination of LPT3-04™ from the diet. Zucker diabetic fatty (ZDF) rats fed diet containing LPT3-04™ also showed a significant reduction in weight gain compared to control animals, and preliminary evidence indicated that onset of diabetes was delayed. Treatment of Sprague-Dawley rats with LPT3-04™ appears to be safe. No treatment related abnormalities were reported at necropsy of animals fed a diet supplemented with LPT3-04™ for 26 weeks. Histopathological examination revealed no remarkable results for all of the organs and tissues tested. No adverse changes in hematology and blood chemistry were observed. No behavioral changes were noted during daily observations in any of the animal studies conducted. Total proteins from various organs and tissues were extracted from LPT3-04™ treated and control animals. These samples were assayed for their content of the apoptosis marker, BAD phosphorylated at position 136. The data clearly demonstrated a dose-dependent decrease in this marker in white adipose tissue (WAT) while no such decrease was observed in brown adipose tissue or the other tissues tested. The results indicate that a high LPT3-04™ diet leads to apoptosis specifically in white adipose tissue, probably via a currently unrecognized pathway.

LPT3-04™ is a compound that has been extensively studied in humans with regard to its role in the possible treatment of several unrelated disorders, but it has not previously been studied for weight loss. At daily doses that were somewhat higher than the amount proposed for use as an aid in weight loss, no significant side effects were reported over the several month periods of the studies. Subjects occasionally complained of mild nausea and dry mouth, but these effects were either self-resolving, or disappeared when use was discontinued. LPT3-04™ for weight loss has not been the subject of a formal human trial to date. However, information exists from a number of individuals who have taken LPT3-04™ that demonstrates a level of effectiveness that would be expected based on animal studies.

Antibiotics Platform Technology

DPOLT™ Antibiotic Synthesis Platform Technology. Differentially Protected Orthogonal Lantionine Technology (DPOLT™) is a solid/liquid phase peptide synthesis platform technology that has broad application for the cost-effective manufacture of a number of bioactive peptides, particularly lantibiotics, a potentially important class of antibiotics. Approximately fifty lantibiotics have been identified, including our lead antibiotic, MU 1140. Lantibiotics constitute a family of polycyclic peptides that are produced by bacteria, and are highly modified structurally. Attempts to study lantibiotics for their potential usefulness as therapeutic agents have been hindered by difficulties in producing sufficiently pure material, in amounts adequate for preclinical testing.

Many strains of medically important bacteria have become increasingly resistant to currently marketed antibiotics. We are completing work to establish proof-of-principle for the DPOLT™ platform technology and eventually to synthesize a number of novel lantibiotic analogs that may be effective in treating various infections, including ones caused by drug-resistant bacteria. Based on progress to date, we were awarded a Phase 2 SBIR grant from NSF to support our continuing efforts to synthesize and produce an MU 1140 analog.

MU1140™ Antibiotic. MU1140™ is a chromatographically purified lantibiotic derived from a strain of *Streptococcus mutans*. MU1140 is a peptide belonging to a small group of antibiotics called type A(I) lantibiotics. Lantibiotics, as a group, are ribosomally synthesized, they range in size from 19 to 34 amino acids, and they have extensive posttranslational modifications. The defining characteristic of lantibiotics is that they contain the unusual amino acids lanthionine (Lan) and/or β-methyllanthionine (MeLan), as well as other amino acids and functional groups not found elsewhere in nature.

MU1140 is active at low concentrations against most Gram positive bacteria against which it has been tested *in vitro*, including methicillin resistant *Staphylococcus aureus* (MRSA) and vancomycin resistant *Enterococcus faecalis.* It is also active against some Gram negative pathogens, including *Helicobacter pylori,* the bacterium responsible for most peptic ulcers. Preclinical testing of MU1140 suggests that it will be well suited to serve as a drug in the treatment of a number of infectious agents that are currently resistant to other existing antibiotics. Our research has demonstrated that MU1140:

- has a broad spectrum of activity, principally against Gram positive bacteria;
- has demonstrated in preliminary studies bacteriocidal activity against both growing and dormant cells of *Mycobacterium tuberculosis;*
- is chemically stable and resistant to hydrolytic enzymes *in vitro*, including those present in human and murine plasma;
- does not provoke a measurable immune response in experimental animals, indicating that allergy to MU 1140 will be rare;
- showed negligible cytotoxicity when therapeutic doses were tested against yeast cells and fibroblast and kidney cell lines;
- demonstrated *in vivo* efficacy in mouse and rat models in which animals were infected intraperitoneally with *S. aureus* and MU 1140 was administered intravenously at doses well below its maximum tolerated dose;
- has a novel mechanism of action that involves binding to and abducting Lipid II, which is required for cell wall biosynthesis (Science, 313:1636, 2006; Biochemistry, web release date Feb 12, 2008);
- attempts to find spontaneous, genetically stable resistant mutants to MU 1140 have been unsuccessful to date (interestingly, the producer strain has no immunity to its own antibiotic); relatively small increases in minimum inhibitory concentrations (MICs) following repeated subculture in sublethal concentrations of MU 1140 are probably due to self-limiting changes in the composition of target cell plasma membrane;
- demonstrated synergy with an aminoglycoside in a preliminary study; and
- binds reversibly to plasma proteins and, based on preliminary studies, has a half-life in the serum of Sprague-Dawley rats of approximately 2 hours.

Our research has optimized fermentation methods to obtain product yields sufficient to undertake the above mentioned preclinical studies. A simple and fast chromatography method has also been devised to achieve MU 1140 with purity equal to or greater than 95%. Large scale, cost effective cGMP production of an MU 1140 analog, for use as clinical trial material in human safety and efficacy studies, is expected to be achieved using our proprietary small peptide antibiotic synthesis platform technology, DPOLT™.

The various product features described above illustrate the potential of MU1140 to serve as a therapeutic agent for the management of infections caused by certain important Gram-positive pathogens. We have exclusively in-licensed this patented technology from the University of Florida Research Foundation, Inc. See"—Our In-Licensed Technology Agreements" and "Our Intellectual Property."

Diagnostics Platform Technology

Proteomics-based In Vivo Induced Antigen Technology (PIVIAT™). PIVIAT™ is a platform technology that efficiently identifies proteins of microbial pathogens that are specifically expressed when the pathogen is engaged in an actual infectious process involving a host that can mount a humoral (antibody) immune response. Such proteins are referred to as *in vivo* induced (IVI), and they are very likely targets for use in a variety of applications, such as the development of new vaccine, diagnostic and antibiotherapy strategies.

PIVIAT™ has three major advantages over other existing technologies for identifying IVI genes: 1) it does not rely on animal models of infection, which may be misleading or may not exist at all for many pathogens; 2) it can identify IVI genes that are turned on at any point in the infectious process, rather than those that happen to be turned on at just a single time point; 3) it can be used to identify IVI genes in any microbial pathogen that can be grown in the laboratory, and is not limited to those that can be genetically manipulated. In addition, compared to other existing methods (e.g., microarrays, proteomic arrays) for identifying IVI genes/proteins, PIVIAT™ is significantly more sensitive, faster and less expensive.

The major conceptual breakthrough that enables PIVIAT™ to display all of these advantages relative to other technologies stems from the recognition that the host makes antibodies against the vast majority of the proteins manufactured by the pathogen from the moment it enters the host until it is cleared by the host's defenses. Thus, a serum samples from convalescent hosts have antibodies that can be used to probe for IVI genes. By pooling sera from several different patients, PIVIAT™ is able to find the widest possible array of antigens produced during different stages of infection. The pooled serum is absorbed with whole cells and cellular extracts prepared from the pathogen grown *in vitro* to remove antibodies reactive with constitutively produced proteins. The resulting adsorbed serum contains the subpopulation of antibodies reactive against proteins expressed only during the actual infectious process. This adsorbed serum is used to capture proteins of the pathogen (made by a genomic expression library) that are very likely to be essential for virulence or survival of the pathogen in the human host.

Since its creation in 2000, PIVIAT™ has been successfully applied to the identification of IVI genes in a significant number of pathogens. It is worth noting that, even though a relatively recent technology, PIVIAT™ has already identified several targets that have been licensed and are under development for clinical applications. Most recently, PIVIAT™ analysis of *Mycobacterium tuberculosis*, using rapid and sensitive proteomic methods, identified 44 novel IVI proteins that were the subject of a PCT patent application filed in March 2007. These currently are being validated by preeminent tuberculosis experts to determine their potential usefulness in new diagnostic and vaccine applications.

More than 30 peer reviewed publications detailing all aspects of PIVIAT™ have appeared. We have a patent on this technology as well as patents application pending. See "—Our Intellectual Property."

Proteomics-based Change Mediated Antigen Technology (PCMAT™). The remarkable impact of PIVIAT™ on the study of human and animal pathogens led us to ask if this method could be made more general; to include, for example, diseases of plants where the host does not mount an antibody response. The solution to this problem follows: infected plant tissue can be harvested and snap frozen or otherwise treated to preserve antigens of the pathogen that are present at the exact moment of collection. At the same time, proteins made by the plant in response to the infection are also preserved. When this tissue is mixed with adjuvant and used to immunize an appropriate host, the immune serum that is obtained can be adsorbed with *in vitro* grown cells of the pathogen to create a probe for identifying virulence/survival proteins of the pathogen. It can also be adsorbed with healthy plant tissue to identify resistance genes of the host. Proof of principle has been accomplished using *Xanthomonas campestris* infection of the common bean plant, where we have identified both novel virulence genes of the pathogen and novel resistance genes of the host.

Further reflection on the PCMAT™ method brought to our attention that this method can also be used to study a vast array of problems ranging from autoimmune diseases to biofilms to cancer. In the last of these, for example, an ongoing study by us used surgically excised colon cancer tissue representing early, middle and late stage disease. The tissue samples were flash frozen and homogenates were used to immunize an appropriate host. The resulting antibodies were adsorbed with homogenates of healthy tissue from the autologous human subjects so that remaining antibodies were directed at proteins made by the cancer cells but not by normal, healthy cells. Proteins reactive with these antibodies have been captured and identified using rapid, sensitive proteomic methods and are the subject of a US provisional patent application filed on July 21, 2008. The collection of change mediated proteins identified by PCMAT™, which are expressed when a normal bowel cell undergoes transformation to become a cancer cell, has been licensed by a major diagnostic company.

Change mediated proteins identified by PCMAT™ are expected to make excellent targets for new approaches to diagnose diseases, for biomarkers to evaluate the efficacy of a treatment regimen, and possibly in novel vaccine or antibiotherapy approaches. In the case of both plant and animal diseases, identification of change mediated proteins may enable rationally-based strategies to help prevent, retard or cure the disease.

We have several patent applications pending on this technology. See "—Our Intellectual Property".

Replacement Therapy

SMaRT™ Replacement Therapy™. SMaRT™ Replacement Therapy™ is a professional/Rx product intended for the prevention of dental caries (tooth decay). Dental caries remain a major health problem afflicting a majority of the population in the United States and worldwide. Lactic acid production by the oral bacterium *Streptococcus mutans* has long been known to be integral to the pathogenic process for dental caries. Oragenics, Inc.'s replacement therapy technology replaces the indigenous, acid-producing *S. mutans* with a SMaRT effector strain, which has been genetically modified so as not to produce the acid associated with caries formation.

The wild-type *S mutans* originally used for construction of the SMaRT™ strain was isolated from a human subject and was carefully selected based on its ability to produce the antibiotic, MU1140. MU1140 has been shown to kill all other strains of *S. mutans* that it has been tested against. The SMaRT™ effector strain was generated by transforming this wild-type parent strain with recombinant DNA that introduced a large deletion mutation in the gene for lactate dehydrogenase (LDH) eliminating the strain's ability to produce lactic acid. The careful genetic construction of the SMaRT™ strain using deletion mutations makes it extremely genetically stable, as demonstrated by *in vitro* spontaneous reversion frequencies that are less than 10^{-11}. To further stabilize *S. mutans* against genetic instability caused by a process called transformation, a deletion mutation was introduced into the chromosome that eliminated the *comE* gene, which is critical for DNA uptake by *S. mutans* from its environment.

Our SMaRT™ effector strain for the replacement therapy of dental caries has the following advantages over existing decay-prevention technologies: (1) a single treatment regimen involving application of SMaRT™ cells onto patients' tooth surfaces using a cotton tipped swab for five minutes has the potential to provide lifelong protection against most tooth decay; (2) the possibility of deleterious side-effects are negligible since the effector strain is essentially identical to the microorganism which is found universally on the teeth of humans; (3) minimal patient education and compliance is required. The SMaRT™ effector strain has been extensively and successfully tested in the laboratory and in animal models with the following results obtained:

- The SMaRT™ strain makes no lactic acid under any cultivation conditions tested.
- In place of lactic acid, the SMaRT™ strain makes the neutral compounds ethanol and acetoin in amounts comparable to other microorganisms that colonize the human oral cavity.
- The spontaneous reversion frequency for *ldh* was estimated at $<10^{-11}$; furthermore, the exchange of DNA into and out of SMaRT™ is very low, based on results of *in vitro* mixed culture and biofilm studies and an *in vivo* cross-over rodent model study.
- The level of MU1140 production by SMaRT™ is comparable to its wild-type parent strain, which was previously shown to readily colonize the human oral cavity.
- The SMaRT™ strain aggressively displaces indigenous strains of *S. mutans* and preemptively colonizes its niche on the teeth of laboratory rats.

More than 30 peer reviewed publications detailing all aspects of replacement therapy and the SMaRT™ technology have appeared. We have in-licensed this patented technology from the University of Florida Research Foundation, Inc. See "—Our Intellectual Property" and "—Our In-Licensed Technology Agreements."

Government Regulations

The formulation, manufacturing, processing, packaging, labeling, advertising distribution and sale of our products are subject to regulation by federal agencies, including, but not limited to:

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

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

In foreign countries these same activities may be regulated by Ministries of Health, or other local regulatory agencies. The manner in which products sold in foreign countries are registered, how they are formulated, or what claims may be permitted may differ from similar products and practices in the U.S.

Generally Recognized As Safe("GRAS") Status

Under the FDCA any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by the FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive. The specific data and information that demonstrate safety depend on the characteristics of the substance, the estimated dietary intake, and the population that will consume the substance.

Dietary Supplements

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

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

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

The FDA may take enforcement action against a dietary supplement if the FDA believes the supplement presents a significant or unreasonable risk of illness or injury under conditions of use suggested in the labeling or under ordinary conditions of use. Under DSHEA, the FDA bears the burden of proof to show that a dietary supplement presents a significant or unreasonable risk of illness or injury. The FDA may also take enforcement action for unlawful promotion of a dietary supplement.

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

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

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

Our advertising of dietary supplement products is also subject to regulation by the Federal Trade Commission under the Federal Trade Commission Act, in addition to state and local regulation. The Federal Trade Commission Act prohibits unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce. The Federal Trade Commission Act also provides that the dissemination or the causing to be disseminated of any false advertisement pertaining to drugs or foods, which would include dietary supplements, is an unfair or deceptive act or practice. Under the Federal Trade Commission's Substantiation Doctrine, an advertiser is required to have a "reasonable basis" for all objective product claims before the claims are made. Failure to adequately substantiate claims may be considered either deceptive or unfair practices. Pursuant to this Federal Trade Commission requirement we are required to have adequate substantiation for all material advertising claims made for our products.

In recent years the Federal Trade Commission has initiated numerous investigations of dietary supplement and weight loss products and companies. The Federal Trade Commission is reexamining its regulation of advertising for dietary supplements and has announced that it will issue a guidance document to assist supplement marketers in understanding and complying with the substantiation requirement. Upon release of this guidance document we will be required to evaluate our compliance with the guideline and may be required to change our advertising and promotional practices. We may be the subject of investigation in the future. The Federal Trade Commission may impose limitations on our advertising of products. Any such limitations could materially adversely affect our ability to successfully market our products. The Federal Trade Commission has a variety of processes and remedies available to it for enforcement, both administratively and judicially, including compulsory processes, cease and desist orders, and injunctions. Federal Trade Commission enforcement can result in orders requiring, among other things, limits on advertising, corrective advertising, consumer redress, divestiture of assets, rescission of contracts and such other relief as may be deemed necessary. A violation of such orders could have a material adverse affect on our business, financial condition and results of operations.

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

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

We may be subject to additional laws or regulations by the Food and Drug Administration or other federal, state or foreign regulatory authorities, the repeal of laws or regulations which we consider favorable, such as the Dietary Supplement Health and Education Act of 1994, or more stringent interpretations of current laws or regulations, from time to time in the future. We are unable to predict the nature of such future laws, regulations, interpretations or applications, nor can we predict what effect additional governmental regulations or administrative orders, when and if promulgated, would have on our business in the future. The Food and Drug Administration or other governmental regulatory bodies could, however, require the reformulation of certain products to meet new standards, the recall or discontinuance of certain products not able to be reformulated, imposition of additional record keeping requirements, expanded documentation of the properties of certain products, expanded or different labeling and scientific substantiation. Any or all of such requirements could have a materially adverse affect on our business, financial condition, results of operations and cash flows.

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

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

FDA Regulation — Approval of Biological Products and New Drug Products

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

Biological products, like other drugs, are used for the treatment, prevention or cure of disease in humans. In contrast to chemically synthesized small molecular weight drugs, which have a well-defined structure and can be thoroughly characterized, biological products are generally derived from living material—human, animal, or microorganism— are complex in structure, and thus are usually not fully characterized. The *Public Health Service (PHS) Act* defines a biological product as a “virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, applicable to the prevention, treatment, or cure of a disease or condition of human beings.” FDA regulations and policies have established that biological products include blood-derived products, vaccines, in vivo diagnostic allergenic products, immunoglobulin products, products containing cells or microorganisms, and most protein products. Biological products subject to the *PHS Act* also meet the definition of *drugs* under the *Federal Food, Drug and Cosmetic Act (FDCA)*. Biological products are a subset of drugs; therefore both are regulated under provisions of the FDCA. However, only biological products are licensed under the PHS Act. The overall development process is similar to that for drugs. The steps ordinarily required before a biological product or new drug may be marketed in the United States include:

- completion of preclinical studies according to good laboratory practice regulations;
- the submission of an IND application to the FDA, which must become effective before human clinical trials may commence;

- performance of adequate and well-controlled human clinical trials according to good clinical practices to establish the safety and efficacy of the proposed biological product for its intended use;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product is manufactured, processes, packaged or held to assess compliance cGMP; and

- the submission to, and review and approval by, the FDA of a biologics license application "BLA", or new drug application ("NDA"), that includes satisfactory results of preclinical testing and clinical trials.

Preclinical tests include laboratory evaluation of the product candidate, its formulation and stability, as well as animal studies to assess the potential safety and efficacy of the product candidate. The FDA requires that preclinical tests be conducted in compliance with good laboratory practice regulations. The results of preclinical testing are submitted as part of an IND application to the FDA together with manufacturing information for the clinical supply, analytical data, the protocol for the initial clinical trials and any available clinical data or literature. A 30-day waiting period after the filing of each IND application is required by the FDA prior to the commencement of clinical testing in humans. In addition, the FDA may, at any time during this 30-day waiting period or any time thereafter, impose a clinical hold on proposed or ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization.

Clinical trials to support BLAs and NDAs involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated. Clinical trials are typically conducted in three sequential phases, but the phases may overlap.

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

Phase II clinical trials usually involve studies in a limited patient population to identify possible adverse effects and safety risks, preliminarily assess the efficacy of the product candidate in specific, targeted indications; and assess dosage tolerance and optimal dosage.

If a product candidate is found to be potentially effective and to have an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken within an expanded patient population at multiple study sites to further demonstrate clinical efficacy and safety, further evaluate dosage and establish the risk-benefit ratio of the product and an adequate basis for product labeling.

Phase IV, or post-marketing, trials may be mandated by regulatory authorities or may be conducted voluntarily. Phase IV trials are typically initiated to monitor the safety and efficacy of a biological product in its approved population and indication but over a longer period of time, so that rare or long-term adverse effects can be detected over a much larger patient population and time than was possible during prior clinical trials. Alternatively, Phase IV trials may be used to test a new method of product administration, or to investigate a product's use in other indications. Adverse effects detected by Phase IV trials may result in the withdrawal or restriction of a drug.

If the required Phase I, II and III clinical testing is completed successfully, the results of the required clinical trials, the results of product development, preclinical studies and clinical trials, descriptions of the manufacturing process and other relevant information concerning the safety and effectiveness of the biological product or new drug candidate are submitted to the FDA in the form of a BLA or NDA. In most cases, the BLA must be accompanied by a substantial user fee. The FDA may deny a BLA or NDA if all applicable regulatory criteria are not satisfied or may require additional data, including clinical, toxicology, safety or manufacturing data. It can take several years for the FDA to approve a BLA or NDA once it is submitted, and the actual time required for any product candidate may vary substantially, depending upon the nature, complexity and novelty of the product candidate.

Before approving an application, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve a BLA unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements.

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

The required testing, data collection, analysis and compilation of an IND and a new biological or drug application are labor intensive and costly and may take a great deal of time. Tests may have to be redone or new tests performed in order to comply with FDA requirements. It can take considerable time (e.g. 5-10 years) and resources to establish a Phase II or III clinical trial and achieve enrollment sufficient to commence such trials and ultimately proceed through to approval. Therefore, we cannot estimate with any certainty the length or the costs of the approval process. We can offer no assurance that we will ever receive FDA approval of products derived from our licensed, patented technologies.

FDA Regulation — Approval of Medical Devices

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

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

Medical devices are also subject to extensive regulation by the FDA. To be commercially distributed in the United States, medical devices must receive either 510(k) clearance or pre-market approval, or PMA, from the FDA prior to marketing. Devices deemed to pose relatively low risk are placed in either Class I or II, which requires the manufacturer to submit a pre-market notification requesting permission for commercial distribution, or 510(k) clearance. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, devices deemed not substantially equivalent to a previously 510(k) cleared device and certain other devices are placed in Class III which requires PMA.

To obtain 510(k) clearance, a manufacturer must submit a pre-market notification demonstrating that the proposed device is substantially equivalent in intended use and in safety and efficacy to a previously 510(k) cleared device, a device that has received PMA or a device that was in commercial distribution before May 28, 1976. The FDA's 510(k) clearance pathway usually takes from four to twelve months, but it can last longer.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require PMA. The FDA requires each manufacturer to make this determination, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA is obtained.

A product not eligible for 510(k) clearance must follow the PMA pathway, which requires proof of the safety and efficacy of the device to the FDA's satisfaction. The PMA pathway is much more costly, lengthy and uncertain than the 510(k) approval pathway. A PMA application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with quality system regulation requirements, which impose elaborate testing, control, documentation and other quality assurance procedures. Upon acceptance by the FDA of what it considers a completed filing, the FDA commences an in-depth review of the PMA application, which typically takes from one to two years, but may last longer. The review time is often significantly extended as a result of the FDA asking for more information or clarification of information already provided.

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

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

FDA Regulation — Post-Approval Requirements

Even if regulatory clearances or approvals for our product candidates are obtained, our products and the facilities manufacturing our products will be subject to continued review and periodic inspections by the FDA. For example, as a condition of approval of a new drug application, the FDA may require us to engage in post-marketing testing and surveillance and to monitor the safety and efficacy of our products. Holders of an approved new BLA, PMA or 510(k) clearance product are subject to several post-market requirements, including the reporting of certain adverse events involving their products to the FDA, provision of updated safety and efficacy information, and compliance with requirements concerning the advertising and promotion of their products.

In addition, manufacturing facilities are subject to periodic inspections by the FDA to confirm the facilities comply with cGMP requirements. In complying with cGMP, manufacturers must expend money, time and effort in the area of production and quality control to ensure full compliance. For example, manufacturers of biologic products must establish validated systems to ensure that products meet high standards of sterility, safety, purity, potency and identity. Manufacturers must report to the FDA any deviations from cGMP or any unexpected or unforeseeable event that may affect the safety, quality, or potency of a product. The regulations also require investigation and correction of any deviations from cGMP and impose documentation requirements.

In addition to regulations enforced by the FDA, we are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other federal, state and local regulations. Our research and development activities involve the controlled use of hazardous materials, chemicals, biological materials and radioactive compounds.

International Regulation

Our product candidates are subject to regulation in every country where they will be tested or used. Whether or not we obtain FDA approval for a product candidate, we must obtain the necessary approvals from the comparable regulatory authorities of foreign countries before we can commence testing or marketing of a product candidate in those countries. The requirements governing the conduct of clinical trials and the approval processes vary from country to country and the time required may be longer or shorter than that associated with FDA approval.

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

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

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

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

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

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

In some cases, we may plan to submit applications with different endpoints or other elements outside the United States due to differing practices and requirements in particular jurisdictions. However, in cases where different endpoints will be used outside the United States, we expect that such submissions will be discussed with the FDA to ensure that the FDA is comfortable with the nature of human trials being conducted in any part of the world. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution, would apply to any product that is approved in Mexico or Europe.

Competition

Industry. Our industry is subject to rapid and intense technological change. Competition is intense among manufacturers of nutritional, non-prescription, and prescription pharmaceuticals. We face, and will continue to face, retail, competition from neutraceutical, pharmaceutical, biopharmaceutical, medical device and biotechnology companies developing similar products and technologies both in the United States and abroad, as well as numerous academic and research institutions, governmental agencies and private organizations engaged in drug funding or research and discovery activities both in the United States and abroad. Academic institutions, government agencies and other public and private research organizations may also conduct research, seek patent protection and establish collaborative arrangements for discovery, research and clinical development of technologies and products similar to ours. We also face competition from entities and healthcare providers using more traditional methods. We believe there are a substantial number of products under development by numerous neutraceutical, pharmaceutical, biopharmaceutical, medical device and biotechnology companies, and it is likely that other competitors will emerge.

Many of our existing and potential competitors are large, well established pharmaceutical, chemical or healthcare companies with considerably greater research and product development capabilities and financial, scientific, marketing and human resources than we do. As a result, these competitors may succeed in developing competing products earlier than we do; obtain patents that block or otherwise inhibit our ability to further develop and commercialize our product candidates; obtain approvals from the FDA or other regulatory agencies for products more rapidly than we do; or develop treatments or cures that are safer or more effective than those we propose to develop. These competitors may also devote greater resources to marketing or selling their products and may be better able to withstand price competition. In addition, these competitors may introduce or adapt more quickly to new technologies or scientific advances, which could render our technologies obsolete, and may introduce products or technologies that make the continued development, production, or marketing of our product candidates uneconomical. These competitors may also be more successful in negotiating third party licensing or collaborative arrangements and may be able to take advantage of acquisitions or other strategic opportunities more readily than we can. These actions by competitors or potential competitors could materially affect our business, financial condition and results of operations. We cannot assure you that we will be able to compete successfully.

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

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

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

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

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

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

Our Intellectual Property

We rely upon a combination of licenses, patents, trade secrets, know-how, and licensing opportunities to develop our business. Our future prospects depend on our ability to protect our intellectual property, particularly our patents. We also need to operate without infringing the proprietary rights of third parties.

License Agreements. We have exclusively licensed the intellectual property for our Replacement Therapy and Mutacin 1140 technologies from the University of Florida Research Foundation, Inc., a non profit, Florida corporation. The related patents to which our exclusive license applies are U.S. patent 5,607,672, “Replacement Therapy for Dental Caries,” and U.S. patent 5,932,469, “Antimicrobial Polypeptide and Methods of Use” (including derivative patents: 6,391,285, 6,475,771, 6,964,760 and 7,067125). See “Our In-licensed Technology Agreements.”

Patents. We attempt to protect our technology and products through patents and patent applications. We have built a portfolio of patents and applications covering certain of our technologies. As of December 31, 2008, we hold one issued U.S. patent and we have 7 non-provisional U.S. patent applications directed toward our products and technologies. Our pending applications cover a range of technologies, including specific embodiments and applications for treatment of various medical indications, improved application methods and adjunctive utilization with other therapeutic modalities. We reassess the value of each patent at the time maintenance fees are due, and in cases where maintaining the patent is judged to be of no significant strategic value we decline to pay the fee. The patents and patent applications we have with respect to our products and technologies are set forth below:

Consumer products. We filed a patent application on our probiotic technology on August 10, 2004 (U.S. patent application serial number 10/567592). We also filed a patent application entitled "Methods for Size and Weight Reduction" (U.S. patent application serial number 11/265, 414).

Diagnostics. In our diagnostic division we acquired the rights to our platform technology in November 2006 in connection with our acquisition of IviGene Corporation. We own patents and applications directed toward the identification of polynucleotides expressed during the process of infection: *In Vivo* Induced Antigen Technology-U.S. Patent 7,033,748, and U.S. Patent Application Serial Nos. 10/092,243; 10/505,054 and 12/291,929; Method of Detection of *Mycobacterium Tuberculosis*, U.S. Patent Application Serial No. 12/293,497 filed 3/13/07.

Antibiotics. In our Antibiotics division we have filed a patent application directed at the intellectual property surrounding the DPOLT™ solid/liquid phase peptide synthesis platform technology, as well as associated areas of lantibiotics technology, in the U.S. (Serial No. 11/502,805) and internationally (August 2006). In addition, we have the exclusive license for our MU 1140 lantibiotic technology from the University of Florida Research Foundation. See "License Agreements" above.

Replacement Therapy. We have licensed Replacement Therapy technology, the use of recombinant *Streptococcus* strains to combat dental caries, from the University of Florida Research Foundation. See License Agreements above.

We also have applications pending and/or allowed in Australia, Canada, China, Hong Kong, Israel, Japan, Mexico, New Zealand, South Korea, as well as in the European Patent Office. Because of the differences in patent laws and laws concerning proprietary rights, the extent of protection provided by U.S. patents or proprietary rights owned by us may differ from that of their foreign counterparts.

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

We also have rights to use other names essential to our business. Federally registered trademarks have a perpetual life, as long as they are maintained and renewed on a timely basis and used properly as trademarks, subject to the rights of third parties to seek cancellation of the trademarks if they claim priority or confusion of usage. We regard our trademarks and other proprietary rights as valuable assets and believe they have significant value in marketing our products.

Protection of Trade Secrets. We attempt to protect our trade secrets, including the processes, concepts, ideas and documentation associated with our technologies, through the use of confidentiality agreements and non-competition agreements with our current employees and with other parties to whom we have divulged such trade secrets. If our employees or other parties breach our confidentiality agreements and non-competition agreements or if these agreements are not sufficient to protect our technology or are found to be unenforceable, our competitors could acquire and use information that we consider to be our trade secrets and we may not be able to compete effectively. Most of our competitors have substantially greater financial, marketing, technical and manufacturing resources than we have and we may not be profitable if our competitors are also able to take advantage of our trade secrets.

Research and Development Costs

We have spent $1,955,488, $1,569,551 and $2,023,896 on research and development of our technologies in 2008, 2007 and 2006, respectively.

Employees

As of December 31, 2008, we had 17 full-time and no part-time employees. We have 6 employees in research and development and 11 in general and administrative, which includes marketing and business development. Seven of our employees have received their Ph.D. We enjoy good employee relations. None of our employees are members of any labor union, and we are not a party to any collective bargaining agreement.

Available Information

Our website is www.oragenics.com. On our website we make available at no cost our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished as soon as reasonably practicable after we electronically file such material with, or furnish them to, the United States Securities and Exchange Commission ("SEC"). The information contained on our website is not a part of this annual report on Form 10-K.

ITEM 1A. RISK FACTORS.

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

Risks Related to Our Business

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

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

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

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

$2,935,719 for the year ended December 31, 2006

These losses, among other things, have had and will continue to have an adverse effect on our working capital, total assets and stockholders' (deficit) equity. In light of our recurring losses, accumulated deficit and cash flow difficulties, the report of our independent registered public accounting firm on our financial statements for the fiscal year ended December 31, 2008 contains an explanatory paragraph raising substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that may be necessary in the event we are unable to continue as a going concern.

We have experienced losses from operations during the last three years and have an accumulated deficit of $19,992,535 as of December 31, 2008. We have an operating cash flow deficit of $3,835,190 for the year ended December 31, 2008 and we sustained operating cash flow deficits of $1,913,760 and $2,224,538 in 2007 and 2006, respectively. In the fourth quarter of 2008, we incurred significant additional expenses that were attributable to our delisting from the NYSE Alternext and listing on the NYSE Euronext Alternext Paris Exchange (the "New Paris Listing). Our accounts payable and accrued expenses have also increased due to the listing issues as well as due to other operational changes instituted in connection with the launch of our consumer products. At December 31, 2008 and December 31, 2007, we had working capital of approximately ($500,672) and $260,534, respectively.

Since December 31, 2008, we have continued to incur additional expenses attributable to our operations and our New Paris Listing. The Company's principal source of liquidity at December 31, 2008 was $1,165,933 in cash and cash equivalents. The Company currently does not have sufficient capital to operate beyond mid-April 2009.

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

We do not have sufficient capital to sustain our operations beyond April 2009 and we will require additional financing as soon as possible. If we are not able to raise additional capital, among other things:

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

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

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

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

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

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

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

We are currently dependent upon a single company for the manufacture our products.

Since we currently have no manufacturing facilities, we are dependent upon establishing relationships with independent manufacturers to supply our product needs. We currently rely on one key contract manufacturer as our single source supplier for ProBiora3™ and the Evora™ line of products. If our contract manufacturer is unable or unwilling to produce these products we would not be able to manufacture them until a qualified alternative manufacturer is identified, which could impair our ability to commercialize these products and harm our business. We may not be able to find alternative manufacturers on favorable terms to provide us with these services or at all. In addition, competitors who do own their own manufacturing may have an advantage over us with respect to pricing, availability of product and in other areas through their control of the manufacturing process.

The manufacture of our products is a highly exacting and complex process, and if our manufacturers or suppliers encounters problems manufacturing products, our business could suffer.

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

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

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

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

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

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

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

Each of the technologies we are commercializing and developing for eventual commercialization will face various forms of competition from other products in the marketplace.

The pharmaceutical and biotechnology industries are characterized by intense competition, rapid product development and technological change. Most of the competition that the products developed from our technologies will face will come from companies that are large, well established and have greater financial, marketing, sales and technological resources than we have. Commercial success of our technologies will depend on our ability and the ability of our sub licensees to compete effectively in marketing and product development areas such as, but not limited to, sales and branding, drug safety, efficacy, ease of use, patient or customer compliance, price, marketing and distribution. There can be no assurance that competitors will not succeed in developing and marketing products that are more desirable or effective than the products developed from our technologies or that would render our products obsolete and non-competitive.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our dependence on collaborative arrangements with third parties subjects us to a number of risks. These collaborative arrangements may not be on terms favorable to us. Agreements with collaborative partners typically allow partners significant discretion in electing whether or not to pursue any of the planned activities. We cannot control the amount and timing of resources our collaborative partners may devote to products based on the collaboration, and our partners may choose to pursue alternative products. Our partners may not perform their obligations as expected. Business combinations or significant changes in a collaborative partner's business strategy may adversely affect a partner's willingness or ability to complete its obligations under the arrangement. Moreover, we could become involved in disputes with our partners, which could lead to delays or termination of the collaborations and time-consuming and expensive litigation or arbitration. Even if we fulfill our obligations under a collaborative agreement, our partner can terminate the agreement under certain circumstances. If any collaborative partner were to terminate or breach our agreement with it, or otherwise fail to complete its obligations in a timely manner, our chances of successfully commercializing products would be materially and adversely affected.

We are subject to the risks of doing business in Mexico and internationally.

We have initiated steps to conduct a joint venture in Mexico through a subsidiary related to the research, development, manufacture, registration, marketing and commercialization of certain of our products. While we anticipate that this joint venture will provide us with certain advantages including reduced costs for clinical trials and access to the Mexican market, we have no experience in conducting business in Mexico. We may encounter certain risks of doing business in Mexico including:

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

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

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

Our success depends in part on our ability to obtain patents or rights to patents, protect trade secrets, operate without infringing upon the proprietary rights of others, and prevent others from infringing on our patents, trademarks and other intellectual property rights. We will be able to protect our intellectual property from unauthorized use by third parties only to the extent that it is covered by valid and enforceable patents, trademarks and licenses. Patent protection generally involves complex legal and factual questions and, therefore, enforceability of patent rights cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from others may not provide adequate protection against competitors. In addition, any future patent applications may fail to result in patents being issued. Also, those patents that are issued may not provide us with adequate proprietary protection or competitive advantages against competitors with similar technologies. Moreover, the laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States.

In addition to patents and trademarks, we rely on trade secrets and proprietary know-how. We seek protection of these rights, in part, through confidentiality and proprietary information agreements. These agreements may not provide meaningful protection or adequate remedies for violation of our rights in the event of unauthorized use or disclosure of confidential and proprietary information. Failure to protect our proprietary rights could seriously impair our competitive position.

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

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

The production and marketing of products which may be developed from our technologies and our ongoing research and development, preclinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities. For example, while we plan to market Probiora3™ and LPT3-04™ products in the United States under self proclaimed GRAS (Generally Recognized As Safe) status; most of the technologies we are developing must undergo rigorous preclinical and clinical testing and an extensive regulatory approval process before they can be marketed in the United States or internationally. If the FDA or any other governmental regulatory body does not agree with our contention that certain of our products are exempt from testing and approval, we could be required to undergo the regulatory authority approval process. This process makes it longer, harder and more costly to bring products which may be developed from our technologies to market, and we cannot guarantee that any of such products will be approved. The pre-marketing approval process can be particularly expensive, uncertain and lengthy, and a number of products for which FDA or other governmental regulatory approval has been sought by other companies have never been approved for marketing. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling, and record-keeping procedures. If we do not comply with applicable regulatory requirements, such violations could result in warning letters, non-approval, suspensions of regulatory approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

Delays in or rejection of FDA or other government entity approval of our technologies may also adversely affect our business. Such delays or rejection may be encountered due to, among other reasons, government or regulatory delays, lack of efficacy during clinical trials, unforeseen safety issues, slower than expected rate of patient recruitment for clinical trials, inability to follow patients after treatment in clinical trials, inconsistencies between early clinical trial results and results obtained in later clinical trials, varying interpretations of data generated by clinical trials, or changes in regulatory policy during the period of product development. More stringent regulatory oversight in product clearance and enforcement activities could result in our experiencing longer approval cycles, more uncertainty, greater risk, and higher expenses. Even if regulatory approval of a product is granted, this approval may entail limitations on uses for which the product may be labeled and promoted. It is possible, for example, that we may not receive FDA approval to market products based on our licensed, patented technologies for broader or different applications or to market updated products that represent extensions of our basic technologies. In addition, we may not receive FDA approval to export our products based on our licensed, patented technologies in the future, and countries to which products are to be exported may not approve them for import.

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

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

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

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

The commercial success of our MU 1140 and SMaRT Replacement Therapy, Probiora3, LPT3-04 and other technologies will depend in part on government and public acceptance of their production, distribution and use. Biotechnology has enjoyed and continues to enjoy substantial support from the scientific community, regulatory agencies and many governmental officials in the United States and around the world. Future scientific developments, media coverage and political events may diminish such support. Public attitudes may be influenced by claims that health products based on biotechnology are unsafe for consumption or pose unknown risks to the environment or to traditional social or economic practices. Securing governmental approvals for, and consumer confidence in, such products poses numerous challenges, particularly outside the United States. The market success of technologies developed through biotechnology such as ours could be delayed or impaired in certain geographical areas because of such factors. Products based on our technologies may compete with a number of traditional dental therapies and drugs manufactured and marketed by major pharmaceutical companies and other biotechnology companies. Market acceptance of products based on our technologies will depend on a number of factors including potential advantage over alternative treatment methods. We can offer you no assurance that dentists, physicians, patients or the medical and dental communities in general will accept and utilize products developed from our technologies. If they do not, we may be unable to generate sufficient revenues from our technologies, which may cause us to have to cease operations.

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

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

Pharmaceutical products can develop unexpected safety or efficacy concerns.

Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals, or declining sales, as well as product liability, consumer fraud and/or other claims.

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

Our success in obtaining payment for a new product from third parties such as insurers and government programs depends greatly on the ability to present data which demonstrate positive outcomes and reduced utilization of other products or services as well as cost data which show that treatment costs using the new product are equal to or less than what is currently covered for other products. If we are unable to obtain favorable third party reimbursement and patients are unwilling or unable to pay for our products out-of-pocket, it could limit our revenue and harm our business.

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

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the U.S., given recent federal and state government initiatives directed at lowering the total cost of health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

Our ability to commercialize our proposed products will depend in part on the extent to which appropriate reimbursement levels for the cost of our proposed formulations and products and related treatments are obtained by governmental authorities, private health insurers and other organizations, such as HMOs. Third-party payers are increasingly challenging the prices charged for medical drugs and services. Also, the trend toward managed health care in the U.S. and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and drugs, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our products.

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

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

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

Current levels of securities and financial market volatility are unprecedented.

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

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

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

Risks Related to our Common Stock

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

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

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

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

- quarter-to-quarter variations in our operating results;
- the results of testing, technological innovations, or new commercial products by us or our competitors;
- governmental regulations, rules, and orders;
- general conditions in the healthcare, dentistry, or biotechnology industries;
- comments and/or earnings estimates by securities analysts;
- developments concerning patents or other intellectual property rights;
- litigation or public concern about the safety of our products;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of directors, officers and key personnel;
- release of escrow or other transfer restrictions on our outstanding shares of common stock or sales of additional shares of common stock;
- potential litigation initiated against us;
- adverse announcements by our competitors; and
- the additional sale of common stock by us in capital raising transactions.

Historically, the daily trading volume of our common stock has been relatively low and on some days our stock does not trade at all. We cannot guarantee that an active public market for our common stock will be sustained or that the average trading volume will increase. In addition, the stock market in general, has experienced significant price and volume fluctuations. Volatility in the market price for particular companies has often been unrelated or disproportionate to the operating performance of those companies. Broad market factors may seriously harm the market price of our common stock, regardless of our operating performance. In addition, securities class action litigation has often been initiated following periods of volatility in the market price of a company's securities. A securities class action suit against us could result in substantial costs, potential liabilities, and the diversion of management's attention and resources. Since our initial public offering in June 2003 and through December 31, 2008 our stock price has fluctuated from $5.00 to $0.20 per share. To the extent our stock price fluctuates and/or remains low, it could impair our ability to raise capital through the offering of additional equity securities.

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

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

Future sales of our common stock may depress our stock price.

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur. In addition, these factors could make it more difficult for us to raise funds through future offerings of common stock. As of March 10, 2009, there were 38,316,585 shares of our common stock outstanding, with another 5,777,778 shares of common stock issuable upon exercise of warrants to investors, 4,570,000 shares issuable upon exercise of options outstanding and an additional 430,000 shares available for option grants under our stock option plans. The issuance of shares of our common stock underlying these options is covered by an S-8 registration statement we filed with the SEC and upon exercise of the options, such shares may be resold into the market. We have issued a significant number of shares in connection with private placements that are available for resale as well as shares issuable upon exercise of warrants also issued with respect to such private placements. Most recently, we issued 5,777,778 shares of our common stock with warrants to acquire an additional 5,777,778 shares of our common stock at an exercise price of $1.30 per share in a private placement in June 2008. The resale of shares acquired from us in private transactions, could cause our stock price to decline significantly.

In addition, from time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act of 1933, which we refer to in this memorandum as the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, after satisfying a six month holding period: (i) affiliated stockholders (or stockholders whose shares are aggregated) may, under certain circumstances, sell within any three month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale and (ii) non-affiliated stockholders may sell without such limitations, provided we are current in our public reporting obligations. Rule 144 also permits the sale of securities by non-affiliates that have satisfied a one year holding period without any limitation or restriction. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale memorandum may have a material adverse effect on the market price of our securities.

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

Our board of directors has authority, without action or vote of our shareholders, to issue all or a part of our authorized but unissued shares. Such stock issuances could be made at a price that reflects a discount or a premium from the then-current trading price of our common stock. In addition, in order to raise capital, we may need to issue securities that are convertible into or exchangeable for a significant amount of our common stock. These issuances would dilute your percentage ownership interest, which would have the effect of reducing your influence on matters on which our shareholders vote, and might dilute the book value of our common stock. You may incur additional dilution if holders of stock options, whether currently outstanding or subsequently granted, exercise their options, or if warrant holders exercise their warrants to purchase shares of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

The Company has received no written comments regarding its periodic reports or current reports from the staff of the Securities Exchange Commission that were issued 180 days or more preceding the end of its 2008 calendar year and that remain unresolved.

ITEM 2. PROPERTIES.

Our administrative office and laboratory facilities are located at 13700 Progress Boulevard, Alachua, Florida 32615. We began leasing this property pursuant to a five-year operating lease in November 2004. The facility is approximately 5,300 square feet of which approximately 60% is laboratory space and the remainder is office space and common areas. The twelve months rental for 2008 was approximately $89,753, net of insurance, taxes and utilities that are paid by us. Lease payments escalate by 3% annually. We paid no leasehold improvement in 2008, 2007 or 2006. We also spent $17,501 and $12,906 in 2008 and 2007, respectively, for laboratory equipment to outfit our facility. On October 1, 2008 the Company leased office space for the Sales and Marketing personnel located at 111 2nd Ave NE, Suite 511, St. Petersburg, FL 33701. The lease is approximately 610 square feet and is occupied by four employees. The lease period for the office space is six months in the amount of $1,965 per month net of insurance, taxes and utilities that are paid by us. The lease expires on March 31, 2009 and is being negotiated for renewal.

Due to the increase in our needs, on January 7, 2009, we leased an additional 1,500 square feet of office space in a facility located at 13420 Progress Blvd, Suite 100, Alachua FL 32615. This facility is located in the same business complex as our primary offices. The lease for this office space is for a one-year period with the option to extend thereafter. Under the lease, we are not responsible for building insurance, common area maintenance or taxes. The twelve month rental rate is $24,375.

ITEM 3. LEGAL PROCEEDINGS.

We are not a party to any material legal proceedings and there are no material legal proceedings pending with respect to our property. We are not aware of any legal proceedings contemplated by any governmental authorities involving either us or our property. None of our directors, officers or affiliates is an adverse party in any legal proceedings involving us, or has an interest in any proceeding which is adverse to us.

ITEM 4. SUBMISSION OF MATTER TO A VOTE OF SECURITY HOLDERS.

None during the fourth quarter of the 2008 fiscal year covered by this report.

PART II

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

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

Period	2008		2007	
	High	Low	High	Low
First quarter	$ 0.58	$ 0.40	$ 1.18	$ 0.73
Second quarter	$ 0.76	$ 0.43	$ 1.10	$ 0.33
Third quarter	$ 0.85	$ 0.47	$ 0.75	$ 0.38
Fourth quarter	$ 0.81	$ 0.20	$ 0.59	$ 0.28

On March 12, 2009, the closing bid price of the common stock, as reported by the OTCBB, was $0.27. As of March 18, 2009, there were approximately 55 registered holders of our common stock according to Broadridge Corporation. The number of record holders does not reflect the number of beneficial owners of the common stock for whom shares are held by banks, brokerage firms and others.

Dividends

To date, we have neither declared nor paid any dividends on our common stock nor do we anticipate that such dividends will be paid in the foreseeable future. Rather, we intend to retain any earnings to finance the growth and development of our business. Any payment of cash dividends on our common stock in the future will be dependent, among other things, upon our earnings, financial condition, capital requirements and other factors which the board of directors deems relevant. In addition, restrictive covenants contained in any financing agreements entered into in the future may preclude us from paying any dividends.

ITEM 6 SELECTED FINANCIAL DATA.

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following information should be read in conjunction with the Financial Statements, including the notes thereto, included elsewhere in this Form 10-K. This discussion contains certain forward-looking statements that involve risks and uncertainties. Our actual results and the timing of certain events could differ materially from those discussed in these forward-looking statements as a result of certain factors, including, but not limited to, those set forth herein and elsewhere in this Form 10-K.

Overview

We are a multi-faceted biopharmaceutical company focused on the discovery, development and commercialization of a variety of products and technologies. We are located in Alachua, Florida, near the University of Florida where we have experienced scientific and management teams in place in which to lead us into an exciting new phase of operations. We have historically operated largely within the confines of the United States. Over the past several months we have positioned ourselves for development of a global foundation, with potential international investors, partners and customers.

We are currently transitioning from a company with a historic focus on research and development to a company with increased focus on immediate and long term commercialization. We possess a number of proprietary products and technologies some of which we have begun to commercialize. We believe that each of our products and platform technologies addresses potentially large market opportunities.

We expect to generate revenue through the sale of our consumer healthcare products. We have currently received orders for our lead branded consumer products, Probiora3 and EvoraPlus, which we have begun to fulfill. While we were initially more optimistic about the level of sales interest for these products when earlier this year our former Chief Executive Officer revealed our internal sales estimates, which were intended for internal use only, we are currently experiencing slower sales with our products at this time and such internal estimates are no longer applicable and have been significantly revised downward. As the launch of Probiora3 and EvoraPlus progressed, we also experienced a higher level of overall expenses associated with: manufacturing, marketing and selling initiatives; our global expansion efforts and international initiatives; our new listing on the NYSE Alternext Paris; and our expanded general and administrative needs, including for professional services, related to such items. We do not expect the increases in our expenses to continue into the near future as we have gone into a more reduced expense operation which will place certain initiatives on hold.

Given our lowered expectations for sales of our products and the potential expected cash flows from such activities as well as the previous higher level of expenses from continued operations and increased accounts payable associated with our marketing, development, current and previous fund raising strategies and other strategic initiatives, we are in need of substantial additional funds in order to continue our operations. Our cash and cash equivalent position is currently less than our total accounts payable. We are continuing to seek additional funding. We currently do not have any commitments for funding and there can be no assurances that we will be able to obtain funding or implement any strategic options in the future to acquire funding. Our available capital resources are expected to be utilized to sustain operations while we continue to explore opportunities to raise additional capital. Our working capital at December 31, 2008 was a deficit of $500,672 and our cash and cash equivalents at December 31, 2008 were $1,165,933. Absent raising additional capital in the near term, we do not have sufficient liquidity to enable us to continue to operate through April 2009 as our cash position has decreased. While additional capital may become available through cash flows from the sale of our probiotic healthcare products or through grants or the possible future exercises of outstanding warrants, there can be no assurance of the same and portions of any such capital raised will be required for payment of outstanding accounts payable versus future operations. If we issue additional debt or equity securities to raise capital, these securities are likely to have rights, preferences or privileges senior to those of our common stock, and or current shareholders may experience substantial dilution. In the event adequate capital is not raised or sufficient cash flows generated we would likely need to significantly curtail and possibly cease our operations until we are able to raise additional capital and we could seek to reorganize under the protection of Federal Bankruptcy Laws. In addition, we expect to explore strategic alternatives that may be available to us and for our technologies.

Recent Developments

We believe we are making great strides operationally based upon the following significant recent events we announced over the past several months:

Consumer Healthcare

· ***Marketing of ProBiora3™ and EvoraPlus™.*** On December 12, 2008, the Company announced that its website for EvoraPlus™ was now available for direct sales to consumers. EvoraPlus™ is the first comprehensive oral probiotic on the market.

· ***Garden of Life.*** On February 4, 2009, we announced that Garden of Life has been awarded rights to use our revolutionary oral-care probiotic ingredient, ProBiora3. This agreement gives Garden of Life exclusive rights to use ProBiora3 in the natural products market. ProBiora3 is a patent-pending probiotic formula containing a blend of three bacteria that work above and below the gum line to address oral health at its root cause.

· ***Progress in Marketing ProBiora3™ and EvoraPlus™.*** As of the date of this report, we believe we have made significant progress in our efforts to market ProBiora3™ and EvoraPlus™. Regarding ProBiora3, we are in meaningful discussions with several large consumer products and pet care companies to incorporate the ProBiora3™ technology into existing products and technologies. We anticipate licensing ProBiora3 for use in such products and producing Probiora3 and selling it to third parties for incorporation in widely recognized products. We are also in later stage discussions with large consumer products companies and companies in the dental space that are considering private labeling agreements whereby we manufacture products through our third-party manufacturer for them with their branding. Lastly, we have been successful in our efforts to sell our own product, EvoraPlus, which can now be found at such sites as cvs.com, walgreens.com, target.com and drugstore.com. We anticipate that EvoraPlus will also be stocked and available at many of the nation's top retailers by the end of 2009.

Antibiotics

· ***Successful Synthesis of Lantibiotic using DPOLT™.*** On October 14, 2008, we announced the successful synthesis of an antibiotic using its proprietary DPOLT™ technology. The molecule belongs to a class of antibiotics called Lantibiotics that were first discovered over 80 years ago. Although there are now over 50 different Lantibiotics known, this is the first report of a synthetic method for making one in sufficient amounts and with sufficient purity to enable comprehensive testing and commercial viability. As a first step in further development, we have retained Almac Sciences, a leading contract manufacturer and a division of the Almac Group, to refine and scale-up GMP production of the synthetic MU 1140 analogue to achieve sufficient quantities for it to be fully tested for regulatory approval. We currently estimate that the regulatory process will take four years before this drug could become available. We believe other synthetic Lantibiotics will follow as they are developed and tested.

Diagnostics

· ***Diagnostics Collaboration Agreement.*** On September 29, 2008, we entered into a Collaboration Agreement with a major, global diagnostics company regarding our gene targets for various stages of colorectal cancer that we discovered using the PCMAT™ platform. We have also initiated a new internal program for both the PIVIAT™ and PCMAT™ platforms. Under this initiative we expect to augment our development work by including the validation of gene targets we have discovered through the use of the platforms. We anticipate that this will in turn make our gene targets more valuable and decrease the time to market for any tests that may utilize them.

Global Reach

· ***Formation of Mexican Subsidiary.*** On November 28, 2008, we formed ONIBIOTEC SAPI de C.V., our Mexican subsidiary. We anticipate that this subsidiary will provide us with several advantages including the ability to conduct clinical trials at reduced costs and access to the Mexican market. We expect to begin marketing EvoraPlus™ in Mexico in the near future as regulatory approval has been achieved. We also expect to initiate further clinical trials with the SMaRT™ Replacement Therapy. We have also begun collaborating with the Instituto de Biolotecnología, Universidad Nacional Autónoma de México ("IBUNAM"), the premier biotechnology institute in Mexico, which we believe is generally recognized as having the best and brightest scientists in Mexico. We are working with IBUNAM on several projects including projects to discover novel gene targets using our PIVIAT™ and PCMAT™ platforms.

· ***US Listing on NYSE Euronext Alternext Paris.*** In November, 2008, the Company began the process of listing on the NYSE Euronext Alternext Paris exchange. We were sponsored by Bryan Garnier, a reputable European investment banking firm. We were approved in early December, and on Monday, December 15, 2008, the Company's shares on Alternext Paris were listed but as the date of this filing no trading has occurred.

U.S. Trading Market for Our Common Stock

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

Corporate Name

· ***The ONI BioPharma name change was abandoned.*** On January 30, 2009, we announced that we would not seek shareholder approval to change our corporate name to ONI BioPharma Inc., but would continue to be registered as Oragenics, Inc. This action was taken to reduce investor confusion in light of our delisting from the NYSE Alternext and listings on the (OTC) Bulletin Board and NYSE Euronext Alternext Paris.

Management Team

· ***Dr. Martin Handfield joins the Company.*** On Jan 1, 2009, Dr. Martin Handfield was appointed to the new position of Director of Research and Development. Prior to joining the Company, Dr. Handfield was a tenured faculty member at the Center for Molecular Microbiology and Department of Oral Biology, University of Florida. Martin received his Ph.D. from Laval University in Canada and is a co-inventor of the Company's IVIAT platform technology that enables the rapid identification of novel and potentially important gene targets associated with the natural onset and progression of human infections.

· ***Management Team Change.*** On March 19, 2009, we announced that Stanley Stein resigned from his position as the Company's President and Chief Executive Officer, that David Hirsch was appointed acting Chief Executive Officer and would remain as the Company's Chief Financial Officer, and that Robert Zahradnik, Vice President of Business Development, was appointed acting Chief Operational Officer.

Business Objectives and Milestones

We have a number of products and platforms. For ease in understanding, we have broken these products and platforms down into four distinct divisions as follows:

- ***Consumer Healthcare***, which consists of oral probiotics that revolve around the ProBiora3™ technology, and weight loss products that are centered on the LPT3-04™ weight loss agent;
- ***Antibiotics***, which consists of the DPOLT™ lantibiotic synthesis platform and MU 1140;
- ***Diagnostics***, which consists of the PIVIAT™ and PCMAT™ platforms; and
- ***Replacement Therapy***, which consists of our SMaRT™ Replacement Therapy technology.

Provided we are able to raise additional capital, we expect to continue the progress we have experienced to date. Since our inception, the Company has funded a significant portion of its operations from the public and private sales of its securities. There have been no significant revenues from operations during the last two years. All of our revenues have been from sponsored research agreements and various governmental grants. At this time we just started to generate revenues from sales of products. In Q4 2008, we began receiving minor purchase orders and/or revenues from the sale of EvoraPlus[tm], our oral probiotic.

Although, management believes that we are now positioned over the next several months to generate revenues from a number of our healthcare products, we will require substantial capital to continue our business operations and we will continue to need to seek capital to effectuate our business plan.

We have experienced significant negative cash flow from operations to date, and we expect to continue to experience significant negative cash flow in the future. Our inability to generate sufficient funds from operations and external sources will have a material adverse effect on our business, results of operations and financial condition. If we are not able to raise additional funds, we will be forced to significantly curtail or cease our operations or seek to reorganize under the protection of Federal Bankruptcy Laws. See "Liquidity and Capital Resources" below for additional information. Furthermore, with respect to products that are not ready for immediate commercialization, we are taking what we regard to be concrete steps in completing the research and development of pending products and platforms. Consequently, our proofs of concept are essentially complete, and we are taking the steps necessary to bring our product portfolio to market, with the expectation, but not assurance that our products, where necessary, will be approved for marketing.

Consumer Healthcare

The goal of our Consumer Healthcare unit is to successfully commercialize our oral probiotics products and to launch a product that contains our weight loss agent LPT3-04.

Oral Probiotics: Our goals are to penetrate the mass and specialty retail channels for our branded products, establish several private labeling relationships in a variety of channels where we can leverage other companies' brands and distribution and to successfully negotiate licensing arrangements with major companies for the incorporation of our ProBiora3™ technology in several well-known and widely recognized consumer products.

Weight Loss: We are currently in the process of re-formulating the delivery mechanism of LPT3-04 such that it provides an enhanced consumer experience. Once this is finished, we will conduct a clinical trial to fully establish efficacy. After the clinical trial has been completed and efficacy is established, we will then begin marketing our first product in the weight loss category. We anticipate that this will occur by the end of 2009.

Antibiotics

We are currently scaling production of Synthetic MU 1140. We anticipate that this process will be complete in the first half of 2009. We then plan on conducting pre-clinical testing. If pre-clinical testing is positively concluded, we will file an IND with the FDA, which will include a protocol for Phase I clinical safety trials.

Diagnostics

The goal of our Diagnostics unit is to utilize the PIVIAT™ and PCMAT™ platforms to identify and secure intellectual property rights to gene targets associated with the natural onset and progression of infections, cancers and other diseases in humans, animals, and agricultural products. We believe these platforms provide a number of profitable business models from which to realize value. We are in the process of establishing a joint venture with the Instituto de Biolotecnología, Universidad Nacional Autonoma de Mexico ("IBUNAM"), which is the premier biotechnology institute in Mexico. IBUNAM has excellent facilities and a substantial talent base from which the Company can draw. We are in the process of initiating several projects with scientists at IBUNAM.

SMaRT Replacement Therapy™

Our Replacement Therapy Division is centered on SMaRT Replacement Therapy™, our product for dental caries (tooth decay). We are currently investigating the possibility of conducting clinical trials for SMaRT in Mexico. We believe that SMaRT Replacement Therapy™ will be appealing to governments of emerging nations such as Mexico since the healthcare systems of these countries are more focused on proactive or preventative medicine. SMaRT Replacement Therapy™ can potentially provide substantial back-end savings to countries since the long-term costs associated with dental caries are substantial. We have been approved by the FDA for a Phase I(b) clinical trial. As such, we are also investigating the possibility of beginning the Phase I(b) clinical trial in the United States in the immediate future.

Global Expansion

Our technologies have global implications. To address the potential international implications of our products and technologies we have developed a global strategy. Although we are domiciled in the United States, we believe that there are numerous advantages in accessing overseas talent and markets for a variety of our products and technologies.

Some of the international strategic initiatives that we currently have in progress are as follows:

Europe

We have several strategic initiatives underway in Europe. Some of the projects include:

***Listing on the NYSE Euronext Alternext – Paris Exchange*.** On December 15, 2008, our common stock was listed on the Alternext – Paris exchange. Although there has been no trading volume, we believe the listing of our stock on the Alternext will facilitate our access to potential capital through both public and private offerings in Europe. This provides an alternative to raising capital exclusively in the United States. We view this as a strategic advantage, especially in times of economic turbulence.

French Subsidiary. We are currently in the process of establishing a subsidiary in France, which we expect to be headquartered in Lyon.

The Production of Synthetic MU 1140. Almac Sciences, a top-tier European peptide manufacturer, is currently scaling production of Synthetic MU 1140. The Company may thereafter be positioned to conduct clinical trials for a number of potential products in Europe. Lastly, we plan on establishing a major marketing initiative in Europe for our Consumer Healthcare Products. These products would also be expected to be manufactured in Europe.

Mexico

ONIBIOTEC SAPI de C.V., our Mexican Subsidiary is the first of several anticipated subsidiaries in strategic locations worldwide. We have several initiatives in various stages in Mexico. Some of the projects include:

Collaboration with the Instituto de Biolotecnología, Universidad Nacional Autonoma de Mexico ("IBUNAM"). We are in the process of establishing a joint venture with the Instituto de Biolotecnología, Universidad Nacional Autonoma de Mexico ("IBUNAM"), which is the premier biotechnology institute in Mexico. IBUNAM has excellent facilities and a substantial talent base from which the Company can draw.

SMaRT Replacement Therapy™. We are currently investigating the possibility of conducting clinical trials for SMaRT in Mexico. We believe that SMaRT™ will be appealing to governments of emerging nations such as Mexico since the healthcare systems of these countries are more focused on proactive or preventative medicine. SMaRT Replacement Therapy™ can potentially provide substantial back-end savings to countries since the long-term costs associated with dental caries are substantial.

Clinical Trials. Mexico is expected to provide a more cost effective environment for the conduct of clinical trials as well as a regulatory environment where the focus is on the promotion of preventative medicine, which should make our technologies and products more appealing.

South America

We are also exploring partnerships or strategic collaborations in Chile, which may lead to the licensing of our products in Chile or further collaborations similar to that in Mexico.

Mutual Recognition & Treaties

We are contemplating several strategies that will allow us to leverage our Subsidiaries and expedite or facilitate entry into alternative markets. One such example is through mutual recognition, which allows us regulatory approval throughout Europe once one member country has given approval. Also, our Mexican Subsidiary will utilize Mexican treaty benefits with Spain in furtherance of the commercialization of its products in Spain. Utilizing EU mutual recognition provisions, we expect to further commercialize our consumer products and diagnostic platforms in other EU member states on a cost-effective basis.

The above actions, individually and in the aggregate, are expected to be costly to undertake and complete and will require additional capital over and above what we currently have available to us. Our current available capital limits our ability to fully market our products and develop our technologies. We expect to allocate our limited capital resources to the development of our technologies while we continue to explore additional capital raising opportunities. There can be no assurances that such additional capital will be available to us. The time periods for the expected continued development of our technologies have been extended from those previously indicated due primarily to our insufficient capital position and the time periods for the expected developments could change in the future depending on the progress of our ability to negotiate a partnering arrangement, as well as our efforts to raise additional capital**.** We have a contractual obligation to pay a minimum royalty of $25,000 per quarter and spend or cause to be spent an aggregate of $1,000,000 per annum toward research, development and regulatory prosecution, in order to maintain our license with the University of Florida Research Foundation, Inc. for our SMaRT Replacement Therapy™ and MU 1140™ technologies. We believe we have exceeded the $1,000,000 per annum threshold for research, development and regulatory prosecution in 2008. If we are unable to make the minimum royalty payments in the future, our license could be terminated which will substantially diminish the value of our company.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires us to make estimates and assumptions that affect reported amounts and related disclosures. We consider an accounting estimate to be critical if it requires assumptions to be made that were uncertain at the time the estimate was made; and changes in the estimate or different estimates that could have been made could have a material impact on our results of operations or financial condition. Our financial statements do not include any significant estimates that would have a material impact on our results of operations or financial condition.

New Accounting Pronouncements

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

Results of Operations:

Operating Results Summary
For the years and periods ended December 31, 2008, 2007 and 2006

	Years ended December 31			Three months ended December 31	
	2008	2007	2006	2008	2007
Revenue	$ 233,539	133,088	66,176	8,539	26,743
Cost of sales	14,864	-	-	14,864	-
Operating expenses:					
Research and development	1,955,488	1,569,551	2,023,896	480,763	460,254
Selling, general and administrative	4,312,246	902,655	1,004,099	2,502,833	257,930
Total operating expenses	6,267,734	2,472,206	3,027,995	2,983,596	718,184
Loss from operations	(6,049,059)	(2,339,118)	(2,961,819)	(2,989,921)	(691,441)
Other income (expense):					
Interest income	32,511	29,385	24,931	3,044	6,590
Interest expense	(10,054)	-	(855)	(10,000)	-
Gain (loss) on sale of property and equipment	4,860	(1,979)	2,024	-	(1,979)
Total other income, net	27,317	27,406	26,100	(6,956)	4,611
Loss before income taxes	(6,021,742)	(2,311,712)	(2,935,719)	(2,996,877)	(686,830)
Net Loss	$ (6,021,742)	(2,311,712)	(2,935,719)	(2,996,877)	(686,830)

For the Quarters Ended December 31, 2008 and 2007

We had $8,539 in revenue during the three months ended December 31, 2008 and $26,743 during the three months ended in December 31, 2007. Revenue recorded in Q4 2008 represents the initial sales of ProBiora and EvoraPlus products as we begin to commercialize the ProBiora technology; there was no grant funding received during this period compared to $26,743 received in 2007. Our operating expenses increased 315% to $2,983,596 in the three months ended December 31, 2008 from $718,184 in the same period in 2007. Research and development (R&D) expenses increased 4.5% to $480,763 in the three months ended December 31, 2008 from $460,254 in the same period in 2007. The R&D increase is represented by $60,765 of consulting expenses to support the development of Probiotics and Lilliput technologies. Selling, general and administration (S,G&A) expenses increased 870% to $2,502,833 in the three months ended December 31, 2008 from $257,930 in same period in 2007. Almost half of this amount or $1,104,969 is in legal fees associated with services to expand our global business in Mexico and France; a portion of legal expense also includes costs associated with the change in our common stock listing from the NYSE Alternext US LLC to the OTC Bulletin Board. Other major S,G&A increases include filing and registration fees $326,539, officer/staff salaries and benefits $231,473, consulting services $211,788, selling and marketing expenses of $129,553, and travel related expenses $72,522.

Interest income decreased by 53.8% to $3,044 in the three months ended December 31, 2008 from $6,590 in the same period in 2007. Interest expense of $10,000 was incurred in Q4 2008 representing costs to secure a credit line with Signature Bank.

Our net loss increased 336% to $2,996,877 during the three months ended December 31, 2008 from $686,830 loss in the same period in 2007. The loss is represented by the overall increase in G&A expenses.

For the Years Ended December 31, 2008 and 2007

We had $233,539 in revenue in the year ended December 31, 2008 as compared to $133,088 in 2007. This is a result of a Small Business Innovation Research (SBIR) grant for DPOLT, a National Science Foundation (NSF) grant for our Mutacin technology and the initial sales of ProBiora and EvoraPlus products. Our operating expenses increased 154% to $6,267,734 for the year ended December 31, 2008 from $2,472,206 in 2007. Research and development (R&D) expenses increased 24.6% to $1,955,488 in 2008 from $1,569,551 in 2007. The growth in R&D expense is represented by R&D salaries $53,916, options expense $176,393, and consulting services/clinical trials for Probiotics and Lilliput technologies $140,365. Selling, general and administration (S,G&A) expenses increased 378% to $4,312,246 in 2008 from $902,655 in 2007. The most significant increase was in legal fees by $1,208,259 incurred during Q4. As mentioned above, the fees are directly related to services to expand our global business in Mexico and France, and also including fees to the change our common stock listing from the NYSE Alternext US LLC to the OTC Bulletin Board. Other major S,G&A increases include consulting services for $523,279 to promote the company and investor relations, filing and registration fees $358,342, officer/staff salaries and benefits $421,870, options expense $175,747, selling and marketing expenses of $129,553, travel related expenses $145,602, and accounting fees/services $177,038.

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

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

For the Years Ended December 31, 2007 and 2006

We had $133,088 in revenue in the year ended December 31, 2007 as compared to $66,176 in 2006. This is a result of two grants, one a Small Business Innovation Research (SBIR) grant for DPOLT and the second from a NIH/NCI grant for our CMAT technology. Our operating expenses decreased 18.3% to $2,472,206 for the year ended December 31, 2007 from $3,027,995 in 2006. Research and development (R&D) expenses decreased 22.4% to $1,569,551 in 2007 from $2,023,896 in 2006, reflecting the reduction in clinical and outside consultants expenses, legal and patent expenses, stock option expense and a decrease in lab expenses, totaling approximately $508,000. This R&D expense decrease was partially offset by the increase in salary expenses in hiring a Director of our Microbiology Lab, benefit expenses and vacation accruals of approximately $56,000. General and administration (G&A) expenses decreased 10.1% to $902,655 in 2007 from $1,004,099 in 2006, reflected by reduction in staff expense, advertising fees, legal and accounting, and general office expenses of approximately $195,000. This decrease was partially offset by our increase in contracting with investor relations services of $84,328, the increase in our stock option compensation expense of approximately $19,000 and increase in rent and property taxes of approximately $12,000.

Interest income increased 17.9% to $29,385 in the year ended December 31, 2007 from $24,931 in the year ended December 31, 2006. There was no interest expense in 2006.

Our total net loss decreased 21.3% to $2,311,712 in the year ended December 31, 2007 from $2,935,719 in 2006. The decrease in our net loss was principally caused by our reduced legal and patent fees and less expense for clinical trials, offset by the increase in our stock option compensation expenses and the contract with investor advisory services.

Liquidity and Capital Resources

Since our inception, we have funded our operations through the sale of equity securities in private placements and our initial public offering, the sale of equity securities and warrants in private placements, debt financings and grants. In 2009, the Company has received $100,000 of restricted funds as part of the $500,000 NSF Phase II grant to advance development of its small peptide antibiotic synthesis program using the Company's proprietary DPOLT[tm]. This federal grant will support studies focused on the synthesis and testing of our lead antibiotic, MU 1140. In 2008, restricted funds totaling $225,000 were received.

Our operating activities used cash of $3,835,190 for the year ended December 31, 2008 and $1,913,760 for the year ended December 31, 2007. We had a working capital deficit of $500,672 as of December 31, 2008. Cash used by operations in the year ended December 31, 2008 resulted primarily from the operating loss of $6,021,742.
Our investing activities used cash of $13,072 for the year ended December 31, 2008 as a result of the acquisitions totaling $55,322 offset by the sale of assets totaling $42,250. Acquisitions in 2008 included a new telephone system, computers and lab equipment. We do not anticipate any significant spending on additional property and equipment during 2009.

Our financing activities provided $4,538,687 in cash for the year ended December 31, 2008. Of this balance $4,511,000 was provided by proceeds from the placement of common stock and $ 27,688 represents net proceeds from a short term note payable to finance D&O and employment related practices liability insurance. Additional details of these financings are provided below:

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

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

Warrant Exercises Q1 2007. – On December 14, 2005, we issued a total of 2,937,500 shares of our common stock and warrants to purchase 2,937,500 shares of our common stock in a private placement to accredited investors. The issuance of the shares of common stock and warrants was made pursuant to the exemptions from registration provided by Section 4(2) of the Securities Act and Regulation D promulgated there under. We received gross proceeds of $1,175,000 in the private placement and incurred estimated costs of approximately $70,000 resulting in net proceeds of approximately $1,105,000. The warrants representing shares of common stock were exercisable by the accredited investors at any time over a two-year period at an exercise price of $0.60 per share. On January 16, 2007, we called all outstanding warrants associated with our December, 2005 private placement pursuant to the terms of the warrant. A total of 997,500 warrants were exercised that provided $478,500 in additional working capital and following the call of the warrants no further warrants associated with the private placement remain outstanding.

NSF SBIR Grants – On February 15, 2008, we were awarded a two year NSF SBIR Phase II grant to advance development of our small peptide antibiotic synthesis program using the Company's proprietary DPOLT^{tm}. This federal grant will support studies focused on the synthesis and testing of our lead antibiotic, MU 1140. While the grant will total $500,000, to date we have received $225,000 of these restricted funds with the remaining balance to be issued during the remaining two-year grant period.

Short Term Note Payable – The Company entered into a short term note payable in June 2008 with an interest rate of 5.75% to finance D&O and employment related practices liability insurance. At December 31, 2008 the balance due was $27,687. There were no loans during the year 2007.

Line of Credit – On October 20, 2008, the Company obtained from Signature Bank of New York, a revolving line of credit in the amount of up to $1,000,000, for the purpose of providing working capital to the Company. It is secured by cash collateral of the Company in the same amount deposited with Signature Bank, bears interest at the Prime Rate of Signature Bank, as effective from time to time, and has a final maturity of October 20, 2009. Other than submission of periodic financial information of the Company to Signature Bank, the loan documentation evidencing the revolving line of credit does not contain any financial covenants. On January 21, 2009, this line of credit was terminated by the Company.

Our business is based on commercializing entirely new and unique technologies, and our current business plan contains a variety of assumptions and expectations that are subject to uncertainty, including assumptions and expectations about manufacturing capabilities, clinical testing cost and pricing, continuing technological improvements, strategic licensing relationships and other relevant matters. These assumptions take into account recent financings, as well as expected but currently unidentified additional financings. We have experienced losses from operations during the last three fiscal years and have an accumulated deficit of $19,992,535 as of December 31, 2008. Cash used in operations during 2008, 2007 and 2006 was $3,835,190, $1,913,760 and $2,224,538, respectively. At December 31, 2008, our principal source of liquidity was $1,165,933 of cash and cash equivalents. These operating results occurred while developing and attempting to commercialize and manufacture products from entirely new and unique technologies. Our business plan requires significant spending related primarily to clinical testing expenditures, as well as conducting basic research. These factors place a significant strain on our limited financial resources and adversely affect our ability to continue as a going concern. Our ultimate success depends on our ability to continue to raise capital for our operations.

Because of our limited available financial resources, we have continued to adopt several approaches to reduce expenditures by reducing our matching contributions for the employee retirement plan, appreciably reducing travel and other operating costs, decreasing the use of outside consultants and delaying the production of additional supplies of our SmaRT Replacement Therapy™ technology to be used in later clinical studies. As of December 31, 2008 deferred payments totaling $143,583 were owed to Jeffrey D. Hillman, David Hirsch, Stanley Stein and $34,000 to members of the former Board of Directors and Audit Committee and are included in the accompanying balance sheet in accounts payable and accrued expenses as of December 31, 2008. These salary payments and meeting fees were agreed to be deferred until such time as we obtain sufficient funding that payment can be made. There is no time period on the payment of the deferred amounts concerning our officers and former directors. The deferrals of payments to our officers and former directors, do not reduce our expenses, but serve to preserve our limited cash resources to the extent necessary to maintain our operations.

Our capital requirements for the remainder of 2009 will depend on numerous factors, including the success of our commercialization efforts and of our research and development, the resources we devote to develop and support our technologies and the success of pursuing strategic licensing and funded product development relationships with external partners. Subject to our ability to generate revenue and cash flow from our consumer products and our ability to raise additional capital through joint ventures and/or partnerships, we expect to need to incur substantial expenditures to further commercialize or develop each of our technologies including continued increases in costs related to research, preclinical testing and clinical studies, as well as significant costs associated with being a public company. We will require substantial funds to conduct research and development and preclinical and Phase I clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase II and III clinical testing and manufacture and marketing of any products that are approved for commercial sale. We must generate additional capital resources to enable us to continue as a going concern. Our plans include seeking financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to assure continuation of our operations and research and development programs as well as seeking equity financing.

Our future success depends on our ability to continue to raise capital and ultimately generate revenue and attain profitability. We cannot be certain that additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, these securities are likely to have rights, preferences, or privileges senior to those of our common stock, and our current stockholders may experience substantial dilution.

To date, we have not obtained financing sufficient to support our plans going forward. Until such time as additional financing for our operations is obtained, we expect to continue to need to curtail our spending and we could cease operations. While we continue to focus on our products and technologies, we do not have sufficient capital resources to market our products and complete the development of our technologies. We had a working capital deficit at December 31, 2008 of $500,672. Our currently available cash and cash equivalents of $1,165,933 is insufficient to enable us to continue to operate through April 2009. Our cash and cash equivalent position is currently less than our total accounts payable. In the event adequate capital is not raised we would need to curtail or cease all operations until we are able to raise additional capital or we could seek to reorganize under the protection of Federal Bankruptcy Laws. In addition, we expect to explore strategic alternatives that may be available to us and our technologies.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements.

Inflation

Inflation affects the cost of raw materials, goods and services that we use. In recent years, inflation has been modest. However, high energy costs and fluctuations in commodity prices can affect the cost of all raw materials and components. The competitive environment somewhat limits our ability to recover higher costs resulting from inflation by raising prices. Although we cannot precisely determine the effects of inflation on our business, it is management's belief that the effects on revenues and operating results will not be significant. We do not believe that inflation has had a material impact on our results of operations for the periods presented, except with respect to payroll-related costs and other costs arising from or related to government imposed regulations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Incorporated by reference to pages F-1 to F-19 at the end of this report.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

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

Changes in Internal Controls

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

Limitations on the Effectiveness of Controls

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

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

CEO and CFO Certifications

Appearing after the Signatures section of this report there are Certifications of the acting CEO and the CFO. The Certifications are required in accordance with Section 302 of the Sarbanes-Oxley Act of 2002 (the Section 302 Certifications). This Item of this report, which you are currently reading is the information concerning the Evaluation referred to in the Section 302 Certifications and this information should be read in conjunction with the Section 302 Certifications for a more complete understanding of the topics presented.

Management's Report on Internal Control over Financial Reporting

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

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

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

Our management, under the supervision of the acting CEO and CFO, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2008. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework*. Based on our assessment, we believe that, as of December 31, 2008, the Company's internal control over financial reporting was effective based on those criteria.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only management's report in this annual report.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

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

Code of Ethics

We have adopted a Code of Conduct, which is applicable to all of our directors and employees, including our principal executive officer, our principal financial officer and our controller. A copy of the Code of Conduct can be found on our website at *www.oragenics.com*. Any possible future amendments to or waivers from the Code of Conduct will be posted on our website.

Section 16(a) Beneficial Ownership Reporting Compliance

Information regarding compliance with Section 16(a) of the Exchange Act is set forth under the heading "Section 16(a) Beneficial Ownership Reporting Compliance" will be in our 2009 Proxy Statement and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION.

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

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

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

Equity Compensation Plan Information

We maintain an equity-based compensation plan—the Amended and Restated 2002 Stock Option and Incentive Plan (as amended, the "Incentive Plan"). A description of our equity based compensation plan can be found in Note 7 of the Notes to Financial Statements. The Incentive Plan has been approved by our shareholders. The following table sets forth the number of shares of our common stock subject to outstanding options and rights under the Incentive Plan, the weighted-average exercise price of outstanding options, and the number of shares remaining available for future award grants under the Incentive Plan as of December 31, 2008 (in thousands, except exercise price):

	Equity Compensation Plan Information		
Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	4,570,000	$ 0.60	430,000
Equity compensation plans not approved by security holders[1]	–	–	–
Total	4,570,000	$ 0.60	430,000

[1] The Company does not have any equity compensation plans that have not been approved by security holders. The Company does have warrants to acquire 5,777,778 shares of common stock outstanding at an exercise price of $1.30 per share. These warrants were issued in connection with a private placement in June 2008.

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

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

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

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

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

1. The financial statements and accompanying report of independent registered public accounting firm are listed in the Index to Financial Statements and are filed as part of this report.

All financial statement schedules are omitted because they are inapplicable, not required or the information is included elsewhere in the financial statements or the notes thereto.

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

(b) Other Exhibits

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

(c) Not Applicable

SIGNATURES

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

Dated: March 31, 2009

ORAGENICS, INC.
(Registrant)

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

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ David B. Hirsch David B. Hirsch	Acting President, Acting Chief Executive Officer, and Chief Financial Officer (Principal Executive Officer, Principal Financial and Accounting Officer)	March 30, 2009
s/ Jeffrey D. Hillman Jeffrey D. Hillman	Chief Scientific Officer and Director	March 30, 2009
/s/ Richard Welch Richard Welch	Chairman of the Board and Director	March 30, 2009
/s/ Derek Hennecke Derek Hennecke	Director	March 30, 2009
/s/ Kevin H. Sills Kevin H. Sills	Director	March 30, 2009
/s/ Marc K. Siegel Marc K. Siegel	Director	March 30, 2009

Oragenics, Inc.

Financial Statements

Years ended December 31, 2008, 2007 and 2006

Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Oragenics, Inc. as of December 31, 2008 and 2007, and the related statements of operations, shareholders' equity (deficit), and cash flows for the years ended December 31, 2008, 2007and 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion of the effectiveness of the company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Oragenics, Inc. as of December 31, 2008 and 2007, and the results of its operations and its cash flows for the years ended December 31, 2008, 2007 and 2006 in conformity with accounting principles generally accepted in the United States of America.

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

March 31, 2009 /s/ Kirkland Russ Murphy & Tapp, PA

Clearwater, Florida Certified Public Accountants

Oragenics, Inc.
Balance Sheets
December 31, 2008, 2007

	2008	2007
Assets		
Current assets:		
Cash and cash equivalents	$ 1,165,933	475,508
Accounts receivables, net	6,286	-
Inventory	11,814	-
Prepaid expenses and other current assets	86,666	116,520
Total current assets	1,270,699	592,028
Property and equipment, net	323,424	559,349
Total assets	$ 1,594,123	1,151,377
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,743,684	331,494
Short term note payable	27,687	-
Total current liabilities	1,771,371	331,494
Shareholders' equity (deficit):		
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; 38,316,585 and 28,002,443 shares issued and outstanding as of December 31, 2008 and 2007, respectively	38,316	28,002
Additional paid-in capital	19,776,971	14,762,674
Accumulated deficit	(19,992,535)	(13,970,793)
Total shareholders' equity (deficit)	(177,248)	819,883
Total liabilities and shareholders' equity (deficit)	$ 1,594,123	1,151,377

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

Oragenics, Inc.
Statements of Operations
For the Years Ended December 31, 2008, 2007 and 2006

	Year Ended December 31		
	2008	**2007**	**2006**
Revenue	$ 233,539	133,088	66,176
Cost of sales	14,864	-	-
Operating expenses:			
Research and development	1,955,488	1,569,551	2,023,896
Selling, general and administration	4,312,246	902,655	1,004,099
Total operating expenses	6,267,734	2,472,206	3,027,995
Loss from operations	(6,049,059)	(2,339,118)	(2,961,819)
Other income (expense):			
Interest income	32,511	29,385	24,931
Interest expense	(10,054)	-	(855)
Gain (loss) on sale of property and equipment	4,860	(1,979)	2,024
Total other income, net	27,317	27,406	26,100
Loss before income taxes	(6,021,742)	(2,311,712)	(2,935,719)
Net loss	$ (6,021,742)	(2,311,712)	(2,935,719)
Basic and diluted net loss per share	$ (0.17)	(0.09)	(0.15)
Shares used to compute basic and diluted net loss per share	35,069,261	25,092,183	20,038,177

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

Oragenics, Inc.
Statements of Changes in Shareholder's Equity (Deficit)
For the Years Ended December 31, 2008, 2007 and 2006

	Common Stock		Additional Paid In Capital	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount			
Balances at December 31, 2005	18,146,117	$ 18,146	$10,476,786	$ (8,723,362)	$ 1,771,570
Exercise of common stock warrants	2,390,000	2,390	1,424,610	-	1,427,000
Issuance of common stock and warrants	1,683,640	1,684	572,354	-	574,038
Issuance of common stock for the acquisition of iviGene Corporation	185,186	185	199,815	-	200,000
Compensation credit relating to option issuances	-	-	241,385	-	241,385
Net loss	-	-	-	(2,935,719)	(2,935,719)
Balances at December 31, 2006	22,404,943	$ 22,405	$12,914,950	$ (11,659,081)	$ 1,278,274
Exercise of common stock warrants	997,500	997	599,502	-	600,499
Issuance of common stock and warrants	4,600,000	4,600	1,086,751	-	1,091,351
Compensation expense relating to option issuances	-	-	161,471	-	161,471
Net loss	-	-	-	(2,311,712)	(2,311,712)
Balances at December 31, 2007	28,002,443	$ 28,002	$14,762,674	$ (13,970,793)	$ 819,883
Exercise of common stock warrants	4,536,364	4,536	1,991,464	-	1,996,000
Issuance of common stock and warrants, net of expenses	5,777,778	5,778	2,509,222	-	2,515,000
Compensation expense relating to option issuances	-	-	513,611	-	513,611
Net loss	-	-	-	(6,021,742)	(6,021,742)
Balances at December 31, 2008	38,316,585	$ 38,316	$19,776,971	$ (19,992,535)	$ (177,248)

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

Oragenics, Inc.
Statements of Cash Flows
For the Years Ended December 31, 2008, 2007 and 2006

	Year Ended December 31		
	2008	2007	2006
Cash flows from operating activities:			
Net loss	$(6,021,742)	(2,311,712)	(2,935,719)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	253,857	273,230	280,901
Stock-based compensation expense	513,611	161,471	241,385
Patents acquired from iviGene Corp	-	-	200,000
(Gain) loss on sale of property and equipment	(4,860)	1,979	(2,024)
Changes in operating assets and liabilities:			
Accounts receivable, net	(6,286)	-	-
Inventory	(11,814)	-	-
Prepaid expenses and other current assets	29,854	(42,649)	38,176
Accounts payable and accrued expenses	1,412,190	3,921	(47,257)
Net cash used in operating activities	(3,835,190)	(1,913,760)	(2,224,538)
Cash flows from investing activities:			
Purchase of property and equipment, net	(55,322)	(12,906)	(12,011)
Proceeds from sale of property and equipment, net	42,250	3,046	5,000
Net cash used in investing activities	(13,072)	(9,860)	(7,011)
Cash flows from financing activities:			
Borrowings under short term note payable	79,518	-	-
Payments on short term note payable	(51,831)	-	-
Net proceeds from issuance of common stock	4,511,000	1,691,850	2,001,038
Net cash provided by financing activities	4,538,687	1,691,850	2,001,038
Net increase (decrease) in cash and cash equivalents	690,425	(231,770)	(230,511)
Cash and cash equivalents at beginning of year	475,508	707,278	937,789
Cash and cash equivalents at end of year	$ 1,165,933	475,508	707,278
Supplemental disclosure of cash flow information			
Non-Cash acquisition of iviGene Corporation	$ -	-	200,000
Interest paid	$ 10,054	-	855

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

1. Organization and Significant Accounting Policies

Oragenics, Inc. (formerly known as Oragen, Inc.) (the Company) was incorporated in November, 1996; however, operating activity did not commence until 1999. The Company is dedicated to developing technologies associated with oral health, broad spectrum antibiotics and other general health benefits.

Basis of Presentation

The accompanying financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) including the assumption of a going concern basis which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company incurred a net loss of $6,021,742 for the year ended December 31, 2008 and as of that date had an accumulated deficit of $19,992,535. Cash used in operations for the year ended December 31, 2008 was $3,835,190 and cash flow from operations was negative throughout 2008. The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes the working capital at December 31, 2008 will be insufficient to meet the business objectives as presently structured. Management recognizes that the Company must generate additional capital resources or consider modifications to its technology development plans to enable it to continue as a going concern. Management's plans include seeking financing, alliances or other partnership agreements with entities interested in the Company's technologies, or other business transactions that would generate sufficient resources to assure continuation of the Company's operations and research and development programs.

The Company intends to seek additional funding through sublicensing arrangements, joint venturing or partnering, sales of rights to technology, government grants and public or private financings. The Company's future success depends on its ability to raise capital and ultimately generate revenue and attain profitability. The Company cannot be certain that additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to it or, if available, will be on terms acceptable to the Company. If the Company issues additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of its common stock, and the Company's current shareholders may experience dilution. If the Company is unable to obtain funds when needed or on acceptable terms, the Company may be required to curtail their current development programs, cut operating costs and forego future development and other opportunities. Without sufficient capital to fund their operations, the Company will be unable to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Use of Estimates

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

Fair Value of Financial Instruments

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

Cash and Cash Equivalents

Cash and cash equivalents consist of all cash balances and highly liquid investments with an original maturity of three months or less. The Company's cash and cash equivalents are deposited in a financial institution and consist of demand deposits and overnight repurchase agreement investments and at times deposits are in excess of federally insured limits.

Inventory

Inventories are stated at the lower of cost or market. Cost, which includes material, labor and overhead, is determined on a first-in, first-out basis.

Property and Equipment

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

Business Segments

Pursuant to Statement of Financial Accounting Standards (SFAS) No. 131, *Disclosure About Segments of a Business Enterprise and Related Information*, the Company is required to report segment information. As the Company only operates principally in one business segment, no additional reporting is required.

Stock-Based Compensation

In December 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure* (FAS 148). FAS 148 amends an earlier standard on accounting for stock-based compensation, Accounting for Stock-Based Compensation (FAS 123), to provide alternative methods of transition to the fair value based method of accounting for stock-based employee compensation which is required beginning January 1, 2006. In December 2004, FASB issued FASB Statement No. 123 (revised 2004), *Share-Based Payment (*"FAS 123(R)"*),* a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. FAS 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees,* and amends FASB Statement No. 95, *Statement of Cash Flows.* FAS 123(R), which we have adopted in the first quarter of 2006, is generally similar to Statement 123; however, it requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. The Company has elected to adopt the Modified Prospective Method. This method requires the Company to prospectively expense all new grants and unvested pre-adoption grants. The resulting stock-based compensation expense is recorded over the service period in which the employee or non-employee provides services to Oragenics, to the extent the options or warrants do not vest at the grant date and are not subject to forfeiture.

Net Loss Per Share

During all periods presented, the Company had securities outstanding that could potentially dilute basic earnings per share in the future, but were excluded from the computation of diluted net loss per share, as their effect would have been antidilutive. Because the Company reported a net loss for all periods presented, shares associated with the stock options and warrants are not included because they are antidilutive. Basic and diluted net loss per share amounts are the same for the periods presented. Net loss per share is computed using the weighted average number of shares of common stock outstanding.

Revenue Recognition

The Company recognizes revenue from the sales of product when title and risk of loss pass to the customer, which is generally when product is shipped.

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

Impairment of Long-Lived Assets

The Company periodically reviews their long-lived assets for impairment and reduces the carrying value to fair value whenever events or changes in circumstances indicate that the carrying value may not be recoverable. There were no impairment losses recorded during the years ended December 31, 2008, 2007 and 2006.

Research and Development Expenses

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

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rate is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced to estimated amounts expected to be realized by the use of a valuation allowance.

Concentrations

The Company is dependent on one major manufacturer of it's EvoraPlus products.

Recent Issued Accounting Pronouncements

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

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

In December 2007, the FASB issued SFAS No. 141(R) (revised 2007), *Business Combinations*, which replaces SFAS No. 141. SFAS No. 141(R) establishes principles and requirements for how an acquirer in a business combination recognizes and measures in its financial statements, the identifiable assets acquired, the liabilities assumed, and any controlling interest; recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS No. 141(R) is to be applied prospectively to business combinations for which the acquisition date is on or after an entity's fiscal year that begins after December 15, 2008. The Company will adopt this statement for acquisitions consummated after its effective date.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51*. SFAS No. 160 establishes accounting and reporting standards for noncontrolling interests in a subsidiary and for the deconsolidation of a subsidiary. Minority interests will be recharacterized as noncontrolling interests and classified as a component of equity. It also establishes a single method of accounting for changes in a parent's ownership interest in a subsidiary and requires expanded disclosures. SFAS No. 160 is effective for fiscal years beginning on or after December 15, 2008. The implementation of this standard does not impact on our financial position and results of operations.

In February 2008, FASB issued a FSP to allow a one-year deferral of adoption of SFAS No. 157 for non-financial assets and non-financial liabilities that are recognized at fair value on a nonrecurring basis. The Company will adopt the FSP on January 1, 2009 and we expect the adoption to not have an impact on our financial position and results of operations.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities — an amendment to FASB Statement No. 133.* SFAS No. 161 is intended to improve financial standards for derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance, and cash flows. Entities are required to provide enhanced disclosures about: (a) how and why an entity uses derivative instruments; (b) how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations; and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years beginning after November 15, 2008, with early adoption encouraged. SFAS No. 161 does not have an impact on the Company's financial statements and results of operations.

In April 2008, the FASB issued FSP 142-3, *Determination of the Useful Life of Intangible Assets.* FSP No. 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset

under SFAS No. 142, *Goodwill and Other Intangible Assets*. FSP No. 142-3 is effective for fiscal years beginning after December 15, 2008. The implementation of this standard does not impact on our consolidated financial position and results of operations.

In June 2008, the FASB issued FSP EITF No. 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities.* Under EITF No. 03-6-1, unvested share-based payment awards that contain rights to receive nonforfeitable dividends (whether paid or unpaid) are participating securities, and should be included in the two-class method of computing EPS. EITF

No. 03-6-1 is effective for fiscal years beginning after December 15, 2008, and interim periods within those years. The Company is not affected by the impact of EITF No. 03-6-1 on its financial statements.

In October 2008, the FASB issued FSP No. FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active.* FSP No. 157-3 clarifies the application of SFAS No. 157, which the Company adopted as of January 1, 2008, in cases where a market is not active. The Company has considered the guidance provided by FSP No. 157-3 in its determination of estimated fair values as of December 31, 2008, and there is not an impact to the financial statements and results of operations.

2. Property and Equipment, net

Property and equipment, net consists of the following as of December 31, 2008 and 2007:

	2008	2007
Furniture and fixtures	$ 8,035	$ 8,035
Laboratory equipment	825,193	894,247
Leasehold improvements	481,606	481,606
Office and computer equipment	82,915	45,092
	1,397,749	1,428,980
Accumulated depreciation and amortization	(1,074,325)	(869,631)
Property and equipment, net	$ 323,424	$ 559,349

Depreciation and amortization expense for the years ending December 31, 2008, 2007, and 2006 were $253,857, $273,230 and $280,901 respectively.

3. Related Party Transactions

At December 31, 2008 deferred payments totaling $143,583 were owed to Jeffrey D. Hillman, David Hirsch, Stanley Stein and $34,000 to the former members of the Board of Directors and Audit Committee and are included in the accompanying balance sheet in accounts payable and accrued expenses as of December 31, 2008. These salary payments and meeting fees were agreed to be deferred until such time as we obtain sufficient funding that payment can be made. There is no time period on the payment of the deferred amounts concerning our officers and former directors. The deferrals of payments to our officers and former directors, do not reduce our expenses, but serve to preserve our limited cash resources to the extent necessary to maintain our operations. These amounts are non-interest bearing.

At December 31, 2007, deferred payments totaling $52,500 were owed to our former President and CEO, Robert T. Zahradnik and to the CSO, Jeffrey D. Hillman and are included in the accompanying balance sheet in accounts payable and accrued expenses at December 31, 2007. After Dr. Zahradnik's resignation on December 31, 2007, the Company paid this deferred compensation of $26,250 on January 15, 2008, no interest is being accrued on these balances.

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

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

As of December 31, 2007, Dr. Robert Zahradnik resigned as President and CEO and from the Board. The Board ratified a twelve month consulting agreement, commencing on January 1, 2008, whereby he provided certain consulting and advisory services to the Company. Dr Zahradnik compensation arrangement for his consulting service consisted of cash compensation of $50,000 and 150,000 stock options granted based on the terms stated in the Company's 2002 stock option plan. The options vest at various times within two years of the grant date. Dr. Zahradnik subsequently terminated his consulting arrangement in early 2008 and became a full-time employee as the Director of Business Development a under substantially similar compensation arrangement. More recently Dr. Zahradnik assumed a position of Chief Operating Officer.

4. Accounts Payable and Accrued Expenses

	2008	2007
Legal fees	$ 909,881	$ -
Accounts payable trade	493,799	115,945
Deferred compensation	143,583	86,500
Consulting fees	70,000	55,000
Vacation	65,907	49,049
Royalties payable	50,000	25,000
Other	10,714	-
Total accounts payable and accrued expenses	$1,743,884	$ 331,494

Accounts payable and accrued expenses as of December 31, 2008 and 2007 were $1,743,884 and $331,494, respectively. Legal fees represent the most significant expense totaling $909,881 as of December 31, 2008. These fees were incurred to support the legal activities related to the delisting from the NYSE Alternext US (formerly known as the American Stock Exchange), listing on the Alternext – Paris exchange, listing on the Over-the-Counter (OTC) Bulletin Board exchange and global expansion activities in Mexico and France. None of the legal fees are litigation related.

5. Short Term Note Payable

The Company entered into a short term note payable in June of 2008 with an interest rate of 5.75% to finance D&O and employment related practices liability insurance at December 31, 2008, the balance due was $27,687. There were no loans during the fiscal year 2007.

6. Line of Credit

The Company opened a Line of Credit with Signature Bank, NY during 2008. The line of credit was established for short term loans for working capital purposes, provided the aggregate principal amount of loans at any time outstanding would not exceed $1,000,000. Signature Bank was entitled to receive interest at a fluctuating rate per annum equal to the Prime Rate and the interest rate was subject to change as the Prime Rate changes. The Company agreed to pay the Bank an additional compensation facility fee in the amount of $10,000 which was payable upon the Company's acceptance. The Line of Credit was fully secured by the Company's Signature Bank Fidelity Prime Fund money market. As of December 31, 2008 there were no amounts outstanding on the line of credit. The Company canceled the line of credit on January 24, 2009.

7. Shareholders' Equity

Common Stock

On June 24, 2003, the Company completed the filing of 2,400,000 units at $1.25 per unit as an initial public offering (IPO) for gross proceeds of $3,000,000. Each unit consisted of one share of the Company's common stock, one-half Series A Common Share Purchase Warrant and one-half Series B Common Share Purchase Warrant. One whole Series A warrant allowed the holder to purchase a share of the Company's stock at $2.00 per share until December 24, 2003. All Series A warrants were exercised before the expiration date providing proceeds to the Company of $2,400,000. One whole Series B warrant allowed the holder to purchase a share of the Company's

stock at $3.00 per share until March 24, 2004. A total of 995,400 Series B warrants were exercised on or before March 24, 2004 providing proceeds of $2,986,200 and the remaining 204,600 Series B warrants expired unexercised on March 24, 2004. In addition to receiving a cash commission for each share sold, the underwriting agent for the IPO received 100,000 shares of common stock of the Company and warrants to purchase 500,000 shares of common stock of the Company at $1.25 per share until June 24, 2005. All 500,000 underwriter warrants were exercised, of which 276,180 shares of common stock were issued in 2005 providing additional proceeds to the Company of $345,225. The cost of the IPO, including the filing of a post effective amended registration statement in October 2004, was $779,809 including the agent's commission.

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

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

On December 14, 2005, the Company issued a total of 2,937,500 shares of its common stock and warrants to purchase 2,937,500 shares of our common stock in a private placement to accredited investors. The Company received gross proceeds of $1,175,000 in the private placement and incurred estimated costs of approximately $70,000 resulting in net proceeds of approximately $1,105,000. The warrants representing shares of common stock are exercisable by the accredited investors at any time over a two-year period at an exercise price of $0.60 per share. In connection with the termination of an investment advisor agreement, the Company issued warrants on similar terms as those issued in the private placement. The warrants represented the right to acquire 130,000 shares of common stock, of which 95,000 were at an exercise price of $0.60 per share and 35,000 were at an exercise price of $0.40 per share.

On March 6, 2006, the Company issued a total of 1,500,000 shares of our common stock and warrants to purchase 1,500,000 shares of our common stock in a private placement to accredited investors. The Company received gross proceeds of $600,000 in the private placement and incurred estimated costs of approximately $75,000 resulting in net proceeds of approximately $525,000. There was no underwriter or placement agent associated with this transaction. Each warrant was exercisable on or before February 8, 2008 to acquire one share of common stock at a price of $0.60 per share.

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

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

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

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

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

Warrants

On December 14, 2005, we issued a total of 2,937,500 shares of our common stock and warrants to purchase 2,937,500 shares of our common stock in a private placement to accredited investors. The issuance of the shares of common stock and warrants was made pursuant to the exemptions from registration provided by Section 4(2) of the Securities Act and Regulation D promulgated there under. We received gross proceeds of $1,175,000 in the private placement and incurred estimated costs of approximately $70,000 resulting in net proceeds of approximately $1,105,000. The warrants representing shares of common stock were exercisable by the accredited investors at any time over a two-year period at an exercise price of $0.60 per share. On January 16, 2007, we called all outstanding warrants associated with our December, 2005 private placement pursuant to the terms of the warrant. During 2007, a total of 997,500 warrants were exercised that provided $478,500 in additional working capital and following the call of the warrants no further warrants associated with the private placement remain outstanding.

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

On January 29, 2008 the Company approved an amendment to the outstanding warrants that were originally issue in connection with the Company's private placement on August 7, 2007. The original warrants that totaled 4,600,000 shares of common stock and expire on August 7, 2008, were amended prior to expiration by the Board of Directors from the original $0.58 to $0.44. This amended price was only exercisable during the period from January 28, 2008 to February 29, 2008. On February 29, 2008, we issued an aggregate of 3,386,364 shares of common stock to warrant holders in connection with their exercise of the warrants at a reduced exercised price of $0.44. The warrants were originally issued to accredited investors in connection with our August 7, 2007 private placement. The remaining 1,213,636 outstanding warrants associated with this original private placement expired August 8, 2008 at an exercise price of $0.58. Proceeds of $1,490,000 were received from the exercise of warrants. As part of this offering, George T. Hawes, an affiliate, acquired 500,000 shares of the Company.

Coupled with the private offering on June 12, 2008 investors also received warrants to purchase 5,777,778 shares common stock at a price of $1.30 per share. These warrants expire five years from their date of issuance.

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

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

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

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

Stock Compensation Plan

The Company's 2002 Stock Option and Incentive Plan (the Plan) was adopted by the Board of Directors (the Board). The purpose is to advance the interests of the Company by affording certain employees and directors of the Company and key consultants and advisors an opportunity to acquire or increase their proprietary interests in the Company. The Plan authorizes the grant of stock options (incentive and non-statutory), stock appreciation rights and restricted stock. As of December 31, 2008 and 2007, the Company had not awarded stock appreciation rights or restricted stock under the Plan. The Company has reserved an aggregate of 5,000,000 and 3,000,000 shares of common stock for grants under the Plan at December 31, 2008 and 2007, respectively, of which 430,000 and 1,655,000 shares, respectively, are available for future grants as of December 31, 2008 and 2007. The exercise price of each option shall be determined by the Board and an option's maximum term is ten years.

In September 2002, the Company issued 195,000 options that were re-priced upon the change in the initial public offering price. As a result, these options were subjected to variable accounting treatment. In accordance with Financial Accounting Standards Board Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation* (FIN 44), stock options must be accounted for as variable under such circumstances. Variable accounting requires companies to re-measure compensation costs for the variable options until the options are exercised, cancelled, or forfeited without replacement. Compensation is dependent on fluctuations in the quoted stock prices for the Company's common stock. Such compensation costs will be recognized over a three-year vesting schedule until the options are fully vested, exercised, cancelled, or forfeited. During the years ended December 31, 2008 , 2007 and 2006, the Company recognized a stock compensation expense of $513,611, $161,471 and $241,385, respectively based on FAS 123 (R).

As of the date of this filing there are approximately 5,855,278 warrants outstanding and there are approximately 3,945,000 stock options have been granted that have not been forfeited. The total number of outstanding warrants and unexercised stock options is 9,800,278. If all warrants and stock options were exercised, the total number of outstanding shares would be approximately 48,118,756.

A summary of the status of the Company's outstanding stock options as of December 31, 2008 and 2007 and changes during the periods ending on those dates is presented below:

	Options	Option Price Per Share	Weighted Average Exercise Price
Outstanding at December 31, 2006	1,255,000	$ 0.53 – 4.25	$ 1.90
Forfeited	(155,000)	0.74 – 1.25	0.96
Granted	245,000	0.32 – 1.03	0.59
Outstanding at December 31, 2007	1,345,000	$ 0.32 – 4.25	$ 1.25
Forfeited	(930,000)	0.32 – 4.25	1.37
Granted	4,155,000	0.28 – 2.00	0.56
Outstanding at December 31, 2008	4,570,000	$ 0.28 – 4.25	$ 0.60
Exercisable at end of year	1,913,335	$ 0.28 – 4.00	$ 0.65

The range of exercise price for outstanding options at December 31, 2008 is $0.28 to $4.25 per share. The weighted-average per option fair value of options granted during 2008 and 2007 was $0.56 and $0.59, respectively, and the weighted average remaining contractual life of those options is 9.5 years and 8.3 years, respectively. Options vest over a period of two to three years from respective grant dates and the options expire 10 years after the date of grant. The fair value of these options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions: weighted average risk-free interest rate of 2.08%; dividend yields of 0%; weighted-average volatility factors of the expected market price of the Company's common stock of 27.2%; and an expected life of the option of ten years.

8. Licenses

The Company has two license agreements with the University of Florida Research Foundation, Inc. ("UFRF") for their technologies. The Company issued 599,940 shares of common stock as partial consideration in 1998. The license agreements provide for, among other things, the

Company to make minimum annual research expenditures of $1,000,000 and to adhere to specific milestones. Beginning in 2005, the Company was required to pay minimum royalties on product sales of $50,000 annually per agreement. If the Company fails to perform certain of its obligations, UFRF may terminate the license agreements. The Company's milestones are in compliance with UFRF and the Company had $50,000 and $25,000 of royalties payable to UFRF recorded in the accompanying balance sheets in accounts payable and accrued expenses at December 31, 2008 and 2007, respectively.

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

9. Retirement Plan

In January 2004, the Company established a defined contribution retirement plan, replacing the previous plan that had been established in 2001. The new plan covers all employees and provides for a Company match of up to 3% of all employee contributions to the plan. During 2008, 2007, and 2006, employee contributions were limited to $15,500, $15,500, and $15,000, respectively, except for

individuals 50 years or older for which the contribution limitations were $20,500, $20,500, and $20,000, respectively. Total matching contributions made by the Company in 2008, 2007, and 2006 were $17,644, $5,383, and $6,409, respectively.

10. Income Taxes

At December 31, 2008 and 2007, the Company had temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and their respective income tax bases, as measured by enacted state and federal tax rates, as follows:

	2008	2007
Deferred tax assets:		
Net operating loss carryforward	$ 7,075,638	$ 5,030,163
Compensation to Directors & Officers and consulting services	38,601	17,121
Total deferred tax assets	7,114,239	5,047,284
Less valuation allowance	(7,114,239)	(5,047,284)
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, 2008, 2007 and 2006:

	Years Ended December 31		
	2008	**2007**	**2006**
Income tax benefit computed at statutory federal rate of 34%	$ (2,047,392)	$ (785,982)	$ (998,144)
State income tax benefits, net of federal expense/benefit	(218,589)	(83,915)	(106,567)
Change in valuation allowance	2,066,955	814,662	1,042,086
Non-deductible expenses	199,026	61,144	91,198
Research and development credit	—	—	(40,792)
Other	—	(5,909)	12,219
Total	$ —	$ —	$ —

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based upon the levels of historical taxable income and projections of future taxable income over which the deferred tax assets are deductible, the Company believes that it is more likely than not that it will not be able to realize the benefits of some of these deductible differences. Accordingly, a valuation allowance of $7,114,239 and $5,047,284 has been provided in the accompanying financial statements as of December 31, 2008 and 2007, respectively. The 2008 net change in valuation allowance related to deferred tax assets was an increase of $2,066,955 primarily relating to net operating loss carryforwards.

At December 31, 2008, the Company has federal and state tax net operating loss carryforwards of approximately $18,803,184. The federal and state tax loss carryforward will expire through 2022, unless previously utilized. The Company also has federal research and development tax credit carryforwards of approximately $341,219. The federal tax credit carryforward will expire through 2022, unless previously utilized.

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

In July 2006, the FASB issued Interpretation No. 48, which clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with FASB Statement No. 109 and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under Interpretation 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, Interpretation 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

The Company adopted Interpretation 48 on January 1, 2007. As a result of the implementation of Interpretation 48, the Company recognized a $252,827 increase in the liability for unrecognized tax benefits that are related to research and development credits, which was accounted for as a reduction to the January 1, 2007 balance of the deferred tax asset valuation allowance. The entire amount of this unrecognized tax benefit, if recognized, would result in an increase to the deferred tax asset valuation allowance, and would not have an impact on the effective tax rate.

For the years ended December 31, 2008 and 2007, the Company incurred $50,890 and $37,502, respectively, of additional unrecognized tax benefits that resulted in a decrease to the deferred tax asset valuation allowance, related to research and development credits. The entire amount of this unrecognized tax benefit, if recognized, would result in an increase to the deferred tax asset valuation allowance, and would not have an impact on the effective tax rate.

The Company files its income tax returns in the U.S. federal jurisdiction and in Florida. With few exceptions, the Company is no longer subject to federal or state income tax examinations by tax authorities for years before 2003.

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

Balance as of December 31, 2006	$ 252,827
Additions based on tax positions related to the current year	37,502
Additions for tax positions of prior years	—
Reductions for tax positions of prior years	—
Balance as of December 31, 2007	$ 290,329
Additions based on tax positions related to the current year	50,890
Additions for tax positions of prior years	—
Reductions for tax positions of prior years	—
Balance as of December 31, 2008	$ 341,219

Included in the balance at December 31, 2008 and 2007, are $341,219 and $290,329, respectively, of tax positions for which there is uncertainty about the validity of certain credits. The disallowance of the credits would impact the amount of gross deferred tax assets reflected in the accompanying footnotes.

During the years 2008, 2007 and 2006 the Company did not recognize any interest and penalties. Due to the potential offset of the Company's operating loss carryforward for any future activity, the amount attributed to interest and penalties would be immaterial.

11. Commitments and Contingencies

The Company's facility is being leased from a real estate developer for a term of five years subject to renewal provisions that include 3% increases in lease payments. This operating lease agreement required the Company to pay a deposit of $6,400 and provides for monthly lease payments of $6,793, exclusive of utilities, insurance, sales taxes and real estate taxes. Rent expense under this lease was $89,753, $89,524, and $84,131 for the years ended December 31, 2008, 2007, and 2006, respectively. On October 1, 2008 the Company leased office space for the Sales and Marketing personnel located in St. Petersburg, FL. The lease is for approximately 610 square feet and is occupied by four employees. The lease period for the office space is six months in the amount of $1,965 per month net of insurance, taxes and utilities that are paid by us. The lease expires on March 31, 2009 and is being negotiated for renewal.

On December 31, 2008 the Company entered into an additional operating lease for office space necessary to accommodate accounting and IT personnel. The lease term is for one year and includes a deposit of $2,500 and monthly payments of $2,031 exclusive of utilities, insurance, sales taxes and real estate taxes. In addition, the Company has entered into operating leases for certain office equipment.

Future annual minimum payments under all non-cancelable operating leases are approximately as follows as of December 31, 2008:

Year ended:	
2009	$121,400
2010	4,300
	$125,700

12. 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.

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

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

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

13. Subsequent Event

Effective March 18, 2009, Mr. Stanley B. Stein resigned as President, Chief Executive Officer and director of the Company, but will thereafter continue to provide services to the Company as an advisor. Mr. Stein's resignation was not due to any disagreement with the Company on any matter related to its operations, policies or practices. Under the severance contract, Mr. Stein will receive nine months of base salary plus a monthly fee for fringe benefits.

Mr. Stein and the Company have simultaneously entered into a Separation Agreement which ended his duties as an employee and director of the Company and entered into a Consulting Agreement pursuant to which Mr. Stein will continue to provide services to the Company on an as needed basis. The Consulting Agreement is effective March 18, 2009.

EXHIBIT INDEX

Incorporated by Reference

Exhibit Number	Exhibit Description	Form	File No	Exhibit	Filing Date	Filed Herewith
3.1	Amended and Restated Articles of Incorporation	SB-2	333-100568	3.3	10/16/02	
3.2	Bylaws	SB-2	333-100568	3.2	10/16/02	
4.1	Specimen Stock Certificate	SB-2	333-100568	4.1	10/16/02	
4.2	Securities Purchase Agreement, dated November 20, 2005, among the purchasers and Oragenics, Inc.	S-3	333-131015	4.2	01/13/06	
4.3	Registration Rights Agreement dated November 20, 2005, among the investors and Oragenics, Inc.	S-3	333-131015	4.3	01/13/06	
4.4	Securities Purchase Agreement dated January 6, 2006	8-K	001-32188	4.1	3/10/06	
4.5	Registration Rights Agreement dated January 6, 2006	8-K	001-32188	4.2	3/10/06	
4.6	Specimen Warrant Certificate dated March 7, 2006	8-K	001-32188	4.3	3/10/06	
4.7	First Amendment to March Warrant dated January 11, 2008	8-K	001-32188	4.2	1/11/08	
4.8	Stock Purchase Agreement by and among Oragenics, Inc. and iviGene Corporation and the stock holders of iviGene Corporation and amendment thereto (including registration rights)	SB-2/A	333-125660	4.10	12/22/06	
4.9	Securities Purchase Agreement and Form of Warrant Agreement dated August 7, 2007 (the "August Warrant")	10-QSB	001-32188	4.1	8/13/07	
4.10	Registration Rights Agreement dated August 7, 2007 among the purchasers and Oragenics, Inc.	10-QSB	001-32188	4.2	8/13/07	
4.11	First Amendment to the August Warrant dated January 28, 2008	8-K	001-32188	4.2	1/17/08	
4.12	Securities Purchase Agreement between George Hawes, William Matlack and Oragenics, Inc. dated June 12, 2008 (including form of Warrant)	8-K	001-32188	10.1	6/16/08	
10.1	License Agreement between the Company and the University of Florida Research Foundation, Inc. effective August 4, 1998 for Replacement Therapy for Dental Caries (the "Replacement Therapy License Agreement")	SB-2	333-100568	10.1	10/16/02	
10.2	First Amendment to Replacement Therapy License Agreement dated September 15, 2000	SB-2	333-100568	10.2	10/16/02	
10.3	Second Amendment to Replacement Therapy License Agreement dated	SB-2	333-100568	10.3	10/16/02	

	June 2002				
10.4	Third Amendment to Replacement Therapy License Agreement dated September 25, 2002	SB-2	333-100568	10.4	10/16/02
10.5	Fourth Amendment to Replacement Therapy License Agreement and Antimicrobial Polypeptide License Agreement dated March 2003	SB-2/A-3	333-100568	10.36	4/9/03

Exhibit Number	Exhibit Description	Exhibit Description	File No	Form	Filing Date	File No
10.6	License Agreement between the Company and the University of Florida Research Foundation, Inc. effective June 22, 2000 (the "Antimicrobial Polypeptide License Agreement")	SB-2	333-100568	10.5	10/16/02	
10.7	First Amendment to the Antimicrobial Polypeptide License Agreement dated September 15, 2000	SB-2	333-100568	10.6	10/16/02	
10.8	Second Amendment to the Antimicrobial Polypeptide License Agreement dated June 10, 2002	SB-2	333-100568	10.7	10/16/02	
10.9	Third Amendment to the Antimicrobial Polypeptide License Agreement dated September 25, 2002	SB-2	333-100568	10.7	10/16/02	
10.10+	Amended and Restated 2002 Stock Option and Incentive Plan (including Form of Stock Option Agreement)	10-QSB/A	001-32188	10.1	9/29/06	
10.11	First Amendment to Amended and Restated Stock Option Plan	8-K	001-32188	4.2	4/14/08	
10.12	Proprietary Information and Invention Agreement between ourselves, Robert Zahradnik, Howard Kuramitsu, and Steven Projan	SB-2	333-100568	99.23	10/16/02	
10.13*	Proprietary Information and Invention Agreement between the Company and Jeffrey D. Hillman	SB-2	333-100568	99.4	10/16/02	
10.14	Employment Agreement of Jeffrey D. Hillman	10-KSB	000-50614	10.43	3/17/04	
10.15	Lease Agreement between the Company and Hawley-Wiggins LLC dated January 28, 2004; Subordination Agreement dated April 14, 2004; and First Amendment dated November 15, 2004	10-KSB	001-32188	10.46	3/14/05	
10.16	Revolving Line of Credit Agreement between Signature Bank and Oragenics Inc. dated October 20, 2008	8-K	001-32188	10.1	10/24/08	
10.17	Employment Agreement of David Hirsch dated May 14, 2008 and the Addendum of June 27, 2008	10-Q	001-32188	10.1	08/14/08	
23.1	Consent of Kirkland Russ Murphy & Tapp, PA, an independent public accounting firm					X
24.	Powers of Attorney (included on signature page)					
31.1	Rule 13a-14(a)/15d-14(a) Certification					X
31.2	Rule 13a-14(a)/15d-14(a) Certification					X
32.1	Section 1350 Certifications					X
32.2	Section 1350 Certifications					X

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the inclusion in this Annual Report (Form 10-K) of Oragenics, Inc. of our report dated March 31, 2009, with respect to the 2008 financial statements of Oragenics, Inc. We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-110646) of Oragenics, Inc. pertaining to the Oragenics, Inc. 2002 Stock Incentive Plan;

/s/ Kirkland, Russ, Murphy & Tapp, PA

Certified Public Accountants

Clearwater, Florida

March 31, 2009

Exhibit 31.1

CERTIFICATION

I, David B. Hirsch, certify that:

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

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

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

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

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

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

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

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

5. The registrant's other certifying officer 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 functions):

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

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

Date: March 31, 2009

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

Exhibit 31.2

CERTIFICATION

I, David B. Hirsch, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 31, 2009

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

Exhibit 32.1

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

In connection with the Annual Report of Oragenics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2008 as filed with the Securities and Exchange Commission on the date here of (the "Report"), I, David B. Hirsch, Acting Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

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

Dated this March 31, 2009

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

Exhibit 32.2

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

In connection with the Annual Report of Oragenics, Inc. (the "Company") on Form 10-K for the period ended December 31, 2008 as filed with the Securities and Exchange Commission on the date here of (the "Report"), I, David B. Hirsch, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

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

Dated this March 30, 2009

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