
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

POST-EFFECTIVE AMENDMENT NO. 2
TO FORM SB-2
REGISTRATION STATEMENT
Under
THE SECURITIES ACT OF 1933

ORAGENICS, INC.

(Name of small business issuer in its charter)

Florida
(State or Other Jurisdiction
of Organization)

2836
(Primary Standard
Industrial Classification Code)

59-3410522
(IRS Employer
Identification #)

ORAGENICS, INC.
13700 Progress Boulevard
Alachua, Florida 32615
Tel: (386) 418-4018
(Address and telephone of registrant's executive office)

Robert T. Zahradnik
532 SW 117th St.
Gainesville, Florida 32607
Tel: (386) 418-4018
(Name, address and telephone number of agent for service)

Copies of all communications and notices to:

Darrell C. Smith, Esq.
Shumaker, Loop & Kendrick, LLP
101 E. Kennedy Boulevard
Suite 2800
Tampa, Florida 33602
Tel: (813) 229-7600
Fax: (813) 229-1660

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the *Securities Act of 1933*, as amended (the "Securities Act") check the following box.

If this Form is filed to register additional securities for an offering under Rule 462(b) of the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed under Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed under Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If delivery of the prospectus is expected to be made under Rule 434, please check the following box.

Registration fees were previously paid in connection with the original filing of this registration statement. This post-effective amendment No. 1 is being filed solely to update the prospectus contained therein.

Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, or until the registration statement shall become effective on such date as the commission, acting under said Section 8(a), may determine.

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SUBJECT TO COMPLETION, DATED DECEMBER 19, 2006.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the securities and exchange commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting offers to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS

ORAGENICS, INC.

4,109,689 Shares of Common Stock

This prospectus relates to the sale of up to 4,109,689 shares of our common stock by Fusion Capital Fund II, LLC. The prices at which Fusion Capital Fund II, LLC may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of our shares by Fusion Capital Fund II, LLC.

Our common stock is quoted on the American Stock Exchange under the symbol "ONI." On December 15, 2006, the last reported sale price for our common stock as reported on the American Stock Exchange was \$0.97 per share.

Investing in the common stock involves certain risks. See “ [Risk Factors](#)” beginning on page 6 for a discussion of these risks.

Fusion Capital is an “underwriter” within the meaning of the Securities Act of 1933, as amended.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this Prospectus is ___.

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You should rely only on the information contained in this prospectus. We have not, and the selling stockholder has not, authorized anyone to provide you with different information. If anyone provides you with different information you should not rely on it. We are not, and the selling stockholder is not, making an offer to sell the common stock in any jurisdiction where the offer is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

Unless the context otherwise requires, the terms “we,” “our,” “us,” “the company” and “Oragenics” refer to Oragenics, Inc., a Florida corporation, and not to the selling stockholders.

PROSPECTUS SUMMARY

This summary is not complete and does not contain all of the information that you should consider before investing in our common stock. You should read the entire prospectus carefully, including the more detailed information regarding our company, the risks of purchasing our common stock discussed under "Risk Factors" on page 6 and our financial statements and the accompanying notes.

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

We are in need of substantial additional funds in order to continue the development of our technologies. We are continuing to seek additional funding. Other than the Fusion Capital agreement, we currently do not have any commitments for funding or other strategic options pending and there can be no assurances that we will be able to obtain funding or implement any strategic options in the future. Since the fourth quarter 2005, we deferred partial payments to our Chief Executive Officer and President, Chief Scientific Officer, Board of Directors and Audit Committee members, and our former chief executive officer and president. Through employee attrition we have reduced our full time staff even though we have hired one R&D employee as a Senior Research Chemist. As we move into more advanced stages concerning our products and their testing, our monthly budget and burn rate is likely to increase accordingly. Our remaining capital resources are expected to be utilized to sustain operations while we continue to explore opportunities to raise additional capital. Our available working capital at September 30, 2006 is \$259,386. When considered with the proceeds of \$420,000 we received from a recent warrant exercise, our currently available working capital is insufficient to enable us to continue to operate after the first quarter of 2007. While we believe additional capital will likely become available through grants or through possible future exercises of outstanding warrants, there can be no assurance of the same. In the event adequate capital is not raised we would likely need to cease all operations until we are able to raise additional capital. We have a contractual obligation to pay a minimum royalty of \$25,000 quarterly and spend or cause to be spent an aggregate of \$1,000,000 annually toward research, development and regulatory prosecution, in order to maintain our license with the University of Florida Research Foundation, Inc. for SMaRT Replacement Therapy™ and MU 1140™ (Mutacin 1140) technologies. While we believe we have met our obligations under the license agreement to date, if we are unable to make future payments, our license could be terminated which will substantially diminish the value of our company.

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

SMaRT Replacement Therapy™ is a single, painless one time topical treatment that has the potential to offer lifelong protection against dental caries (tooth decay). The therapy is based on genetically altering the bacterium, *Streptococcus mutans* (*S. mutans*), which is the primary etiologic agent in tooth decay. Present in the normal flora of the mouth, *Streptococcus mutans* converts dietary sugar to lactic acid; the lactic acid, in turn, causes the erosion of tooth enamel that results in the destruction of the tooth surface and eventually the entire tooth. SMaRT Replacement Therapy permanently replaces resident acid producing *Streptococcus mutans* with a patented genetically engineered strain of *Streptococcus mutans* that does not produce lactic acid. Applied topically to tooth surfaces with a swab, the therapy requires only one application. We have begun Phase I clinical trials and expect to partner with a major healthcare products or pharmaceutical company prior to initiating Phase III clinical trials. To facilitate further patient recruitment in our Phase I clinical trial, we opened an additional clinical site in June 2005, however, we had very limited patient enrollment through December 31, 2005 due to the rigorous requirements for enrollment imposed upon us by the FDA. In January 2006, we concluded this study and discussed with the FDA our problems with patient enrollment and how we could modify our protocol to allow us to move forward in our clinical trials. A formal re-submission of an amended protocol was filed with the FDA on March 9,

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2006. We addressed additional protocol changes suggested by the FDA and filed a second re-submission July 20, 2006. We do not anticipate instituting a second Phase I clinical study until such time as the FDA approves our protocol changes for the study. We remain committed to complete the human safety study of SMaRT Replacement Therapy in a manner that is satisfactory to the FDA. Should the FDA approve our re-submitted protocol, we estimate the cost in the first quarter of 2007 will be approximately \$500,000, subject to available funding.

MU 1140™ (Mutacin 1140) is a highly potent bactericidal peptide that is produced by our strain of *Streptococcus mutans*. Our proprietary mutacin was discovered by our researchers during the course of developing SMaRT Replacement Therapy and is a novel antibiotic that has broad-spectrum antimicrobial activity against essentially all Gram-positive bacteria including methicillin-resistant *Staphylococcus aureus*. The antibiotic currently is in preclinical stages of development. During the second quarter of 2005, we completed development of a proprietary manufacturing process for MU 1140, which overcame a previous hurdle to that molecule's development. We are now able to manufacture in sufficient quantities to allow us to conduct preclinical studies needed to enable the filing of an Investigational New Drug (IND) application. During the second quarter of 2006, we completed a significant preclinical study and demonstrated that MU 1140 is effective in an animal infection model against *Staphylococcus aureus*. If we are able to secure adequate funding, we plan to continue to perform in vitro antimicrobial susceptibility and toxicity testing as well as perform more detailed animal safety and efficacy studies using MU 1140. Upon successful completion of this preclinical testing, we would then be positioned to file an IND.

Probiotics are live microorganisms that confer health benefits to the host when administered in adequate amounts; the use of yogurt containing live *Lactobacillus* cultures is an example of a probiotic application. We have identified three natural strains of oral bacteria that provide significant protection against the causative organisms of periodontal disease and dental caries. Because probiotic treatments may be marketed as a cosmetic or as "health supplements" in certain geographic areas without the need for extensive regulatory oversight, we believe that with adequate funding, we may achieve commercialization of our probiotic product (**Probiora3™**) in these markets by the second half of 2007. Having received independent review board approval (Western Institutional Review Board) of our revised protocol in June 2006, we initiated a human trial on July 10, 2006 to support product claims for **Probiora3™**. Two sets of subjects completed our **Probiora3™** human study, and the results confirmed and demonstrated a substantial effect of **Probiora3™** in reducing the levels of specific disease-causing bacteria in the mouths of young, healthy adult subjects. The same trends toward reductions in *Streptococcus mutans*, a bacterium that attacks teeth and two bacterial strains associated with gum disease, *P. gingivalis* and *Campylobacter rectus*, were observed with both sets of subjects after only one week of product use. This trial also demonstrated that the **Probiora3™** mouth rinse was safe and well-tolerated during the course of product use. We are continuing to pursue, both independently and with the help of consulting groups, the process of contacting potential regional and international partners in the oral care and/or food and nutritional supplement industries to determine interest and deal structure preferences for the rights to the **Probiora3™** technology.

IVIAT™ and CMAT™ are technologies that enable the simple, fast identification of novel and potentially important gene targets associated with the natural onset and progression of infections, cancers and other diseases in humans and other living organisms, including plants. These technologies offer the potential to generate and develop a number of product candidates for future out-licensing to corporate partners, particularly in the area of cancer and tuberculosis, as well as agricultural and other non-human uses. We filed for funding under SBIR grants with the National Institutes of Health and, if such funding becomes available, we will pursue additional research.

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

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DPOLT™ (Differentially Protected Orthogonal Lantionine Technology) is a solid phase peptide synthesis platform technology that has broad application for the cost-effective manufacture of a number of commercially important bioactive peptides. Lantibiotics, including our lead antibiotic, MU1140™, are a potentially important class of antibiotics, and constitute a family of polycyclic peptides that are produced by bacteria, and are highly modified structurally. Many strains of medically important bacteria have become increasingly resistant to currently marketed antibiotics. 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. In July, 2006, the Company was awarded a \$100,000 SBIR (Small Business Innovation Research) grant from the National Science Foundation to establish proof-of-principal for DPOLT™ and to eventually synthesize a number of novel lantibiotic analogs that may be effective in treating various infections, including ones caused by drug resistant bacteria. Longer term, we have identified approximately two dozen bioactive peptides that would represent candidates for analog synthesis by DPOLT™, for potentially improved stability or bioavailability. We filed a U.S. patent application in May 2006, covering the DPOLT™ technology.

Business Objectives and Milestones

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

SMaRT Replacement Therapy™

1. Initiate second Phase I clinical safety trial.

MU 1140™

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

Probiora3™

1. Develop appropriate manufacturing and packaging systems.

LPT3-04™

1. Pursue continued discovery through further research.

DPOLT™

1. Pursue proof of principal.

The above actions, individually and in the aggregate, are expected to be costly to undertake and complete and will require additional capital over and above what we currently have available to us. Our current available capital limits our ability to fully develop our technologies. We expect to allocate our limited capital resources to the development of our technologies while we continue to explore additional capital raising opportunities. There can be

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no assurances that such additional capital will be available to us. The time periods for the development of our technologies have been extended due to our insufficient capital position and 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 have exceeded the \$1,000,000 per annum threshold for research, development and regulatory prosecution. If we are unable to make the minimum royalty payments, our license could be terminated which will substantially diminish the value of our company.

We were incorporated in Florida in 1996. We amended our articles of incorporation on May 8, 2002, in order to change our name from Oragen, Inc. to Oragenics, Inc. and to increase our authorized capital from 100,000 shares of common stock to 100,000,000 shares of common stock and 20,000,000 shares of preferred stock. Our executive office is located at 13700 Progress Boulevard, Alachua, FL 32615. This is also our mailing address. Our registered office is 532 SW 117th Street, Gainesville, Florida 32607. Our telephone number is (386) 418-4018. Our corporate website is at www.oragenics.com. We do not intend the reference to our web address to incorporate by reference in this prospectus the information on our website. The information on our website is not intended to be part of this prospectus and you should not rely on it when making a decision to invest in our securities.

Recent Developments

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. IviGene Corporation owned the patent rights to IVIAT™ and CMAT™ that we previously licensed since February 2004. Following the consummation of this transaction, iviGene Corporation will be dissolved and as a result, Oragenics will acquire all of iviGene's assets, including issued and pending patents to two broad based platform technologies. These technologies are capable of identifying gene and protein biomarkers for application to improve the 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.

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The Offering

We entered into a common stock purchase agreement with Fusion Capital Fund II, LLC (Fusion Capital) on May 23, 2005, pursuant to which Fusion Capital agreed, under certain conditions, to purchase on each trading day \$15,000 of our common stock up to an aggregate of \$9.0 million over a 30 month period. In our discretion, we may elect to sell more of our common stock to Fusion Capital than the minimum daily amount if our share price is \$2.00 or higher. The purchase price of the shares of common stock will be based upon the future market price of the common stock without any fixed discount to the market price. Fusion Capital does not have the right or the obligation to purchase shares of our common stock in the event that the price of our common stock is less than \$0.75.

Fusion Capital, is offering for sale up to 4,109,689 shares of our common stock consisting of (i) 315,421 shares that we previously issued to Fusion Capital in connection with its purchase commitment, and (ii) up to 3,794,268 shares, which represents the balance of up to 4,000,000 shares we originally authorized to sell to Fusion Capital. In connection with entering into the agreement, we authorized the sale to Fusion Capital of up to 4,000,000 shares of our common stock for a maximum proceeds of \$9.0 million. In the event that we decide to issue more than 2,900,000 in connection with the agreement, we would first seek shareholder approval in order to be in compliance with American Stock Exchange rules. Assuming Fusion Capital purchases all \$9.0 million of common stock, we estimate that the maximum number of shares we will sell to Fusion Capital under the common stock purchase agreement will be 4,000,000 shares (exclusive of the 315,421 shares issued to Fusion Capital as the commitment fee). The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the common stock purchase agreement.

As of November 30, 2006, there were 21,079,943 shares outstanding, including the 315,421 shares that we issued to Fusion Capital as compensation for its purchase commitment, but excluding the 3,794,268 shares offered by Fusion Capital pursuant to this prospectus which it has not yet purchased from us. If all of the 3,794,268 shares (which are presently not outstanding) included in the shares offered by this prospectus were issued and outstanding as of the date hereof, they would represent 15.3% of the total common stock outstanding (including the 3,794,268 in the shares outstanding.)

RISK FACTORS

You should carefully consider the risks described below together with the other information presented in this prospectus, including the financial statements and notes thereto, before making an investment decision in our common stock. These risk factors are effective as of the date of this prospectus. All of these risks may impair our business operations. The forward-looking statements in this prospectus involve risks and uncertainties and actual results may differ materially from the results we discuss in the forward-looking statements. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected. In that case, the trading price of our stock could decline, and you may lose all or part of your investment.

Risks Associated with Our Company

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

We do not have sufficient capital to sustain our operations beyond the first quarter of 2007 and we will require additional financing as soon as possible. If we are not able to raise additional capital, among other things:

- We will need to cease operations and be unable to pursue further development of our technologies;
- We will be unable to pursue patenting our small molecule anti-obesity agent and development of our technologies and products;
- We will have to lay-off our personnel;
- We could be unable to continue to make public filings;
- We will be de-listed from the American Stock Exchange; and
- Our licenses for our SMaRT Replacement Therapy technology and MU 1140 technology could be terminated which would significantly harm our business.

At September 30, 2006 and December 31, 2005, we had working capital of approximately \$259,400 and \$675,000, respectively. The independent registered public accounting firm's report as of and for the year ended December 31, 2005, includes an explanatory paragraph to their audit opinion stating that our recurring losses from operations and limited working capital raise substantial doubt about our ability to continue as a going concern. We have an operating cash flow deficit of \$1,757,338 for the nine months ended September 30, 2006 and have sustained operating cash flow deficits of \$3,434,382 in 2005 and \$2,745,243 in 2004. Our ability to obtain additional funding will determine our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

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

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

The extent we are able to rely on Fusion Capital as a source of funding will depend on a number of factors, conditions and limitations beyond our control including, the prevailing market price of our common stock. Specifically, Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than \$0.75. If obtaining sufficient financing from Fusion Capital were to prove unavailable or prohibitively dilutive and if we are unable to commercialize and sell products resulting from the development of our technologies, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we are able to access the full \$9.0 million under the common

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stock purchase agreement with Fusion Capital, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences would be a material adverse effect on our business, operating results, financial condition and prospects.

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

We have authorized the sale and issuance of up to 4,000,000 shares of our common stock to Fusion Capital under the common stock purchase agreement of which we are registering the balance available to sell of 3,794,268 remaining shares in the offering together with 315,421 shares issued to Fusion Capital as a commitment fee

In the event that we decide to issue more than approximately 2,900,000 shares, we would first be required to seek stockholder approval in order to be in compliance with American Stock Exchange rules. We have issued 315,421 shares to Fusion Capital as a commitment fee and 205,732 shares pursuant to the common stock purchase agreement and accordingly may issue up to 2,378,847 shares to Fusion Capital before we would be required to seek stockholder approval in order to be in compliance with American Stock Exchange rules. Assuming a purchase price of \$1.30 per share (the closing sale price of the common stock on November 30, 2006) and the purchase by Fusion Capital of 2,378,847 shares under the common stock purchase agreement, proceeds to us would only be \$3,092,501, unless we elect to sell more than 2,378,847 shares to Fusion Capital, which we have the right, but not the obligation, to do.

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

We hold our SMaRT Replacement Therapy and MU 1140 technologies under licenses from the University of Florida Research Foundation, Inc. Under the terms of the licenses, we must spend at least \$1 million per year on development of those technologies before the first commercial sale of products derived from those technologies. In addition, we must pay \$25,000 per quarter as minimum royalties to the University of Florida Research Foundation, Inc. under our license agreements. The University of Florida Research Foundation, Inc. may terminate our licenses in respect of our SMaRT Replacement Therapy technology and our MU 1140 technology if we breach our obligations to timely pay monies to it, submit development reports to it or commit any other breach of the covenants contained in the license agreements. There is no assurance that we will be able to comply with these conditions. If our license is terminated, our investment in development of our SMaRT Replacement Therapy and MU1140 technologies will become valueless and we may have to cease operations.

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

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

Only our SMaRT Replacement Therapy technology has been granted clearance to begin Phase 1 human clinical trials by the FDA. Clinical trials on our SMaRT Replacement Therapy are expected to take several years to fully complete. Our other technologies have not been cleared for testing in humans. Our technologies have not been cleared for marketing by the FDA or foreign regulatory authorities and they will not be able to be commercially distributed in the United States or any international markets until such clearances are obtained. Before regulatory

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approvals can be obtained, our technologies will be subject to extensive preclinical and clinical testing. These processes are lengthy and expensive. We cannot assure that such trials will demonstrate the safety or effectiveness of our technologies. There is a possibility that our technologies may be found to be unsafe or ineffective or otherwise fail to satisfy regulatory requirements. If we are unable to resolve the FDA's concerns, we will not be able to proceed further to obtain regulatory approval for that technology. If we fail to maintain regulatory clearance for our SMaRT Replacement Therapy or fail to obtain FDA clearance for our other technologies, we may have to cease operations.

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

All of our product candidates are in the early development stage. Although we have current data which indicates the promise of the concept of our SMaRT Replacement Therapy, Probiora3 and MU 1140 technologies, we can offer you no assurance that the technologies will be effective at a level sufficient to support a profitable business venture. If they are not, we will be unable to create marketable products, we will not generate revenues from our operations, and we may have to cease operations. The science on which our SMaRT Replacement Therapy, Probiora3 and MU 1140 technologies are based may also fail due to flaws or inaccuracies on which the data are based, or because the data are totally or partially incorrect, or not predictive of future results. If our science proves to be flawed, incorrect or otherwise fails, we will not be able to create a marketable product or generate revenues and we may have to cease operations.

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

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

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

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

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

Our performance is substantially dependent on the continued services and on the performance of our senior management and our team of research scientists, who have many years of experience and specialized expertise in our business. Our performance also depends on our ability to retain and motivate our other key employees. The loss of the services of our Chief Executive Officer, Robert T. Zahradnik and our Chief Scientific Officer, Dr. Jeffrey D. Hillman,

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and any of our senior 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 1140 has been undertaken solely in the laboratory and in animals. We have not yet conducted human studies of Mutacin 1140. It is possible that when these studies are conducted, they will show that Mutacin 1140 is ineffective or harmful. If Mutacin 1140 is shown to be ineffective or harmful, we will be unable to commercialize it and generate revenues from sales of Mutacin 1140. If we are unable to generate revenues from our technologies, we may have to cease operations.

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

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

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

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

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

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

Results from preclinical testing and early clinical trials are often not predictive of results obtained in later clinical trials. A number of new products have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from preclinical and clinical activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including

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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.

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.

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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.

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

The production and marketing of products which may be developed from our technologies and our ongoing research and development, preclinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities. Most of the technologies we are developing must undergo rigorous preclinical and clinical testing and an extensive regulatory approval process before they can be marketed. This process makes it longer, harder and more costly to bring products which may be developed from our technologies to market, and we cannot guarantee that any of such products will be approved. The pre-marketing approval process can be particularly expensive, uncertain and lengthy, and a number of products for which FDA approval has been sought by other companies have never been approved for marketing. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling, and record-keeping procedures. If we do not comply with applicable regulatory requirements, such violations could result in warning letters, non-approval, suspensions of regulatory approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

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

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

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

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

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

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

Because we are testing new technologies, and will be involved either directly or indirectly in the manufacturing and distribution of the technologies, we are exposed to the financial risk of liability claims in the event that the use of the technologies results in personal injury or death. There can be no assurance that we will not experience losses due to product liability claims in the future, or that adequate insurance will be available in sufficient amounts, at an acceptable cost, or at all. A product liability claim, product recall or other claim, or claims for uninsured liabilities or in excess of insured liabilities, may have a material adverse effect on our business, financial condition and results of operations. Although we currently carry \$2,000,000 in general liability insurance, such insurance may not be sufficient to cover any potential liability. We could be sued for a large sum of money and held liable in excess of our liability coverage. If we cannot pay the judgment, we may have to cease operations.

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

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

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

We are evaluating our internal controls in order to allow management to report on, and our independent registered public accounting firm to attest to, our internal controls, as required by Section 404 of the Sarbanes-Oxley Act of 2002. We may encounter unexpected delays in implementing the requirements relating to internal controls,

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therefore, we cannot be certain about the timing of completion of our evaluation, testing and remediation actions or the impact that these activities will have on our operations. We also expect to incur additional expenses and diversion of management's time as a result of performing the system and process evaluation, testing and remediation required in order to comply with the management certification and auditor attestation requirements.

We are a small company with limited resources that will make it difficult for us to timely comply with the requirements of Section 404. If we are not able to timely comply with the requirements set forth in Section 404, we might be subject to sanctions or investigation by regulatory authorities. Any such action could adversely affect our business and financial results. The requirement to comply with Section 404 of the Sarbanes-Oxley Act of 2002 will be adhered to by December 31, 2007.

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

Risk Factors Relating to our Common Stock

The sale of shares by Fusion Capital Fund II, LLC as contemplated by this prospectus may encourage our other shareholders to sell their stock and have an adverse impact on the market price of our common stock, and the sale to Fusion Capital Fund II, LLC of shares under the common stock purchase agreement will result in dilution to our existing shareholders.

The sale by Fusion Capital of our common stock as contemplated by this prospectus will increase the number of our publicly traded shares, which could depress the market price of our common stock. Moreover, the mere prospect of sale by Fusion Capital as contemplated by this prospectus could depress the market price for our common stock. The issuance of shares to Fusion Capital under the common stock purchase agreement will dilute the equity interest of existing shareholders and could have an adverse effect on the market price of our common stock.

The perceived risk of dilution may cause our shareholders to sell their shares, which would contribute to a decline in the price of our common stock. Moreover, the perceived risk of dilution and the resulting downward pressure on our stock price could encourage investors to engage in short sales of our common stock. By increasing the number of shares offered for sale, material amounts of short-selling could further contribute to progressive price declines in our common stock.

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

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

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

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

Although our common stock began trading on the American Stock Exchange under the symbol "ONI" on May 20, 2004, the trading price of our common stock has been, and may be, subject to wide fluctuations in response to a number of factors, many of which are beyond our control. These factors include:

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

Historically, the daily trading volume of our common stock has been relatively low. We cannot guarantee that an active public market for our common stock will be sustained or that the average trading volume will remain at present levels or increase. In addition, the stock market in general, has experienced significant price and volume fluctuations. Volatility in the market price for particular companies has often been unrelated or disproportionate to the operating performance of those companies. Broad market factors may seriously harm the market price of our common stock, regardless of our operating performance. In addition, securities class action litigation has often been initiated following periods of volatility in the market price of a company's securities. A securities class action suit against us could result in substantial costs, potential liabilities, and the diversion of management's attention and resources. Since our initial public offering in June 2003 and through August, 2006 our stock price has fluctuated from \$5.00 to \$0.34 per share. To the extent our stock price fluctuates and/or remains low, it could impair our ability to raise capital through the offering of additional equity securities.

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

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur. In addition, these factors could make it more difficult for us to raise funds through future offerings of common stock. As of November 30, 2006, there were 21,079,943 shares of our common stock outstanding, with another 3,700,000 shares of common stock issuable upon exercise of warrants to investors, 1,315,000 shares issuable upon exercise of options issued and an additional 1,685,000 shares available for issuance under our stock option plans. The issuance of 1,000,000 shares of our stock underlying these options is covered by an S-8 registration statement we filed with the SEC and may be resold into the market. The shares of common stock held in escrow pursuant to Canadian law and underwriter requirements in connection with our initial public offering pursuant to escrow agreements were released as of June 30, 2006 and the escrow arrangement was concluded in accordance with its terms. Released shares may be resold into the market under Rule 144. This could cause the market price of our common stock to drop significantly.

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

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

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

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

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

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

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

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

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

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

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

FORWARD-LOOKING STATEMENTS

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

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USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by Fusion Capital Fund II, LLC. We will receive no proceeds from the sale of shares of common stock in this offering. However, we may receive up to \$9.0 million in proceeds from the sale of our common stock to Fusion Capital under the common stock purchase agreement. Any proceeds from Fusion Capital we receive under the common stock purchase agreement will be used for working capital and general corporate purposes.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock began trading on the American Stock Exchange under the symbol ONI on May 20, 2004. Previously our common stock was traded on the TSX Venture Exchange under the symbol ORA.U. We voluntarily de-listed from the TSX Venture Exchange on October 12, 2004. The following sets forth the high and low closing bid prices for the common stock on the TSX Venture Exchange from the beginning of 2004 through May 19, 2004 and on the American Stock Exchange thereafter.

| Period | 2006 | | 2005 | | 2004 | |
|----------------|--------|--------|--------|--------|--------|--------|
| | High | Low | High | Low | High | Low |
| First quarter | \$0.63 | \$0.34 | \$4.00 | \$1.59 | \$4.35 | \$3.20 |
| Second quarter | \$1.50 | \$0.48 | \$2.40 | \$1.59 | \$4.40 | \$2.80 |
| Third quarter | \$0.90 | \$0.57 | \$1.85 | \$1.15 | \$3.75 | \$2.00 |
| Fourth quarter | | | \$1.00 | \$0.40 | \$4.45 | \$2.65 |

On December 15, 2006, the closing bid price of the common stock, as reported by the American Stock Exchange, was \$0.97. As of November 30, 2006, there were approximately 39 registered holders of our common stock according to our transfer agent. The number of record holders does not reflect the number of beneficial owners of the common stock for whom shares are held by banks, brokerage firms and others.

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 we may enter into in the future may preclude the payment of dividends.

THE FUSION CAPITAL FUND TRANSACTION

General

We entered into a common stock purchase agreement with Fusion Capital Fund II, LLC on May 23, 2005, pursuant to which Fusion Capital has agreed, under certain conditions, to purchase on each trading day \$15,000 of our common stock up to an aggregate of \$9.0 million over a 30 month period. In our discretion, we may elect to sell more of our common stock to Fusion Capital than the minimum daily amount. The purchase price of the shares of common stock will be equal to a price based upon the future market price of the common stock without any fixed discount to the market price. Fusion Capital does not have the right or the obligation to purchase shares of our common stock in the event that the price of our common stock is less than \$0.75.

To date Fusion Capital acquired an aggregate of 205,732 shares from us and we received proceeds of approximately \$200,000. Fusion Capital is offering for sale up to 4,109,689 shares of our common stock consisting of (i) 315,421 shares that we previously issued to Fusion Capital in connection with its purchase commitment, and (ii) up to 3,794,268 shares, which represents the balance of up to 4,000,000 shares we originally were authorized to sell to Fusion Capital. If all of such 4,109,689 shares were issued and outstanding as of the date hereof, the 4,109,689 shares would represent 15.3% of our total outstanding common stock. In the event that we decide to issue more than approximately 2,900,000 shares of common stock, we would first be required to seek stockholder approval in order to be in compliance with American Stock Exchange rules. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the common stock purchase agreement.

Purchase Of Shares Under The Common Stock Purchase Agreement

Under the common stock purchase agreement, on each trading day Fusion Capital is obligated to purchase a specified dollar amount of our common stock subject to our right to suspend such purchases at any time, and our right to terminate the agreement with Fusion Capital at any time, each as described below, Fusion Capital shall purchase on each trading day during the term of the agreement \$15,000 of our common stock. This daily purchase amount may be decreased by us at any time. We also have the right to increase the daily purchase amount at any time, provided however, we may not increase the daily purchase amount above \$15,000 unless our stock price is above \$2.20 per share for five consecutive trading days. The purchase price per share is equal to the lesser of:

- the lowest sale price of our common stock on the purchase date; or
- the average of the three (3) lowest closing sale prices of our common stock during the twelve (12) consecutive trading days prior to the date of a purchase by Fusion Capital.

The purchase price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the trading days in which the closing bid price is used to compute the purchase price. Fusion Capital may not purchase shares of our common stock under the common stock purchase agreement if Fusion Capital, together with its affiliates, would beneficially own more than 9.9% of our common stock outstanding at the time of the purchase by Fusion Capital. Fusion Capital has the right at any time to sell any shares purchased under the common stock purchase agreement which would allow it to avoid the 9.9% limitation. Therefore, we do not believe that Fusion Capital will ever reach the 9.9% limitation.

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The following table sets forth the estimated amount of proceeds we would receive from Fusion Capital from the sale of shares of our common stock offered by this prospectus at varying purchase prices:

| Assumed Average Purchase Price | Number of Shares to be Issued if Full Purchase | Percentage of Outstanding After Giving Effect to the Issuance to Fusion Capital⁽¹⁾ | Proceeds from the Sale of Shares to Fusion Capital Under the Common Stock Purchase Agreement |
|---------------------------------------|---|--|---|
| \$0.75 | 4,000,000 | 15.9% | \$3,000,000 |
| \$1.00 | 4,000,000 | 15.9% | \$4,000,000 |
| \$1.30 ⁽²⁾ | 4,000,000 | 15.9% | \$5,200,000 |
| \$2.00 | 4,000,000 | 15.9% | \$8,000,000 |
| \$3.00 | 3,000,000 | 12.5% | \$9,000,000 |
| \$4.00 | 2,250,000 | 9.6% | \$9,000,000 |

- (1) Based on 21,079,943 shares outstanding as of November 30, 2006 which includes the 315,421 commitment fee shares we issued to Fusion Capital together with the number of shares issuable at the corresponding assumed purchase price set forth in the adjacent column in this calculation.
- (2) Closing sale price of our common stock on November 30, 2006 was \$1.30. At the time we entered into the common stock purchase agreement, we authorized the sale to Fusion Capital of up to 4,000,000 shares of our common stock of which 205,732 have been sold to Fusion Capital. We estimate that we will issue no more than 4,000,000 shares to Fusion Capital under the common stock purchase agreement (exclusive of the 315,421 shares issued to Fusion Capital as the commitment fee). We have the right to terminate the agreement without any payment or liability to Fusion Capital at any time, including in the event that more than 4,000,000 shares are issuable to Fusion Capital under the common stock purchase agreement

Minimum Purchase Price

Under the common stock purchase agreement, we have set a minimum purchase price (“floor price”) of \$0.75. Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock in the event that the purchase price would be less than the floor price. Specifically, Fusion Capital shall not have the right or the obligation to purchase shares of our common stock on any trading day that the market price of our common stock is below \$0.75.

Our Right To Suspend Purchases

We have the unconditional right to suspend purchases at any time for any reason effective upon one trading day’s notice. Any suspension would remain in effect until our revocation of the suspension. To the extent we need to use the cash proceeds of the sales of common stock under the common stock purchase agreement for working capital or other business purposes, we do not intend to restrict purchases under the common stock purchase agreement.

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Our Right To Increase and Decrease the Amount to be Purchased

Under the common stock purchase agreement, Fusion Capital has agreed to purchase on each trading day during the 30 month term of the agreement, \$15,000 of our common stock or an aggregate of \$9.0 million. We have the unconditional right to decrease the daily amount to be purchased by Fusion Capital at any time for any reason effective upon one trading day's notice.

In our discretion, we may elect to sell more of our common stock to Fusion Capital than the minimum daily amount. First, in respect of the daily purchase amount, we have the right to increase the daily purchase amount as the market price of our common stock increases. Specifically, for every \$0.20 increase in Threshold Price (as defined below) above \$2.00, the Company shall have the right to increase the daily purchase amount by up to an additional \$4,500. For example, if the Threshold Price is \$2.20 we would have the right to increase the daily purchase amount to up to an aggregate of \$19,500. The "Threshold Price" is the lowest sale price of our common stock during the five trading days immediately preceding our notice to Fusion Capital to increase the daily purchase amount. If at any time during any trading day the sale price of our common stock is below the Threshold Price, the applicable increase in the daily purchase amount will be void.

In addition to the daily purchase amount, we may elect to require Fusion Capital to purchase on any single trading day our shares in an amount up to \$300,000, provided that our share price is above \$3.00 during the ten (10) trading days prior thereto. The price at which such shares would be purchased will be the lowest Purchase Price (as defined above) during the previous fifteen (15) trading days prior to the date that such purchase notice was received by Fusion Capital. We may increase this amount to \$500,000 if our share price is above \$4.00 during the ten (10) trading days prior to our delivery of the purchase notice to Fusion Capital. We may deliver multiple purchase notices; however at least ten (10) trading days must have passed since the most recent non-daily purchase was completed.

Events of Default

Generally, Fusion Capital may terminate the common stock purchase agreement without any liability or payment to us upon the occurrence of any of the following events of default:

- the effectiveness of the registration statement of which this prospectus is a part of lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to Fusion Capital for sale of our common stock offered hereby and such lapse or unavailability continues for a period of five (5) consecutive trading days or for more than an aggregate of thirty (30) trading days in any 365-day period;
- suspension by our principal market of our common stock from trading for a period of three consecutive trading days;
- the de-listing of our common stock from the American Stock Exchange, our principal market, provided our common stock is not immediately thereafter trading on the NASDAQ Global Market, the NASDAQ Capital Market, the New York Stock Exchange or the OTC Bulletin Board;
- the transfer agent's failure for five trading days to issue to Fusion Capital shares of our common stock which Fusion Capital is entitled to under the common stock purchase agreement;
- any material breach of the representations or warranties or covenants contained in the common stock purchase agreement or any related agreements which has or which could have a material adverse affect on us subject to a cure period of ten trading days;
- any participation or threatened participation in insolvency or bankruptcy proceedings by or against us;
- a material adverse change in our business; or

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- the issuance of an aggregate of 2,917,985 shares to Fusion Capital under our agreement if we fail to obtain the requisite stockholder approval.

Our Termination Rights

We have the unconditional right at any time for any reason to give notice to Fusion Capital terminating the common stock purchase agreement. Such notice shall be effective one trading day after Fusion Capital receives such notice.

Effect of Performance of the Common Stock Purchase Agreement on our Stockholders

All shares registered in this offering will be freely tradable. It is anticipated that shares registered in this offering will be sold from time to time following the date of this prospectus. The sale of a significant amount of shares registered in this offering at any given time could cause the trading price of our common stock to decline and to be highly volatile. Fusion Capital may ultimately purchase up to the 4,000,000 shares of common stock we originally authorized, and it may sell some, none or all of the shares of common stock it acquires upon purchase. Therefore, the purchases under the common stock purchase agreement may result in substantial dilution to the interests of other holders of our common stock. However, we have the right at any time for any reason to: (1) reduce the daily purchase amount, (2) suspend purchases of the common stock by Fusion Capital and (3) terminate the common stock purchase agreement.

No Short-Selling or Hedging by Fusion Capital

Fusion Capital has agreed that neither it nor any of its affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the common stock purchase agreement.

Commitment Shares Issued to Fusion Capital

Under the terms of the common stock purchase agreement Fusion Capital has received 315,421 shares of our common stock as a commitment fee. Unless an event of default occurs, these shares must be held by Fusion Capital until 30 months from the date of the common stock purchase agreement or the date the common stock purchase agreement is terminated.

No Variable Priced Financings

Until the termination of the common stock purchase agreement, we have agreed not to issue, or enter into any agreement with respect to the issuance of, any variable priced equity or variable priced equity-like securities unless we have obtained Fusion Capital's prior written consent.

MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

The following discussion and analysis should be read in conjunction with the Financial Statements and Notes thereto included elsewhere in this prospectus. 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.

Overview

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

We are in need of substantial additional funds in order to continue the development of our technologies. We are continuing to seek additional funding. Other than the Fusion Capital agreement, we currently do not have any commitments for funding or other strategic options pending and there can be no assurances that we will be able to obtain funding or implement any strategic options in the future. Since the fourth quarter 2005, we deferred partial payments to our Chief Executive Officer and President, Chief Scientific Officer, Board of Directors and Audit Committee members, and our former chief executive officer and president. Through employee attrition we have reduced our full time staff even though we have hired one R&D employee as a Senior Research Chemist. As we move into more advanced stages concerning our products and their testing, our monthly budget and burn rate is likely to increase accordingly. Our remaining capital resources are expected to be utilized to sustain operations while we continue to explore opportunities to raise additional capital. Our available working capital at September 30, 2006 is \$259,386. When considered with the proceeds of \$420,000 we received from a recent warrant exercise our currently available working capital is insufficient to enable us to continue to operate after the first quarter of 2007. While we believe additional capital may become available through grants or through possible future exercises of outstanding warrants, there can be no assurance of the same. In the event adequate capital is not raised we would likely need to cease all operations until we are able to raise additional capital. We have a contractual obligation to pay a minimum royalty of \$25,000 quarterly and spend or cause to be spent an aggregate of \$1,000,000 annually toward research, development and regulatory prosecution, in order to maintain our license with the University of Florida Research Foundation, Inc. for SMaRT Replacement Therapy™ and MU 1140™ (Mutacin 1140) technologies. While we believe we have met our obligations under the license agreement to date, if we are unable to make future payments, our license could be terminated which will substantially diminish the value of our company.

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

SMaRT Replacement Therapy™ is a single, painless one time topical treatment that has the potential to offer lifelong protection against dental caries (tooth decay). The therapy is based on genetically altering the bacterium, *Streptococcus mutans* (*S. mutans*), which is the primary etiologic agent in tooth decay. Present in the normal flora of the mouth, *Streptococcus mutans* converts dietary sugar to lactic acid; the lactic acid, in turn, causes the erosion of tooth enamel that results in the destruction of the tooth surface and eventually the entire tooth. SMaRT Replacement Therapy permanently replaces resident acid producing *Streptococcus mutans* with a patented genetically engineered strain of *Streptococcus mutans* that does not produce lactic acid. Applied topically to tooth surfaces with a swab, the therapy requires only one application. We have begun Phase I clinical trials and expect to partner with a major healthcare products or pharmaceutical company prior to initiating Phase III clinical trials. To facilitate further patient recruitment in our Phase I clinical trial, we opened an additional clinical site in June 2005, however, we had very limited patient enrollment through December 31, 2005 due to the rigorous requirements for enrollment imposed upon us by the FDA. In January 2006, we concluded this study and discussed with the FDA our

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problems with patient enrollment and how we could modify our protocol to allow us to move forward in our clinical trials. A formal re-submission of an amended protocol was filed with the FDA on March 9, 2006. We addressed additional protocol changes suggested by the FDA and filed a second re-submission July 20, 2006. We do not anticipate instituting a second Phase I clinical study until such time as the FDA approves our protocol changes for the study. We remain committed to complete the human safety study of SMaRT Replacement Therapy in a manner that is satisfactory to the FDA. Should the FDA approve our re-submitted protocol, we estimate the cost in the first quarter of 2007 will be approximately \$500,000 subject to available funding.

MU 1140™ (Mutacin 1140) is a highly potent bactericidal peptide that is produced by our strain of *Streptococcus mutans*. We completed development of a proprietary manufacturing process for MU 1140 and are now refining the process so that sufficient quantities can be produced to allow us to conduct preclinical studies needed to enable the filing of an Investigational New Drug (IND) application. During the second quarter of 2006, we completed a significant preclinical study and demonstrated that MU 1140 is effective in an animal infection model against *Staphylococcus aureus*. Once secure funding is established, we plan to continue to perform in vitro antimicrobial susceptibility and toxicity testing as well as perform more detailed animal safety and efficacy studies using MU 1140. Upon successful completion of this preclinical testing, we would then be positioned to file an IND.

Probiotics are live microorganisms that confer health benefits to the host when administered in adequate amounts; the use of yogurt containing live *Lactobacillus* cultures is an example of a probiotic application. We have identified three natural strains of oral bacteria that provide significant protection against the causative organisms of periodontal disease and dental caries. Because probiotic treatments may be marketed as a cosmetic or as “health supplements” in certain geographic areas without the need for extensive regulatory oversight, we believe that with adequate funding, we may achieve commercialization of our probiotic product (**Probiora3™**) in these markets by the second half of 2007. Two sets of subjects completed our **Probiora3™** human study, and the results confirmed and demonstrated a substantial effect of **Probiora3™** in reducing the levels of specific disease-causing bacteria in the mouths of young, healthy adult subjects. We are continuing our efforts to seek partners globally, and specifically in Europe and Asia for market opportunities in the oral care and/or food and nutritional supplement industries to determine interest and deal structure preferences for the rights to the **Probiora3™** technology.

IVIAT™ and CMAT™ are technologies that enable the simple, fast identification of novel and potentially important gene targets associated with the natural onset and progression of infections, cancers and other diseases in humans and other living organisms, including plants. These technologies offer the potential to generate and develop a number of product candidates for future out-licensing to corporate partners, particularly in the area of cancer and tuberculosis, as well as agricultural and other non-human uses. We filed for funding under SBIR grants with the National Institutes of Health and, if such funding becomes available, we will pursue additional research.

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

DPOLT™ (Differentially Protected Orthogonal Lantionine Technology) is a solid phase peptide synthesis platform technology that has broad application for the cost-effective manufacture of a number of commercially important bioactive peptides. Lantibiotics, including our lead antibiotic, MU1140™, are a potentially important class of antibiotics, and constitute a family of polycyclic peptides that are produced by bacteria, and are highly modified structurally. Many strains of medically important bacteria have become increasingly resistant to currently marketed antibiotics. 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. In July, 2006, the Company was awarded a \$100,000 SBIR (Small Business Innovation Research) grant from the National Science Foundation to establish proof-

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of-principal for DPOLT™ and to eventually synthesize a number of novel lantibiotic analogs that may be effective in treating various infections, including ones caused by drug resistant bacteria. Longer term, we have identified approximately two dozen bioactive peptides that would represent candidates for analog synthesis by DPOLT™, for potentially improved stability or bioavailability. We filed a U.S. patent application in May 2006, covering the DPOLT™ technology.

Business Objectives and Milestones

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

SMaRT Replacement Therapy™

1. Initiate second Phase I clinical safety trial.

MU 1140™

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

Probiora3™

1. Develop appropriate manufacturing and packaging systems.

LPT3-04™

1. Pursue continued discovery through further research.

DPOLT™

1. Pursue proof of principal.

The above actions, individually and in the aggregate, are expected to be costly to undertake and complete and will require additional capital over and above what we currently have available to us. Our current available capital limits our ability to fully develop our technologies. We expect to allocate our limited capital resources to the development of our technologies while we continue to explore additional capital raising opportunities. There can be no assurances that such additional capital will be available to us. The time periods for the development of our technologies have been extended due to our insufficient capital position and 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 have exceeded the \$1,000,000 per annum threshold for research, development and regulatory prosecution. If we are unable to make the minimum royalty payments, our license could be terminated which will substantially diminish the value of our company.

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Recent Developments

On November 17, 2006 we acquired all of the outstanding shares of the iviGene Corporation, a privately held early-stage company focused on technologies related to infectious diseases, in a stock transaction for 185,186 shares of new Oragenics common stock. The transaction was unanimously approved by the boards of directors of both companies and the independent directors of Oragenics. Our Chief Scientific Officer and a director, Jeffrey Hillman, was a director and shareholder of iviGene and received 20,480 shares of Oragenics common stock for his shares of iviGene common stock. We are required to file a resale registration statement for the shares issued in connection with the transaction within ninety days.

Oragenics has had an exclusive license to specific applications of iviGene's patented IVIAT™ technology since February 2004. With this transaction, however, Oragenics has now acquired all of iviGene's assets, including issued and pending patents to two broad-based platform technologies. With the acquisition of the iviGene Corporation, Oragenics has significantly expanded its product development capabilities, especially in the company's focused areas of infectious disease and cancer. We believe that iviGene's proprietary technologies will position us to create significant future opportunities for Oragenics.

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

In December 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004), *Share-Based Payment* ("Statement 123(R)"), a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Statement 123(R), which we 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. Thus, pro forma disclosure will no longer be an alternative to financial statement recognition for new stock option grants and unvested stock option grants prior to adoption of FAS 123(R).

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| | Nine Months Ended September 30 | |
|--|--------------------------------|-----------------------|
| | 2006 | 2005 |
| Revenue | \$ 66,176 | \$ — |
| Operating expenses: | | |
| Research and development | 1,413,947 | 1,644,370 |
| General and administration | 887,147 | 859,701 |
| Total operating expenses | 2,301,094 | 2,504,071 |
| Loss from operations | (2,234,918) | (2,504,071) |
| Other income (expense): | | |
| Interest income | 21,487 | 36,654 |
| Interest expense | (855) | (22,566) |
| Gain on sale of property and equipment | 2,024 | — |
| Total other income, net | 22,656 | 14,088 |
| Loss before income taxes | (2,212,262) | (2,489,983) |
| Income tax benefit | — | — |
| Net loss | <u>\$ (2,212,262)</u> | <u>\$ (2,489,983)</u> |

| | Years ended December 31 | |
|-----------------------------------|-------------------------|-----------------------|
| | 2005 | 2004 |
| Revenue | \$ — | \$ 196,210 |
| Operating expenses: | | |
| Research and development | 2,097,223 | 1,990,979 |
| General and administration | 1,166,854 | 1,329,983 |
| Total operating expenses | 3,264,077 | 3,320,962 |
| Loss from operations | (3,264,077) | (3,124,752) |
| Other income (expense): | | |
| Interest income | 41,875 | 47,306 |
| Interest expense | (29,176) | (442) |
| Total other income (expense), net | 12,699 | 46,864 |
| Loss before income taxes | (3,251,378) | (3,077,888) |
| Income tax benefit | — | — |
| Net loss | <u>\$ (3,251,378)</u> | <u>\$ (3,077,888)</u> |

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For the Nine Months Ended September 30, 2006 and 2005

We had \$66,176 in revenues associated with an SBIR grant in the nine months ended September 30, 2006 compared with no revenues in the same period in 2005. Our operating expenses decreased 8% to \$2,301,094 in the nine months ended September 30, 2006 from \$2,504,071 in the same period in 2005. Research and development expenses decreased 14% to \$1,413,947 in the nine months ended September 30, 2006 from \$1,644,370 in the same period in 2005. The total decreases of approximately \$230,600 is a result of reduction in staffing and travel of approximately \$367,900, the decrease in laboratory expenses of approximately \$43,600, and the decreased use of outside consultants and contract manufacturing \$310,900. The decreases were offset by the recognition of stock option expense resulting from the adoption of FAS 123(R) and the recognition of credits in 2005 for the variable accounting for stock option awards aggregating approximately \$333,300, an increase in legal and patent filing costs of approximately \$60,100, and the increase in costs relating to our clinical trial program for Probiora3 of approximately \$43,600. Equipment maintenance and depreciation also increased approximately \$45,500 and the cost of \$9,600 associated with our expansion of members to our Scientific Advisory Board.

General and administration expenses increased 3% to \$887,147 in the nine months ended September 30, 2006 from \$859,701 in the same period in 2005. The total increase of approximately \$27,700 reflected the recognition of stock option expense resulting from the adoption of FAS 123(R) and the recognition of credits in 2005 for the variable accounting for stock option awards aggregating approximately \$350,500. These increases were offset by the reduction in fees paid to assist with financing of approximately \$110,500, reduction in staff and their associate expenses approximately \$126,000 and outside professional service fees of approximately \$8,600, including the reduction of legal and accounting costs approximately \$66,600, and the reduction of Board fees of approximately \$11,100. (On September 7, 2006, the Board of Directors approved stock option grants to non-employee directors in lieu of future cash fees for Board and Committee services.)

Interest income decreased 41.4% to \$21,487 in the nine months ended September 30, 2006 from \$36,654 during the same period in 2005, reflecting the lower cash reserves maintained during 2006. We incurred interest expense of \$855 in the first nine months of 2006, as compared to \$22,566 in the same period in 2005. Interest expense in 2006 related to financing of insurance premiums, whereas the expense in 2005 was the result of the initial draw on a note payable to our bank. The note was repaid in December 2005 and we had no outstanding bank debt during the nine months ended September 30, 2006.

We incurred net operating losses of \$2,234,918 and \$2,504,071 during the nine months ended September 30, 2006 and 2005. The decrease in our net loss of approximately \$269,000 was principally caused by the decrease in personnel and travel expense of approximately \$462,000, a decrease in office and laboratory expenses of \$30,400, reduction in fees paid to assist in financing of approximately \$110,500, decrease in the use of outside professional consultants and contract manufacturing totaling approximately \$319,500, and a reduction in legal, accounting, patent filing costs and Board fees and expansions of our Scientific Advisory Board of approximately \$8,000. These expenses were offset by the recognition of stock option expense resulting from the adoption of FAS 123(R) and the recognition of credits in 2005 for the variable accounting for stock option awards approximating \$683,800, and increase in costs relating to the clinical trial program for Probiora3™ of approximately \$43,600.

For the Years Ended December 31, 2005 and 2004

We had no revenues in the year ended December 31, 2005 as compared to \$196,210 in 2004. This is a result of having two Small Business Innovation Research Grants for our Mutacin 1140 and IVIAT technologies in 2004. Our operating expenses decreased 2% to \$3,264,077 for the year ended December 31, 2005 from \$3,320,962 in 2004. Research and development expenses increased 5% to \$2,097,223 in 2005 from \$1,990,979 in 2004, reflecting higher depreciation costs of approximately \$203,000 associated with new equipment purchases in early 2005, higher facility costs of approximately \$70,000 associated with the rent and utilities of the building we began renting in late 2004, the start of paying minimum royalty fees to the University of Florida amounting to \$100,000, higher personnel costs for the entire year of approximately \$46,000 and the payment of product liability insurance premiums of approximately \$19,000 associated with our clinical trials, offset by the reduction of stock option compensation expense of approximately \$208,000, higher recruiting and relocation costs in 2004 of approximately \$77,000, higher outside consulting costs in 2004 of approximately \$44,000 mostly caused by the manufacture of clinical trial materials and higher travel expenses in 2004 of approximately \$11,000. General and administration expenses decreased 12% to \$1,166,854 in 2005 from \$1,329,983 in 2004, reflecting the reduction of stock option

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compensation expense of approximately \$333,000, fees of approximately \$64,000 paid to the American Stock Exchange in 2004 for the initial listing of our shares, the reduction in the use of outside consultants amounting to approximately \$49,000, the reduction of travel and entertainment expenses in 2005 approximating \$47,000, higher than normal supply costs in 2004 to outfit the our new building amounting to approximately \$34,000 and staff lay-offs amounting to approximately \$9,000, offset by fees associated with attempted financings of approximately \$108,000, increased legal and accounting fees approximating \$114,000, the severance charges for our former CEO approximating \$90,000, costs associated with hiring a new CEO totaling approximately \$28,000, higher depreciation costs of approximately \$16,000 in 2005 and higher facility costs in 2005 of approximately \$14,000.

Interest income decreased 11% to \$41,874 in the year ended December 31, 2005 from \$47,306 in 2004, which was a result of higher average cash balances maintained in 2004 due to the exercise of Series A and Series B common stock warrants in December 2003 and March 2004, respectively. Interest expense increased to \$29,176 in 2005 from \$442 in 2004. This increase of \$28,733 reflects the payments on our equipment loan in 2005 that was not active in 2004 and was retired in December 2005.

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.

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

Our operating activities used cash of \$1,757,338 for the nine months ended September 30, 2006 and \$2,900,228 for the nine months ended September 30, 2005. Our working capital was \$259,386 as of September 30, 2006. Cash used by operations in the nine months ended September 30, 2006 resulted primarily from our net loss from operations of \$2,212,262. Our operating activities used cash of \$3,434,382 for the year ended December 31, 2005 and \$2,745,243 for the year ended December 31, 2004. Our working capital was \$675,006 as of December 31, 2005. Cash used by operations in the year ended December 31, 2005 resulted primarily from operating losses from operations of \$3,251,378.

Our investing activities provided cash of \$2,103 for the nine months ended September 30, 2006 as a result of the sale of property and equipment. Our investing activities used cash of \$666,268 for the year ended December 31, 2005 for the acquisition of laboratory equipment. We do not anticipate any significant spending on additional property and equipment during the remainder of 2006.

Our financing activities for the nine months ended September 30, 2006 provided net cash of \$1,287,465 which consists of \$1,398,750 in gross proceeds from a private financing less costs of \$111,285. On March 6, 2006, we issued 1,500,000 shares of our common stock at \$0.40 per share and warrants to purchase 1,500,000 shares of our common stock in a private placement to accredited investors. We intend to use the net proceeds of the private placement, including any proceeds from exercise of the warrants, for working capital and general corporate purposes. The warrants representing shares of common stock are exercisable by the accredited investors at any time over a two-year period at an exercise price of \$0.60 per share. In the third quarter of 2006, 86,659 warrants that were originally issued in November 2004 and December 2005, represented shares of common stock that were exercised at an average exercise price of \$0.78.

During the remainder of 2006 and 2007, provided additional financing is obtained, we expect to spend approximately \$450,000 to maintain normal research and development operations and approximately \$500,000 to perform additional studies on MU 1140™.

On December 5, 2006 we issued 700,000 shares to one of our Directors, Mr. George Hawes, in connection with his exercise of an outstanding warrant to acquire our shares at \$0.60 per share. The proceeds to us from the exercise of the warrant were \$420,000, which we expect to use for our working capital.

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On May 23, 2005, we entered into a stock purchase agreement with Fusion Capital Fund II, LLC (“Fusion Capital”). Pursuant to the terms of the stock purchase agreement, Fusion Capital has agreed to purchase from us up to \$9,000,000 of our common stock over a 30 month period commencing from the date of the stock purchase agreement. Pursuant to the terms of a registration rights agreement, dated May 23, 2005, we filed a registration statement with the Securities and Exchange Commission covering shares which may be purchased by Fusion Capital under the stock purchase agreement and we agreed to file any required post-effective amendments to maintain the effectiveness of such registration statement. On each trading day during the term of the stock purchase agreement and in which the registration statement and any required amendments thereto is effective, we have the right to sell to Fusion Capital \$15,000 of our common stock at a price based upon the market price of the common stock on the date of each sale without any fixed discount to the market price. At our option, Fusion Capital can be required to purchase fewer or greater amounts of common stock each month. We have the right to control the timing and the number of shares sold to Fusion Capital. Fusion Capital does not have the right or the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than \$0.75. Our common stock price has traded below \$0.75 for a significant amount of time since we entered into the stock purchase agreement with Fusion Capital which precludes the availability of funding from Fusion Capital under our agreement with them. The purchase price for the common stock to be sold to Fusion Capital pursuant to the stock purchase agreement with Fusion Capital will fluctuate based on the price of our common stock. We are required to maintain an effective registration statement for the sale of the shares acquired by Fusion Capital. Since the inception of the stock purchase agreement and pursuant thereto, we have issued an aggregate 205,732 shares to Fusion Capital and received aggregate proceeds of approximately \$200,000

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 continuing operations during the last two fiscal years and have an accumulated deficit of \$10,935,624 as of September 30, 2006. Cash used in continuing operations for the first nine months of 2005 was \$2,900,228 and for the first nine months of 2006 was \$1,757,338. At September 30, 2006, our principal source of liquidity was \$470,019 of cash and cash equivalents, which we estimate that we will utilize at the rate of approximately \$150,000 per month. 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. 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 September 30, 2006, salary payments of \$26,250 each to Jeffrey D. Hillman, our Chief Scientific Officer, and Robert T. Zahradnik, our President and Chief Executive Officer and 2005 and 2006 fees of \$34,000 to the Board of Directors and Audit Committee have been deferred. These salary payments and meeting fees were agreed to be deferred until such time as we obtain sufficient funding that payment can be made. There is no time period on the payment of the deferred amounts concerning our officers and directors. As of September 30, 2006, our oral agreement with our former chief executive officer to defer certain payments due pursuant to our separation agreement, amounted to a deferral of \$63,000. As part of the oral agreement with our former chief executive officer, we are currently paying \$7,500 per month which is one half of the monthly amount due of \$15,000 under the separation agreement. These payments were originally to be concluded in July of 2006, but due to the deferred amount and the current payment schedule these payments have continued beyond that time period and will continue until paid in full. The deferrals of payments to our former chief executive officer, current officers and directors, do not reduce our expenses, but serve to preserve our limited cash resources to the extent necessary to maintain our operations.

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Our capital requirements for 2006 will depend on numerous factors, including the success of our research and development, the resources we devote to develop and support our technologies and the success of pursuing strategic licensing and funded product development relationships with external partners. Subject to our ability to raise additional capital, we expect to need to incur substantial expenditures to further develop each of our technologies including continued increases in costs related to research, preclinical testing and clinical studies, as well as significant costs associated with being a public company. Our working capital at September 30, 2006 is not adequate to meet our business objectives as presently structured. We will require substantial funds to conduct research and development and preclinical and Phase I clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase II and III clinical testing and manufacture and marketing of any products that are approved for commercial sale. We recognize that we must generate additional capital resources to enable us to continue as a going concern. Our plans include seeking financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to assure continuation of our operations and research and development programs.

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

To date, we have not obtained financing sufficient to fully support our plans going forward. Until such time as additional financing for our operations is obtained, we expect to continue to need to curtail our spending. While we continue to focus on completing the Phase I clinical trial for our SMaRT Replacement Therapy™ technology, conducting additional studies for our MU 1140™ antibiotic technology and Probiora3™, and developing strategic partners for Probiora3™, we do not have sufficient capital resources to complete these projects. As we move into more advanced stages concerning our products and their testing our monthly budget and of cash usage rate is likely to increase accordingly. Our available working capital at September 30, 2006 is \$259,386. When considered with the proceeds of \$420,000 we recently received from the above described current exercise, our currently available working capital is insufficient to enable us to continue to operate after the first quarter of 2007. While we believe additional capital may become available based upon the SBIR grant, possibly through our arrangement with Fusion Capital or through possible future exercises of outstanding warrants, there can be no assurance of the same. In the event adequate capital is not raised we would likely need to cease all operations until we are able to raise additional capital. Thereafter, without sufficient capital to fund our operations, we will be unable to continue as a going concern and will have to cease operations.

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.

We are a biopharmaceutical company with a pipeline of proprietary technologies. The Company has a number of products in discovery, preclinical and clinical development, with a concentration in two main therapeutic areas: infectious disease and oncology. Oragenics' core pipeline includes products for use in the treatment of dental and periodontal infectious diseases, systemic bacterial infections and obesity. In the discovery stage are three platform technologies for identifying biomarkers of infection, cancer and autoimmune diseases and for the solid state synthesis of bioactive peptides including small molecule antibiotics. As an early-stage biotechnology company, our strategy is to in-license or internally discover and to develop products through human proof-of-concept studies (Phase II clinical trials of the U.S. Food and Drug Administration's (FDA) regulatory process) prior to partnering with major pharmaceutical, biotechnology or healthcare product firms for advanced clinical development and commercialization. Since inception, we have funded a significant portion of our operations from the public and private sales of our securities. We have generated no significant revenues from operations during the last two years. All of our revenues have been from a sponsored research agreement and SBIR grants which all but one have expired. We hope to be in a position to continue to develop several products with the following technologies:

Our Technologies

Replacement Therapy

Dental caries (tooth decay) is a worldwide epidemic that affects the majority of populations in industrialized and developing countries. According to the World Health Organization, tooth decay is the most prevalent infectious disease, affecting approximately 5 billion people. Much of the tooth decay in low-income countries remains untreated until the teeth are extracted.

Tooth decay is characterized by the dissolution of enamel and dentin which eventually results in the destruction of the entire tooth. The immediate cause of tooth decay is organic acid produced by microorganisms on the tooth surface. Studies suggest that of the 400 to 500 microbial species in the mouth, *Streptococcus mutans*, a common bacterium found in virtually all humans, is the principal causative agent in the development of tooth decay. Residing within dental plaque, *Streptococcus mutans* derives its energy from carbohydrate metabolism as it converts dietary sugar to lactic acid which, in turn, erodes the tooth enamel.

Our replacement therapy technology employs a genetically modified strain of *Streptococcus mutans* that does not produce lactic acid. When applied to the teeth, this non acid-producing organism displaces and permanently replaces the indigenous acid-producing strains of *Streptococcus mutans*, thereby potentially providing lifelong protection against most forms of tooth decay.

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

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

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Technical Background

Replacement therapy represents a novel approach to preventing bacterial infections by capitalizing on interactions between different species of bacteria inhabiting the same ecosystem. This approach involves permanently implanting a harmless strain of bacteria in the host's microflora. Once established, the harmless strain prevents the colonization and outgrowth of a potential pathogen. In the case of dental caries, beneficial bacteria are implanted in the mouth of the host to prevent colonization of the harmful bacteria that cause tooth decay.

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

Through extensive scientific research, we eventually found a rare strain of *Streptococcus mutans*, present in only 1% of the population, which secretes a natural antibiotic capable of killing virtually all other strains of *Streptococcus mutans*. We believe this natural antibiotic, referred to as mutacin 1140, enables the bacteria to persistently and preemptively colonize the oral cavity, displace pre-existing strains and gain dominance in its ecosystem, dental plaque.

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

Regulatory Status

We submitted an Investigational New Drug (IND) application for our replacement therapy to the U.S. Food and Drug Administration in 1998 seeking permission to begin clinical trials. Subsequent to review by the Office of Vaccines Research and Review Division of Vaccines and Related Products Application at the Center for Biologics Evaluation and Research (CBER), the FDA placed the application on clinical hold pending the development of a recall mechanism to completely eradicate the organism from human subjects, should it be necessary, until complete safety could be experimentally established in the Phase I clinical trials.

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

In the initial studies to assess product safety (Phase I clinical trials) that began in March 2005, the genetically altered strain of *Streptococcus mutans* requiring D-alanine supplementation was administered to study subjects in conjunction with a twice daily dose of a D-alanine mouth rinse. Once safety is experimentally established, the replacement therapy to be commercialized will consist of the original effector strain which does not require D-alanine to maintain colonization.

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We began our initial study in May 2005; however, during the remainder of 2005 we were unable to enroll a sufficient number of qualified subjects into our study. This initial study was expected to be conducted in eleven couples and an additional four unattached males at Hill Top Research in West Palm Beach, Florida and would look at the safety of Replacement Therapy and the potential for horizontal transmission of the Replacement Therapy organism to the non-treated member of each couple. All of the participants in the trial, according to the FDA approved protocol, were required to be without teeth, with full sets of dentures, and under the age of 55. The study required four days of pretreatment with an antibiotic (chlorhexidine) to kill resident *S. mutans* in each participant's mouth. Male study subjects were to receive Replacement Therapy. The non-treated member of each couple was to be tested repeatedly to see if there was any horizontal transmission of the Replacement Therapy organism from one person to another. The investigators were to determine the genetic stability of the Replacement Therapy organism over time. Seven days after treatment, the subjects were to undergo an eradication phase of the study for one month, using the same antibiotic and the withholding of a D-alanine amino acid supplement that the Replacement Therapy organism requires for its survival. Finally, the protocol required investigators to subsequently follow each study participant for three months to ensure that the eradication was effective.

On December 2, 2005, due to the enrollment of only one subject in our initial clinical study, we re-submitted a new protocol to the FDA that was less restrictive. In January 2006, we held discussions with the FDA about our problems with patient enrollment and how we could modify our protocol. The critical changes to the study are that it will be conducted in 10 patients who have teeth and the patients will be quarantined to a hospital-type setting for up to 12 days with a 2 month follow-up phase. We have concluded the initial study and submitted additional proposed changes in the trial to the FDA in March 2006. We addressed additional protocol changes suggested by the FDA and filed a second re-submission July 2006. Additional protocol changes were suggested by the FDA on September 29, 2006. Protocol changes from FDA will be addressed in our third re-submission anticipated to be submitted in December 2006. We anticipate instituting a second Phase I clinical study by the first quarter of 2007. We believe these changes, if approved in a timely manner by the FDA, will allow the Company to complete the enrollment of patients and thereby complete the study in mid 2007.

Preclinical Studies

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

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

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

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

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

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

Intellectual Property

We have exclusively licensed the intellectual property for our replacement therapy from the University of Florida Research Foundation, Inc. The license is dated August 4, 1998 and was amended on September 15, 2000, July 10, 2002, September 25, 2002 and March 17, 2003. The agreement provides us with an exclusive worldwide license to make, use and sell products and processes covered by Patent No. 5,607,672, which is dated March 4, 1997 and will expire on March 3, 2014. Our license is for the period of the patent, subject to the performance of terms and conditions contained therein. The patent covers the genetically altered strain of *Streptococcus mutans* which does not produce lactic acid, a pharmaceutical composition for administering the genetically altered strain and the method of preventing tooth decay by administering the strain. The University of Florida Research Foundation, Inc. has reserved for itself and the University of Florida the right to use and sell such products and services for research purposes only. Our license also provides the University of Florida Research Foundation, Inc. with a license, for research purposes only, to any improvements that we make to the products and processes covered by the patent.

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

We must also pay all patent costs and expenses incurred by the University of Florida Research Foundation, Inc. for the preparation, filing, prosecution, issuance and maintenance of the patent. In 2003, upon our having received external funding exceeding \$1 million, we reimbursed the university \$100,000 of the initial \$105,000 they paid for patent prosecution. During 2004 and 2005, we paid the university an additional \$83,000 as reimbursement for patent prosecutions. We have agreed to indemnify and hold the University of Florida Research Foundation, Inc. harmless from any damages caused as a result of the production, manufacture, sale, use, lease, consumption or advertisement of the product. Further, we are required to maintain liability insurance coverage appropriate to the risk involved in marketing the products, for which we obtained liability insurance in the amount of \$2,000,000 that expires in August, 2006. There is no assurance that we can obtain continued coverage on reasonable terms.

We received notification from Celunol (formerly B.C. International Corporation) on July 29, 2002 that a gene utilized in its licensed, patented strain of *Streptococcus mutans* infringes a patent which it holds under a license. 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.

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Manufacturing, Marketing and Distribution

The manufacturing methods for producing our genetically engineered strain of *Streptococcus mutans* are standard fermentation methods. These methods involve culturing bacteria in large vessels and harvesting them when mature by centrifuge or filtration. The cells are then suspended in a pharmaceutical medium appropriate for application in the human mouth. These manufacturing methods are commonplace and readily available within the pharmaceutical industry.

Upon successful completion of Phase I clinical trials, we intend to consider sublicensing our replacement therapy technology to one or more strategic partners that would be responsible for advanced clinical development and commercialization including product manufacturing, marketing and distribution.

Market Opportunity

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

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

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

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

Competition

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

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

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

Mutacin 1140

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

Two types of mutacins have been characterized at the molecular level: lantibiotics and non-lantibiotics. Scientists have identified approximately 20 lantibiotics to date, including nisin, a substance used as a food preservative that has been given status as “GRAS” or “generally recognized as safe” by regulatory authorities. In general, lantibiotics have a wider spectrum of activity than the non-lantibiotic bacteriocins.

Technical Background

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

Preclinical Studies

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

We believe the results of our laboratory studies demonstrate that Mutacin 1140 is effective at killing a broad spectrum of bacteria, including the streptococci that cause pharyngitis (“strep throat”), the predominant type of pneumonia, and bacterial endocarditis. The antibiotic has also been shown to be effective against vancomycin-resistant *Staphylococcus aureus* and *Enterococcus faecalis* infections, both of which are rapidly growing problems within the medical community. Mutacin 1140 was found to kill all Gram-positive bacteria tested at concentrations comparable to many therapeutically effective antibiotics. A particularly interesting feature of Mutacin 1140 is that none of the sensitive species of bacteria tested was able to acquire genetically stable resistance to purified Mutacin 1140.

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

Regulatory Status

Currently, Mutacin 1140 is in the mid stages of preclinical development and we have not yet filed an Investigational New Drug (IND) application with the FDA, however, such filing is expected after successful completion of animal studies in early 2007.

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Intellectual Property

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

Manufacturing, Marketing and Distribution

Upon successful completion of animal studies, we will file an IND application for Mutacin 1140 with the FDA. Once the FDA has approved an IND and we have completed Phase I clinical trials, we would expect to seek a strategic partner for further clinical development and commercialization, including establishing large-scale manufacturing and production capabilities.

Market Opportunity

The need for novel antibiotics is increasing as a result of the growing resistance of target pathogens. The Center for Disease Control estimates that bacteria resistant to known antibiotics cause 44% of hospital infections. Vancomycin, introduced in 1956, serves as the last line of defense against certain life-threatening infections. Unfortunately, certain bacteria have developed strains which resist even vancomycin.

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

Competition

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

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

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

Probiotics

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

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The oral cavity provides an ecological niche for 400 -500 bacterial species, some of which are responsible for periodontal disease (gum disease) and dental caries (tooth decay). Of all of the bacteria normally residing in a person's mouth, only about half a dozen are the primary cause of periodontal disease and dental caries. Our oral rinse probiotics' technology employs three natural strains of beneficial bacteria which promote oral health and inhibit the growth of harmful bacteria that cause periodontal disease and tooth decay.

Technical Background

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

Streptococcus oralis and *Streptococcus uberis* are among several hundred bacterial species that constitute normal dental plaque. These bacteria, by virtue of their ability to produce hydrogen peroxide, appear to promote periodontal health by keeping the number of potentially pathogenic organisms below the threshold level necessary to initiate disease. These bacteria have demonstrated an ability to inhibit bacteria implicated in periodontal disease in both laboratory and animal studies. Human studies have correlated presence of these bacteria with the absence of periodontal pathogens. Probiotics containing these bacteria applied frequently can provide significant protection against causative organisms of periodontal disease.

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

Preclinical Studies

We believe preclinical studies have demonstrated the ability of our probiotic to maintain a healthy oral environment. The probiotic creates a healthful balance of total bacteria by reducing the numbers of bacteria that are causative agents of periodontal disease and dental caries.

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

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

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We recently performed two studies to determine an appropriate and stable delivery system for commercialization. We initiated two human trials in July 2006 to support product claims for Probiora 3™. The trials were designed to determine safety and the effectiveness of the mouth rinse against baseline levels of disease-causing bacteria in the mouth. Daily mouth rinsing with Probiora3™ resulted in substantial reductions in the numbers of the bacterium, *S. mutans*, which attacks teeth, as well as two target periodontal strains, *Porphyromonas gingivalis* and *Campylobacter rectus*, associated with gum disease and bad breath. The product was well tolerated by the subjects and no safety issues were identified with the twice daily use of the product over a two-month period.

Regulatory Status

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

Intellectual Property

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

Manufacturing, Marketing and Distribution

Manufacturing methods used to produce probiotic strains are the standard fermentation methods which involve culturing bacteria in large vessels and harvesting them when mature by centrifuge or filtration. These methods are relatively commonplace and readily available within the probiotics industry. We intend to seek one or more strategic partners for the manufacturing, marketing and distribution of our oral probiotic technology in Asia and Europe. European and Asian companies have signaled their intent to establish a licensing agreement with us, while another potential partner is completing a laboratory evaluation of the product before moving forward with possible licensing discussions. Product launch in select markets is currently expected to occur in 2007.

Market Opportunity

Probiotics are relatively common in Japan and are being adopted with increasing frequency in Europe. The probiotics market in the U.S. is still emerging and we expect the U.S. market will develop slowly. If successfully developed, we expect our technology will be one of the first probiotics to be marketed for the promotion of oral health.

Competition

Many companies sell probiotics that are principally designed for digestive health, vaginal and urinary tract health, and immune system support. Our product will not compete directly with the products of these companies. Recently, researchers at the University of Hiroshima in Japan have published studies indicating that *Lactobacillus reuteri* aids in the prevention of tooth decay. *Lactobacillus reuteri* is widely used as a probiotic for other indications and may be used in the future for dental health. We are not aware of any product on the market today that is targeted to maintain periodontal health.

IVIAT and CMAT

On November 17, 2006, we acquired 100% of the outstanding capital stock of iviGene Corporation, in exchange for 185,186 shares of our common stock. Following this transaction, iviGene Corporation will be dissolved and its assets, which primarily consisted of one patent and two additional patent filings (patent pendings) to two novel technologies that enables the simple, fast identification of novel and potentially important gene targets

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associated with the natural onset and progression of cancers and other diseases in humans and other living organisms, including plants which we had previously licensed. This technology will offer us the potential to generate and develop a number of product candidates for future out-licensing to corporate partners, particularly in the area of cancer and tuberculosis.

To support the research for this technology in 2004, we received a \$100,000 Phase I SBIR Grant from the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). This grant supported initial research to help us identify genes of *Mycobacterium tuberculosis* that are specifically induced during human infections with that pathogen. This licensed technology is in its early stages and will require further development which will require additional capital.

Technical Background

This technology platform was developed by our founder and chief scientific officer, Jeffrey D. Hillman, and University of Florida scientists. It is called *in vivo* induced antigen technology (IVIAT). IVIAT can quickly and easily identify *in vivo* induced genes in human infections without the use of animal models, facilitating the discovery of new targets for the development of vaccines, antimicrobials and diagnostics. Dr. Hillman and his collaborators have further developed methods based on this approach to create Change Mediated Antigen Technology (CMAT). CMAT can be used to identify gene targets associated with the onset and progression of cancerous processes and autoimmune diseases. It can also be used to identify novel genes in plant diseases, including genes expressed by the pathogen when it causes the disease and genes expressed by the plant in response to the disease.

Intellectual Property

Since our acquisition of iviGene Corporation on November 17, 2006, we own the exclusive worldwide rights to this broad platform technology in the areas of cancer and tuberculosis, as well as agricultural and other non-human uses. We believe that these proprietary technologies will position us to create significant future opportunities for Orogenics. In December 2006 we filed a U.S. patent application covering a collection of 44 genes of *Mycobacterium tuberculosis* that are specifically induced during active infection of human patients. We believe the identification of these gene targets offers a potential new tuberculosis (TB) diagnostic test to meet a critical need and could potentially serve as a basis for an effective new vaccine against tuberculosis infection.

LPT3-04™

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

DPOLT™

In May 2006 we filed a U.S. patent application for our Differentially Protected Orthogonal Lantionine Technology (“DPOLT”), which is a solid phase peptide synthesis platform technology that has broad application for the cost-effective manufacture of a number of commercially important bioactive peptides. Lantibiotics, including our lead antibiotic, MU1140™, are a potentially important class of antibiotics, and constitute a family of polycyclic peptides that are produced by bacteria, and are highly modified structurally. Many strains of medically important bacteria have become increasingly resistant to currently marketed antibiotics. 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. In July, 2006, the Company was awarded a \$100,000 SBIR (Small Business Innovation Research) grant from the National Science Foundation to establish proof-of-principal for DPOLT™ and to eventually synthesize a number of novel lantibiotic analogs that may be effective in treating various infections, including ones caused by drug resistant bacteria. Longer term, we have identified approximately two dozen bioactive peptides that would represent candidates for analog synthesis by DPOLT™, for potentially improved stability or bioavailability.

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Federal Food and Drug Administration (FDA) Regulation

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

General

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

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

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

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

Clinical Trials

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

Phase I

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

Phase II

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

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Phase III

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

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

Pharmaceutical Development

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

New Drug Application

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

Post Marketing Surveys

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

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

Competition

Industry. The pharmaceutical and biotechnology industries are characterized by intense competition, rapid product development and technological change. Competition is intense among manufacturers of dental therapeutics and prescription pharmaceuticals. Most of our potential competitors are large, well established pharmaceutical, chemical or healthcare companies with considerably greater financial, marketing, sales and technological resources than are available to us. Academic institutions, government agencies and other public and private research organizations may also conduct research, seek patent protection and establish collaborative arrangements for discovery, research and clinical development of technologies and products similar to ours. Many of our potential competitors have research and development capabilities that may allow them to develop new or improved products that may compete with products based on our technologies. Products developed from our technologies could be rendered obsolete or made uneconomical by the development of new products to treat the conditions to be treated by

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products developed from our technologies, technological advances affecting the cost of production, or marketing or pricing actions by our potential competitors. This could materially affect our business, financial condition and results of operations. We cannot assure you that we will be able to compete successfully.

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

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

Research and Development Costs

We have spent \$2,097,223 and \$1,990,979 on research and development of our technologies in 2005 and 2004, respectively. For the nine-month period ended September 30, 2006 and 2005, our research and development expense were \$1,413,947 and \$1,644,370, respectively.

Costs of Enforcing Our Licenses

We have licenses to sell products made using the replacement therapy and mutacin 1140 technologies. The licenses were granted to us by the University of Florida Research Foundation, Inc., which owns the patents to these technologies. There is no assurance, however, that third parties will not infringe on our licenses or their patents. In order to protect our license rights and their patents, we or the University of Florida Research Foundation, Inc. may have to file lawsuits and obtain injunctions. If we do that, we will have to spend large sums of money for attorney fees in order to obtain the injunctions. Even if we do obtain the injunctions, there is no assurance that those infringing on our licenses or the University of Florida Research Foundation's patents will comply with the injunctions. Further, we may not have adequate funds available to prosecute actions to protect or to defend the licenses and patents, in which case those infringing on the licenses and patents could continue to do so in the future.

Our Employees

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

Property

Our administrative office and laboratory facilities are located at 13700 Progress Boulevard, Alachua, Florida 32615. We began leasing this property pursuant to a five-year operating lease in November 2004. The facility is approximately 5,300 square feet of which approximately 60% is laboratory space and the remainder is office space and common areas. The twelve months rental for 2006 will be approximately \$81,500, net of insurance, taxes and utilities that are paid by us. Lease payments escalate by 3% annually. We paid approximately \$12,000 and \$469,000 in 2005 and 2004, respectively, for leasehold improvements to outfit this facility. Such improvements included equipping the building with sufficient air-handling and building laboratory stations. We also spent approximately \$653,000 and \$181,000 in 2005 and 2004, respectively, for laboratory equipment to outfit our facility. We believe our facilities are sufficient for our current needs and do not expect significant purchases of property in 2006.

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.

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MANAGEMENT

The following table and text set forth the names and ages of all directors and executive officers of our company as of November 30, 2006. The Board of Directors is comprised of only one class. All of the directors will serve until the next annual meeting of stockholders and until their successors are elected and qualified, or until their earlier death, retirement, resignation or removal. There are no family relationships between or among the directors, executive officers or persons nominated or charged by our company to become directors or executive officers. Executive officers serve at the discretion of the Board of Directors, and are appointed to serve by the Board of Directors. Also provided herein are brief descriptions of the business experience of each director and executive officer during the past five years and an indication of directorships held by each director in other companies subject to the reporting requirements under the federal securities laws.

| <u>Name</u> | <u>Age</u> | <u>Position</u> |
|---------------------|------------|--|
| David J. Gury | 67 | Chairman of the Board |
| Jeffrey D. Hillman | 58 | Director, Chief Scientific Officer |
| Robert T. Zahradnik | 62 | Director, Chief Executive Officer, President, Secretary, Treasurer and Interim Chief Financial Officer |
| George T. Hawes | 59 | Director |

David J. Gury. Mr. Gury has been a director since October 2003, serving as chairman of the board of directors since December 2004. Mr. Gury was Chief Executive Officer of NABI Biopharmaceuticals from April 1992 to June 2003 and was the chairman of the board from April 1992 to May 2004. From May 1984 until April 1992, Mr. Gury was President and Chief Operating Officer of NABI. During his tenure, the Company successfully transitioned from a plasma supplier into a fully integrated biopharmaceutical company. Prior to joining NABI Biopharmaceuticals, Mr. Gury spent his career with Abbott Laboratories in various administrative and executive positions and with Alpha Therapeutics Corporation, a spin out from Abbott. Mr. Gury completed his A.B. in economics at Kenyon College, Gambier, Ohio, in 1960 and received his MBA at the University of Chicago in 1962, specializing in accounting and finance. Mr. Gury was Founding Chairman and is a Board Member of the Florida Research Consortium and past Chairman and a member of BioFlorida.

Jeffrey D. Hillman. Dr. Hillman has been our chief scientific officer since November 1996 and served as chairman of the board of directors from November 1996 to December 2004. From November 1991, Dr. Hillman has been Professor in the College of Dentistry at the University of Florida in Gainesville, Florida where he teaches classes, trains doctoral candidates and conducts research. However, Dr. Hillman has been on leave from the University of Florida, since February 2001, in order to develop our technologies and technologies owned by IviGene Corporation, Alachua, Florida. Dr. Hillman received undergraduate training from the University of Chicago (Phi Beta Kappa), his D.M.D. degree (cum laude) from the Harvard School of Dental Medicine and Ph.D. from Harvard University Medical School. He has authored or co-authored more than 100 publications and textbook chapters on subjects related to the infectious diseases, including etiology and prevention of tooth decay and other oral diseases and novel antibiotics. He is the inventor or con-inventor of several platform technologies to identify targets for the development of new vaccines and diagnostic tests for a wide variety of infectious diseases and cancer.

Robert T. Zahradnik. Dr. Zahradnik has been our president and Chief Executive Officer since July 2005. Dr. Zahradnik has served as a member of our board of directors since November 1996, except for the period between July 2005 and January 2006. During that period Dr. Zahradnik resigned from the Board so we would satisfy regulatory requirements with regards to independent directors. Dr. Zahradnik was appointed back on the Board to fill the vacancy left by our former chief executive officer and director. Since July 2000 Dr. Zahradnik has been a director of IviGene Corporation, Alachua, Florida. IviGene is engaged in the business of developing vaccines and therapeutics. From September 1999 to June 2005, Dr. Zahradnik was general manager of ProHealth, Inc., Batesville, Arkansas. ProHealth, Inc. is a manufacturer of nutritional supplements and household and skin care products. From February 1993 to June 2005, Dr. Zahradnik was a partner and general manager of Professional Dental Technologies and Therapeutics, Batesville, Arkansas, an oral pharmaceutical manufacturer. From February 1986 until June 2003,

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Dr. Zahradnik has been the chief executive officer and chairman of the board of directors of Advanced Clinical Technologies, Inc., Medfield, Massachusetts, a medical diagnostic manufacturer and technical consulting firm. Dr. Zahradnik is a graduate of Penn State University with a Bachelor of Science degree in Chemistry and Boston University with a PhD in Physical Chemistry.

George T. Hawes. Mr. Hawes, has served as a director since December 2005. Mr. Hawes received a BBA in Accountancy from the University of Notre Dame in 1968 and subsequently amassed over 35 years experience in business and international finance. He has worked for Avon Products Inc. and Hurdman and Cranston, Certified Public Accountants (now part of KPMG). He is currently an investor and sits on the Boards of Gentry Resources, Ltd. a Calgary based oil and gas company, Midway Gold Corp., a Vancouver based gold exploration company, and Proginet Corp., a Garden City, NY based computer software company. He sits on the Audit Committee of all three Companies and serves as Chairman of the Audit Committee for Gentry and Midway.

Scientific Advisory Board (SAB)

Our international Scientific Advisory Board (SAB) is composed of dentists and scientist with expertise related to our technologies. They advise our management team on matters including product development and clinical trials. The five-member Board does not meet formally during the year. Dr. Raman Bedi, Chairman and Senior Consultant contacts the other members for discussion on special issues as needed. As compensation, the Chairman has been granted ONI stock options and the other four members are compensated \$5,000 a year. We also have two independent consultants that are paid for their specific service as needed. Their services have not been used in 2005 and 2006. Currently, our SAB members are:

Dr. Raman Bedi, Chairman, served as the 8th Chief Dental Officer (CDO) for England from 2002 until October 2005 when he retired his post to return to his chair at Kings College London and to take forward the establishment of a global Child Dental Health Taskforce. Dr. Bedi's successful tenure as CDO followed a distinguished academic career. Dr. Bedi was awarded the Foundation chair in Transcultural Oral Health at University College London (1996-2002). He has published over 185 scientific papers and authored four books. He is the past President of the British Society for Disability and Oral Health (2002), Past President of the Education Research Group of the International Association for Dental Research (IADR)(2002-2004) and past chair of the IADR Regional Development Program Committee (2002-2004). He was a member of the WHO Collaborating Center for Oral Health, Disability, and Culture 2003-2004. He was a member of the NHS Top team (2002-2005) and Founder member of the National Health and Social care leadership network (2004-2005). In Higher Education, he is a Board member of the Higher Education Funding Council strategic committee on wider participation and Board member of the HE Leadership Foundation.

Dr. Ayyaz Khan is the most senior dental advisor to the Health Ministry in Pakistan. He is currently the Head of the Department of Oral Health Sciences at the Shaikh Zayed Medical Institute in Lahore, Pakistan. He is also a Research Fellow at the University of Buffalo; the National Coordinator, Oral Health for a Joint WHO/Government of Pakistan Program; and the Principal Research Officer with the Pakistan Medical Research Council. He has been the Convener of the Expert Panel on Oral Health and a member of the Technical Advisory Committee of the Pakistan Medical Research Council for four consecutive three year terms He is the past Chair of the International Dental Federation's (FDI) World Dental Development Health Promotion Committee which is responsible for the management of the World Dental Development Fund.

Dr. Brian Mouatt served as the 5th Chief Dental Officer for England and had previously served as Chief Dental Officer for Zambia. He is the past Chair of the International Dental Federation's (FDI) World Dental Development Health Promotion Committee where he is spear heading the drive to improve oral health in the developing world. This committee is responsible for the management of the World Dental Development Fund. As recent President of the Commonwealth Dental Association (CDA), he revitalized the association and instituted programs of distant learning and virtual meetings.

Dr. Hari Parkash is one of the most senior dental advisors to the federal government of India and is currently the Director for ITS Center Dental Studies and Research, Ghaziabad, (U.P.) India and serves as an adjunct professor at the School of Dental Medicine at the University of Pennsylvania. Dr. Parkash has served as the Chairman of the Hospital

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Management Board and Chief of the Centre for Dental Education & Research, All India Institute of Medical Sciences, New Delhi; Project Director, National Oral Health Care Program of India, Ministry of Health and Family Welfare; President, IDA Delhi State Branch; Past President, Indian Dental Association-HO; Past President, Int. Coll. of Dent. (India & Sri Lanka Sect.); Past President, Faculty Association of AIIMS; Past President, Indian Prosthodontic Society, and received the Pierre Fauchard Academy International Certificate of Merit for 2002 for his contributions in the field of dentistry. He has been conferred Honorary Fellowship of the Institute of Maxillofacial Prosthetics and Technologists, UK.

Dr. Eli Schwarz is the Founder, President, and CEO of Global Alliances for Oral Health, a non-profit organization dedicated to initiate, fund, implement, and support preventative, interceptive, curative, and educational projects that aim to promote oral health and prevent oral disease. He is a founding Fellow of the Hong Kong Academy of Medicine and the Hong Kong College of Dental Surgeons. Dr. Schwarz was Professor of Public Health at the Faculty of Dentistry, University of Hong Kong and served as Associate Dean of Academic Affairs (1990-1995) and Interim Dean of the Faculty of Dentistry 1997. From 1998-2002, he was the Executive Director for Dental Research based in Alexandria, Virginia. In 2003 he was Chair Elect of the Southern Nevada Community Coalition for Oral Health. In 2004 he became Professor and Dean at the Faculty of Dentistry at the University of Sydney, Australia. In 1987 he was conferred the Royal Order, Knight of the Order of Dannebrog, by Her Majesty Queen Margrethe II of Denmark.

SAB Independent Consultants

Dr. Howard K. Kuramitsu, Ph.D., is a retired UB Distinguished Professor at the State University of New York at Buffalo. He is a leading expert in the area of the biology of the oral cavity and studies diseases associated with the oral cavity. Dr. Kuramitsu serves on the Editorial Boards of the International Journal of Oral Biology, Oral Microbiology and Immunology and Infection and Immunity. He also serves on the NIH-NIDCR Advisory Council.

Dr. Per-Erik J. Saris, Ph.D. is a professor in food microbiology at the University of Helsinki in Finland. He is an expert in antibacterial peptides produced by bacteria. His team is part of the Centre of Excellence “Microbial Resources” appointed by the Academy of Finland. He was the first to amplify DNA directly from bacteria in 1990 and has since been active in different fields of molecular biology of bacteria including vaccine development, protein production, metabolic engineering and targeting of bacteria.

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EXECUTIVE COMPENSATION

The following table sets forth the compensation paid by us from January 1, 2003 to December 31, 2005, for our Chief Executive Officer and our next most highly compensated officers who earned more than \$100,000 during the fiscal year ended December 31, 2005 (the "Named Officers").

Summary Compensation Table

| <u>Name and Principal Position</u> | <u>Annual Compensation</u> | | | |
|---|----------------------------|---------------|--------------|----------------------|
| | <u>Year</u> | <u>Salary</u> | <u>Bonus</u> | <u>All Other (1)</u> |
| Robert T. Zahradnik (2) Chief Executive Officer, President, Secretary, Treasurer and Interim Chief Financial Officer | 2005 | \$ 63,750 | \$ 0 | \$ 1,463 |
| Jeffrey D. Hillman (3) Chief Scientific Officer | 2005 | \$153,750 | 0 | \$ 4,613 |
| | 2004 | 180,000 | 0 | 4,950 |
| | 2003 | 135,000 | 0 | 0 |
| Former Officers: | | | | |
| Mento A. Sponis (4) Chief Executive Officer and President | 2005 | \$144,311 | 0 | \$ 2,925 |
| | 2004 | 180,000 | 18,000 | 5,490 |
| | 2003 | 180,000 | 0 | 0 |
| Paul A. Hassie Chief Financial Officer, Secretary and Treasurer (5) | 2005 | \$135,000 | 0 | \$ 4,050 |
| | 2004 | 135,000 | 13,500 | 4,118 |
| | 2003 | 180,000 | 0 | 0 |

- (1) Through 2005, the Company retirement plan requires the Company to match employee contributions up to the first 3% of compensation earned and amounts presented represent the Company's matching contribution. For Dr. Zahradnik the amount excludes meeting fees of \$12,500 that Dr. Zahradnik received in 2005 and 2004 for serving as a director and audit committee member prior to becoming an executive officer.
- (2) Dr. Zahradnik began employment with the Company on July 1, 2005 at an annual salary of \$180,000. During October and November 2005, Dr. Zahradnik orally agreed to an indefinite deferral of \$26,250 in salary. This amount remained deferred and unpaid at December 31, 2005. The amount reflected in the table as salary excludes the deferred amount.
- (3) During October and November in 2005, Dr. Hillman orally agreed to an indefinite deferral of \$26,250 in salary. This amount remained deferred and unpaid at December 31, 2005. The amount reflected in the table excludes the deferred amount.
- (4) Mr. Sponis' employment with the Company ended on July 6, 2005. The salary paid to him through that date including accrued vacation pay totaled \$97,311. After July 6, 2005 Mr. Sponis began receiving severance payments pursuant to a separation agreement with the Company at the rate of \$15,000 per month for one year, of which \$47,000 was paid to him during the year. As of December 31, 2005, we orally agreed with our former chief executive officer to defer certain payments due pursuant to our separation agreement, which amounted to a deferral of \$40,500 of such payments. As part of the oral agreement with our former chief executive officer, we are currently paying \$7,500 per month which is one half of the monthly amount due of \$15,000 under the separation agreement. These payments were originally to be concluded in July of 2006, but due to the deferred amount and the current payment schedule these payments are expected to continue beyond that time period until paid.
- (5) Mr. Hassie voluntarily left the Company on May 5, 2006. Mr. Hassie was paid in accordance with the terms of his employment agreement with the Company.

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Options to Purchase Securities

Our directors and shareholders have previously approved the adoption of our 2002 Stock Option and Incentive Plan and subsequent amendment ("Plan"). There are 1,500,000 shares of common stock available for issuance under the Plan (subject to the approval of proposal II). On May 5, 2006, the shareholders approved an increase from 1,500,000 to 3,000,000 shares of common stock available for issuance under the Plan. The purpose of the Plan is to enable our company to attract, retain and motivate qualified directors and employees, to reward directors and employees and key consultants, such as members of our Scientific Advisory Board, for their contribution toward our long term goals, and to enable and encourage such individuals to acquire our shares as long term investments.

The Company has reserved an aggregate of 3,000,000 shares of the Company's common stock for issuance pursuant to the Plan. The following table represents the number of shares issuable upon exercise, and reserved for future issuance, under these plans as of December 31, 2005.

Securities Authorized For Issuance Under Equity Compensation Plans as of December 31, 2005

| <u>Plan Category</u> | <u>Number of Securities to be issued upon exercise of outstanding option, warrants and rights (a)</u> | <u>Weighted-average exercise price of outstanding options and warrants (b)</u> | <u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column a) (c)</u> |
|---|---|--|--|
| Equity Compensation plans approved by stockholders | 1,260,000 | \$1.90 | 240,000 |
| Equity Compensation plans not approved by security stockholders | 137,500(1) | \$2.75 | — |
| | 25,000(1) | 2.25 | — |
| | 35,000(2) | 1.59 | — |
| | 3,032,500(3) | 0.60 | — |
| | 35,000(3) | 0.40 | — |
| Total | <u>4,525,000</u> | <u>\$1.40</u> | <u>240,000</u> |

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

We will not require or seek shareholder approval for the grant of options under the stock option plan, or the exercise of options. We may grant options under the stock option plan to employees of our company regularly employed on a full-time or part-time basis, our directors and officers, and persons who perform services for us on an ongoing basis or who have provided, or are expected to provide, services of value to us.

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There are no stock option plans or profit sharing plans for the benefit of our officers and directors other than as described herein. We do not have any long-term incentive plans that provide compensation intended to serve as an incentive for performance.

Option Grants in Last Fiscal Year

The following table sets forth grants of options to purchase our common stock during the fiscal year ended December 31, 2005 to each Named Officer.

| <u>Name</u> | <u>Number of Securities Underlying Options</u> | <u>Percentage of Total Options granted to Employees in Fiscal Year</u> | <u>Exercise Price</u> | <u>Expiration Date</u> |
|---------------------|--|--|-----------------------|------------------------|
| Robert T. Zahradnik | 0 | 0% | — | — |
| Jeffrey D. Hillman | 0 | 0 | — | — |
| Paul A. Hassie | 20,000 | 12.3% | \$2/16 | June 15, 2015 |
| Mento A. Sponis | 0 | 0 | — | — |

Aggregated Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values

The following table sets forth information with respect to the aggregate stock option exercises by Named Officers during 2005 and the year end value of unexercised options held by the Named Officers.

| <u>Name</u> | <u>Number of Shares Acquired on Exercise</u> | <u>Value Realized (US \$)</u> | <u>Number of Securities Underlying Options at Fiscal Year End Unexercised Options Exercisable/Unexercisable</u> | <u>Value of Unexercised In-the-Money Options at Fiscal Year End Exercisable/Unexercisable (US \$) (1)</u> |
|---------------------|--|-------------------------------|---|---|
| Robert T. Zahradnik | 0 | 0 | 3,333 / 6,667 | 0 / 0 |
| Jeffrey D. Hillman | 0 | 0 | 0 / 0 | 0 / 0 |
| Paul A. Hassie | 0 | 0 | 61,666 / 48,334 | 0 / 0 |
| Mento A. Sponis | 0 | 0 | 0 | 0 / 0 |

- (1) Values shown in this column reflect the difference between the closing price of the Company's common stock on December 31, 2005 on the American Stock Exchange of \$0.43 per share, and the exercise prices of the underlying options. Because all exercise prices are greater than \$0.43 per share, all values are reported as zero.

Employment Contracts and Change in Control Arrangements

On July 6, 2005, Dr. Robert T. Zahradnik was named acting president and chief executive officer of the Company replacing Mento A. Sponis. We agreed to a compensation arrangement with Dr. Zahradnik in a letter dated July 6, 2005, the material terms included monthly compensation of \$15,000, as well as medical and dental insurance and retirement compensation consistent with the benefits we offered to all employees.

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We have employment agreement with Jeffrey D. Hillman. On January 1, 2004, we entered into an employment agreement with Dr. Hillman that superseded our prior employment agreement with him. Dr. Hillman's agreement is for three years and provides for automatic one-year extensions after December 31, 2006. Under the terms of our employment agreement with Dr. Hillman dated January 1, 2004, we are obligated to pay initial compensation of \$180,000 per annum. Dr. Hillman is also eligible for participation in incentive bonus compensation plans. The employment agreement also provide for other benefits including the right to participate in fringe benefit plans, life and disability insurance plans, expense reimbursement and 4 weeks accumulating vacation/sick leave annually. If Dr. Hillman's employment is terminated by the Company without cause (as defined in the agreement) or within twelve months following a change of control (as defined in the agreement), he will be entitled to severance payments, at their then annual base salary and all stock options granted to Dr. Hillman and any benefits under any benefit plans shall become immediately vested and to the extent applicable, exercisable. The employment agreement also includes non-disclosure and non-compete provisions, as well as salary payments for a three month period in the event of Dr. Hillman's death or disability during the term of the agreement.

We entered into an Agreement of Separation and Release with Mento A. Soponis on July 6, 2005 under which we are obligated to pay \$15,000 per month for twelve months. As a result, we have obtained and executed mutual releases with Mr. Soponis in connection with the rights and obligations of an employment agreement signed on January 1, 2004. During 2005, we paid \$47,000 in cash and deferred \$40,500 of the separation payments due to Mr. Soponis. As of December 31, 2005, we orally agreed with our former chief executive officer to defer certain payments due pursuant to our separation agreement, which amounted to a deferral of \$40,500 of such payments. As part of the oral agreement with our former chief executive officer, we are currently paying \$7,500 per month which is one half of the monthly amount due of \$15,000 under the separation agreement. These payments were originally to be concluded in July of 2006, but due to the deferred amount and the current payment schedule these payments are expected to continue beyond that time period until paid.

Messrs. Gury, Hawes, Hillman, Zahradnik, and Kuramitsu have entered into Proprietary Information and Invention Agreements with us. Under these agreements, they have each agreed to hold all our proprietary information in the strictest confidence, and assigned to us all of their right, title and interest in any inventions which they make during the term of their employment or affiliation with us that incorporate, are based on or relate to any of our proprietary intellectual property rights.

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SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of November 30, 2006 by (i) each person who is known by us to beneficially own more than five percent of our common stock, (ii) each of our directors, (iii) each of our named executive officers, and (iv) all officers and directors as a group.

| Name and Address of Beneficial Owners (1) | Number of Shares Beneficially Owned | Percentage of Ownership |
|---|--|--------------------------------|
| <i>Directors and Officers</i> | | |
| Jeffrey D. Hillman (2) | 4,214,894 | 20.0% |
| Robert Zahradnik (3) | 887,667 | 4.2% |
| David J. Gury (4) | 358,734 | 1.7% |
| George Hawes (5) | 4,246,767 | 20.1% |
| All Officers and Directors as a Group (4 Persons) | 9,702,062 | 46.0% |

- (1) Except as indicated in the footnotes set forth below, the persons named in the table have sole voting and investment power with respect to all shares shown as beneficially owned by them. The numbers of shares shown include shares that are not currently outstanding but which certain shareholders are entitled to acquire or will be entitled to acquire within 60 days upon the exercise of common stock warrants and stock options. Such shares are deemed to be outstanding for the purpose of computing the percentage of common stock owned by the particular shareholder and by the group but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person. The percentage of common stock beneficially owned is based on 21,079,943 shares of common stock outstanding on November 30, 2006. Except as indicated in the table, the business address of all persons named in the table is 13700 Progress Boulevard, Alachua, Florida 32615.
- (2) Represents 4,214,894 shares held directly by Jeffrey D. Hillman which includes the recently acquired 20,480 shares from the iviGene Corp purchase, as well as 62,500 common stock warrants currently exercisable and 75,000 stock options.
- (3) Represents 818,500 shares owned and 62,500 common stock warrants and 6,667 stock options currently exercisable within 60 days.
- (4) Represents 400 shares owned by Mr. Gury; 62,500 shares owned by David Gury and Karen Gury Trustees UA April 26, 2004 for the David J. Gury Revocable Trust (the "Trust"); 62,500 common stock warrants currently exercisable held by the Trust; and 233,334 stock options held by Mr. Gury currently exercisable and exercisable within 60 days.
- (5) Represents 3,588,267 shares owned and 587,500 common stock warrants currently exercisable, 65,000 stock options currently exercisable within 60 days, 5,000 owned by Mr. Hawes spouse and 1,000 owned by his son.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The audit committee of our board of directors is responsible for reviewing all transactions between us and any officer or director or any entity in which an officer or director has a material interest. Any such transactions must be on terms no less favorable than those that could be obtained on an arms-length basis from independent third parties.

iviGene Corporation Agreement

In March 2004, we entered into a license agreement with IviGene Corporation, a company whose shareholders include Messrs. Hillman, Sophonis and Zahradnik, who own 15.13%, 7.57% and 4.01% of IviGene's outstanding shares, respectively. Messrs. Hillman and Zahradnik also serve on the Board of IviGene. Mr. Sophonis resigned in July 2005. The license covers the applications of two novel technologies referred to as IVIAT and CMAT. These technologies are capable of identifying gene and protein biomarkers for application to the improved diagnosis and treatment of a wide range of infectious diseases and cancer.

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. Our CEO, President and director, Robert T. Zahradnik, was an officer, director and former shareholder of iViGene. Dr. Zahradnik did not receive any shares of Oragenics common stock or any other consideration in this transaction. IviGene Corporation owned the patent rights to IVIAT™ and CMAT™ that we previously licensed. With this transaction, Oragenics has now acquired all of iViGene's assets, including issued and pending patents. Following the consummation of the transaction, iViGene Corporation will be dissolved.

Indebtedness

In 2001 and 2002 we incurred consulting fees of \$60,000 and \$15,000, respectively, payable to Dr. Jeffrey Hillman. The entire amount remained outstanding at December 31, 2004; however, \$20,000 was paid in January 2005 leaving a balance currently owed of \$55,000 at September 30, 2006.

Deferred Compensation and Meeting Fees

During the fourth quarter of 2005, Dr. Hillman and Dr. Zahradnik each orally agreed to defer receipt of \$26,250 of their compensation. Also, during the fourth quarter of 2005, our former Chief Executive Officer, Mr. Sophonis, agreed to a deferral \$85,500 of payments due pursuant to his separation agreement. These compensation amounts now totaling \$63,000 remained unpaid at September 30, 2006.

As of the third quarter of 2006, the Board of Directors deferred receipt of \$34,000 as their compensation for attendance at the Board meetings and Audit Committee meetings. This compensation amount remained unpaid as of September 30, 2006. 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.

Financing Transaction

On December 14, 2005 in connection with a private placement of our common stock, Mr. Hawes, purchased an aggregate of 1,000,000 shares from us for \$400,000 and received warrants to acquire an equal number of shares at \$0.60 per share. Upon completion of the private placement transaction Mr. Hawes became a director. As of December 5, 2006, Mr. Hawes has purchased an additional 1,000,000 shares from the warrants issued in connection with the purchase agreement established in December, 2005.

In addition, on March 6, 2006 in conjunction with a second private placement, directors Hillman, Zahradnik, Gury and Hawes acquired 62,500, 62,500, 62,500 and 587,500 shares respectively from us for payments of \$25,000, \$25,000, \$25,000 and \$235,000. In addition to the shares acquired, each of these individuals received warrants to acquire an equal number of shares at \$0.60 per share. This transaction was approved by our independent

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directors and was consummated at the fair market value of our common stock on the day the agreement was entered into. In connection with the financing transactions these directors acquired registration rights pursuant to registration rights agreements with us.

Relationships

Dr. Zahradnik's wife provides administrative services to the Company as an independent contractor on an as-needed basis at an hourly rate.

DESCRIPTION OF SECURITIES

General

We are authorized to issue up to 100,000,000 shares of common stock, \$0.001 par value per share, and 20,000,000 shares of preferred stock, with no par value per share. As of November , 2006, 21,079,943 shares of common stock and no shares of preferred stock were issued and outstanding. All of the outstanding capital stock is, and will be, fully paid and non-assessable.

Common Stock

Holders of common stock are entitled to one vote per share. All actions submitted to a vote of stockholders are voted on by holders of common stock voting together as a single class. Holders of common stock are not entitled to cumulative voting in the election of directors.

Holders of common stock are entitled to receive dividends in cash or in property on an equal basis, if and when dividends are declared on the common stock by our board of directors, subject to any preference in favor of outstanding shares of preferred stock, if there are any.

In the event of liquidation of our company, all holders of common stock will participate on an equal basis with each other in our net assets available for distribution after payment of our liabilities and payment of any liquidation preferences in favor of outstanding shares of preferred stock.

Holders of common stock are not entitled to preemptive rights and the common stock is not subject to redemption.

The rights of holders of common stock are subject to the rights of holders of any preferred stock that we designate or have designated. The rights of preferred stockholders may adversely affect the rights of the common stockholders.

Preferred Stock

Our board of directors has the ability to issue up to 20,000,000 shares of preferred stock in one or more series, without stockholder approval. The board of directors may designate for the series:

- the number of shares and name of the series,
- the voting powers of the series, including the right to elect directors, if any,
- the dividend rights and preferences, if any,
- redemption terms, if any,
- liquidation preferences and the amounts payable on liquidation or dissolution, and
- the terms upon which such series may be converted into any other series or class of our stock, including the common stock and any other terms that are not prohibited by law.

It is impossible for us to state the actual effect it will have on common stock holders if the board of directors designates a new series of preferred stock. The effects of such a designation will not be determinable until the rights accompanying the series have been designated. The issuance of preferred stock could adversely affect the voting power, liquidation rights or other rights held by owners of common stock or other series of preferred stock. The Board of Directors' authority to issue preferred stock without stockholder approval could make it more difficult for a third party to acquire control of our company, and could discourage any such attempt. We have no present plans to issue any additional shares of preferred stock.

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Options and Warrants

As of November 30, 2006, 1,315,000 options for shares were outstanding under our approved stock option plans and 1,685,000 shares were available for future grants under our stock option plans. We have also issued warrants in connection with our financing transactions with respect to our common stock totaling 3,700,000 shares. Holders of options and warrants do not have any of the rights or privileges of our stockholders, including voting rights, prior to exercise of the options and warrants. The number of shares of common stock for which these options and warrants are exercisable and the exercise price of these options and warrants are subject to proportional adjustment for stock splits and similar changes affecting our common stock. We have reserved sufficient shares of authorized common stock to cover the issuance of common stock subject to the options and warrants.

Registrar and Transfer Agent

Continental Stock Transfer & Trust Company is the Company's registrar and transfer agent for our securities.

Registration Rights

Fusion Capital. In connection with the May 2005 Fusion Capital transaction (See Fusion Capital Transaction), we entered into a registration rights agreement with Fusion Capital. Pursuant to the terms of the registration rights agreement, we are obligated to file a registration statement with the Securities and Exchange Commission covering shares which may be purchased by or which have been issued to Fusion Capital under the purchase agreement.

Recent Private Placements. In connection with our private placements of common stock and warrants to accredited investors in December 2005 (4,137,500 shares of common stock and 3,067,500 warrants convertible into common stock) and March 2006 (1,500,000 shares of common stock and 1,500,000 warrants convertible into common stock), we were obligated to file registration statements with the Securities and Exchange Commission covering the resale of such securities. On January 13, 2006 and March 17, 2006 we filed registration statements on Form S-3 to fulfill such obligation which registration statements were declared effective by the Securities and Exchange Commission.

iviGene Corporation Acquisition. In connection with our acquisition of the outstanding capital stock of iviGene Corporation we agreed to file a Form S-3 registration statement within 90 days to register the resale of our common stock by the former iviGene Corporation shareholders.

SHARES ELIGIBLE FOR FUTURE SALE

Future sales of a substantial number of shares of our common stock in the public market could adversely affect market prices prevailing from time to time. Under the terms of this offering, the shares of common stock offered may be resold without restriction or further registration under the Securities Act of 1933, except that any shares purchased by our “affiliates,” as that term is defined under the Securities Act, may generally only be sold in compliance with Rule 144 under the Securities Act.

Sale of Restricted Shares

Certain shares of our outstanding common stock were issued and sold by us in private transactions in reliance upon exemptions from registration under the Securities Act and have not been registered for resale. Additional shares may be issued pursuant to outstanding warrants and options. Such shares may be sold only pursuant to an effective registration statement filed by us or an applicable exemption, including the exemption contained in Rule 144 promulgated under the Securities Act.

In general, under Rule 144 as currently in effect, a stockholder, including one of our affiliates, may sell shares of common stock after at least one year has elapsed since such shares were acquired from us or our affiliate. The number of shares of common stock which may be sold within any three-month period is limited to the greater of: (i) one percent of our then outstanding common stock, or (ii) the average weekly trading volume in our common stock during the four calendar weeks preceding the date on which notice of such sale was filed under Rule 144. Certain other requirements of Rule 144 concerning availability of public information, manner of sale and notice of sale must also be satisfied. In addition, a stockholder who is not our affiliate, who has not been our affiliate for 90 days prior to the sale, and who has beneficially owned shares acquired from us or our affiliate for over two years may resell the shares of common stock without compliance with many of the foregoing requirements under Rule 144.

Options

We have filed a registration statement on Form S-8 under the Securities Act to register shares of common stock issuable under the 2002 Stock Option and Incentive Plan. Shares issued upon the exercise of stock options are eligible for resale in the public market without restriction, subject to Rule 144 limitations applicable to affiliates.

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SELLING STOCKHOLDER

The following table presents information regarding the selling stockholder. Neither the selling stockholder nor any of its affiliates has held a position or office, or had any other material relationship, with us. Unless otherwise indicated, the percentage of outstanding shares beneficially owned is based on 21,079,943 shares issued and outstanding at November 30, 2006.

| <u>Selling Stockholder</u> | <u>Shares Beneficially Owned Before Offering</u> | <u>Percentage of Outstanding Shares Beneficially Owned Before Offering</u> | <u>Shares to be Sold in the Offering</u> | <u>Percentage of Outstanding Shares Beneficially Owned After Offering</u> |
|---------------------------------|--|--|--|---|
| Fusion Capital Fund II, LLC (1) | 315,421 | 1.7% | 4,109,689 | — |

- (1) As of the date hereof, 521,153 shares of our common stock have been acquired by Fusion Capital under the common stock purchase agreement. Fusion Capital may acquire up to an additional 3,794,268 shares under the common stock purchase agreement. Percentage of outstanding shares is based on 21,079,943 shares of common stock outstanding as of November 30, 2006, together with such additional 3,794,268 shares of common stock that may be acquired by Fusion Capital from us under the common stock purchase agreement after the date hereof. Fusion Capital may not purchase shares of our common stock under the common stock purchase agreement if Fusion Capital, together with its affiliates, would beneficially own more than 9.9% of our common stock outstanding at the time of the purchase by Fusion Capital. Fusion Capital has the right at any time to sell any shares purchased under the common stock purchase agreement which would allow it to avoid the 9.9% limitation. Therefore, we do not believe that Fusion Capital will ever reach the 9.9% limitation. Steven G. Martin and Joshua B. Scheinfeld, the principals of Fusion Capital, are deemed to be beneficial owners of all of the shares of common stock owned by Fusion Capital. Messrs. Martin and Scheinfeld have shared voting and disposition power over the shares being offered under this prospectus. See “The Fusion Capital Fund Transaction.”

PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by the selling stockholders. The common stock may be sold or distributed from time to time by the selling stockholders only for cash directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this Prospectus may be effected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents
- "at the market" into an existing market for the common stock;
- in other ways not involving market makers or established trading markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. The compensation paid to a particular broker-dealer may be less than or in excess of customary commissions.

Fusion Capital is an "underwriter" within the meaning of the Securities Act.

Neither we nor Fusion Capital can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between Fusion Capital, any other stockholder, broker, dealer, underwriter, or agent relating to the sale or distribution of the shares offered by this Prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters, or dealers and any compensation from the selling stockholder, and any other required information.

We will pay the entire expenses incident to the registration, offering, and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers, or agents. We have also agreed to indemnify Fusion Capital and related persons against specified liabilities, including liabilities under the Securities Act.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

Fusion Capital and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common stock during the term of the common stock purchase agreement.

We have advised Fusion Capital that while it is engaged in a distribution of the shares included in this Prospectus it is required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the selling stockholders, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this Prospectus.

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This offering will terminate on the date that all shares offered by this Prospectus have been sold by the selling stockholders.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Our Articles of Incorporation limit the personal liability of our officers and directors for monetary damages for breach of their fiduciary duty as directors, except for liability that cannot be eliminated under the Florida Business Corporation Act (the "FBCA"). Our Articles of Incorporation and Bylaws also provide for the Company to indemnify directors and officers to the fullest extent permitted by the FBCA. In addition, we have indemnification agreements with its directors and executive officers.

The indemnification provisions described above would provide coverage for claims arising under the Securities Act and the Exchange Act. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Company pursuant to our Articles of Incorporation, Bylaws, Indemnification agreements, the FBCA, or otherwise, the Company has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

CHANGES IN ACCOUNTANTS

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

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

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

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

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

LEGAL MATTERS

The validity of the issuance of the common stock offered hereby will be passed upon for us by Shumaker, Loop & Kendrick, LLP.

EXPERTS

The financial statements of Oragenics, Inc. as of December 31, 2005 and for the year ended December 31, 2005, included in this prospectus, have been audited by Kirkland Russ Murphy & Tapp, PA, our current independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about Oragenics, Inc.'s ability to continue as a going concern as described in Note 1 to the financial statements). Such financial statements are included herein in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The financial statements of Oragenics, Inc. for the year ended December 31, 2004 included in this prospectus, have been audited by Ernst & Young LLP, our former independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about Oragenics, Inc.'s ability to continue as a going concern as described in Note 1 to the financial statements). Such financial statements are included herein in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We file current, quarterly and annual reports with the SEC on forms 8-K, 10-QSB and 10-KSB. We have filed with the SEC under the Securities Act of 1933 a registration statement on Form SB-2 with respect to the shares being offered in this offering. This prospectus does not contain all of the information set forth in the registration statement, certain items of which are omitted in accordance with the rules and regulations of the SEC. The omitted information may be inspected and copied at the Public Reference Room maintained by the SEC at Judiciary Plaza, 450 Fifth Street, N.W., Washington, D.C. 20549. You can obtain information about operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at <http://www.sec.gov>. Copies of such material can be obtained from the public reference section of the SEC at prescribed rates. Statements contained in this prospectus as to the contents of any contract or other document filed as an exhibit to the registration statement are not necessarily complete and in each instance reference is made to the copy of the document filed as an exhibit to the registration statement, each statement made in this prospectus relating to such documents being qualified in all respects by such reference.

For further information with respect to us and the securities being offered hereby, reference is hereby made to the registration statement, including the exhibits thereto and the financial statements, notes, and schedules filed as a part thereof.

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FINANCIAL STATEMENTS

Oragenics, Inc.

Financial Statements

Years ended December 31, 2005 and 2004
and for the nine months ended September 30, 2006 and 2005

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheet of Oragenics, Inc. as of December 31, 2005, and the related statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Oragenics, Inc. as of December 31, 2005, and the results of its operations and its cash flows for the year ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America.

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

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

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

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Report of Independent Registered Public Accounting Firm on Financial Statements

The Board of Directors and Shareholders of
Oragenics, Inc.

We have audited the statements of operations, changes in stockholders' equity and cash flows of Oragenics, Inc for the year ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

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

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

/s/ Ernst & Young LLP
Certified Public Accountants
Tampa, Florida
January 28, 2005

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Oragenics, Inc.

Balance Sheets

| | <u>December 31,</u> <u>2005</u> | <u>September 30,</u> <u>2006</u> <i>(unaudited)</i> |
|---|------------------------------------|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 937,789 | \$ 470,019 |
| Prepaid expenses and other current assets | 112,047 | 114,686 |
| Total current assets | 1,049,836 | 584,706 |
| Property and equipment, net | 1,096,564 | 885,586 |
| Total assets | <u>\$ 2,146,400</u> | <u>\$ 1,470,291</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | \$ 281,830 | \$ 175,820 |
| Deferred compensation | 93,000 | 149,500 |
| Total current liabilities | 374,830 | 325,320 |
| Stockholders' equity: | | |
| Preferred stock, no par value; 20,000,000 shares authorized; None issued and outstanding | — | — |
| Common stock, \$0.001 par value; 100,000,000 shares authorized; 18,146,117 and 20,894,757 shares issued and outstanding at December 31, 2005 and September 30, 2006, respectively | 18,146 | 20,895 |
| Additional paid in capital | 10,476,786 | 12,059,700 |
| Accumulated deficit | <u>(8,723,362)</u> | <u>(10,935,624)</u> |
| Total stockholders' equity | <u>1,771,570</u> | <u>1,144,971</u> |
| Total liabilities and stockholders' equity | <u>\$ 2,146,400</u> | <u>\$ 1,470,291</u> |

See accompanying notes.

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Oragenics, Inc.
Statements of Operations

| | <u>Year ended December 31,</u> | | <u>Nine months ended September 30,</u> | |
|---|--------------------------------|-----------------------|--|-----------------------|
| | <u>2005</u> | <u>2004</u> | <u>2006</u> | <u>2005</u> |
| Revenue | \$ — | \$ 196,210 | \$ 66,176 | \$ — |
| Operating expenses: | | | | |
| Research and development | 2,097,223 | 1,990,979 | 1,413,947 | 1,644,370 |
| General and administration | 1,166,854 | 1,329,983 | 887,147 | 859,701 |
| Total operating expenses | 3,264,077 | 3,320,962 | 2,301,094 | 2,504,071 |
| Loss from operations | (3,264,077) | (3,124,752) | (2,234,918) | (2,504,071) |
| Other income (expense): | | | | |
| Interest income | 41,875 | 47,306 | 21,487 | 36,654 |
| Interest expense | (29,176) | (442) | (855) | (22,566) |
| Gain on sale of property & equipment | — | — | 2,024 | — |
| Total other income (expense), net | 12,699 | 46,864 | 22,656 | 14,088 |
| Net loss | <u>\$ (3,251,378)</u> | <u>\$ (3,077,888)</u> | <u>\$ (2,212,262)</u> | <u>\$ (2,489,983)</u> |
| Basic and diluted net loss per share | <u>\$ (0.22)</u> | <u>\$ (0.22)</u> | <u>\$ (0.11)</u> | <u>\$ (0.17)</u> |
| Shares used to compute basic and diluted net loss per share | <u>15,082,098</u> | <u>14,118,129</u> | <u>19,983,576</u> | <u>14,856,540</u> |

See accompanying notes.

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Oragenics, Inc.

Statements of Changes in Stockholders' Equity (Deficit)

| | <u>Common Stock</u> | | <u>Additional Paid In Capital</u> | <u>Accumulated Deficit</u> | <u>Total Stockholders' Equity (Deficit)</u> |
|---|---------------------|-----------------|---|--------------------------------|---|
| | <u>Shares</u> | <u>Amount</u> | | | |
| Balance at December 31, 2003 | 13,296,204 | \$13,296 | \$ 5,820,697 | \$ (2,394,096) | \$ 3,439,897 |
| Exercise of common stock warrants | 1,048,720 | 1,049 | 3,034,724 | — | 3,035,773 |
| Costs associated with filing initial public offering post effective amendment | — | — | (62,421) | — | (62,421) |
| Issuance of common stock and warrants | 250,000 | 250 | 544,676 | — | 544,926 |
| Compensation expense relating to option issuances | — | — | 156,157 | — | 156,157 |
| Net loss | — | — | — | (3,077,888) | (3,077,888) |
| Balance at December 31, 2004 | 14,594,924 | 14,595 | 9,493,833 | (5,471,984) | 4,036,444 |
| Exercise of common stock warrants | 276,180 | 276 | 344,949 | — | 345,225 |
| Issuance of common stock and warrants | 3,275,013 | 3,275 | 1,023,695 | — | 1,026,970 |
| Compensation expense relating to option issuances | — | — | (385,691) | — | (385,691) |
| Net loss | — | — | — | (3,251,378) | (3,251,378) |
| Balance at December 31, 2005 | 18,146,117 | 18,146 | 10,476,786 | (8,723,362) | 1,771,570 |
| Exercise of common stock warrants (unaudited) | 1,065,000 | 1,065 | 630,935 | — | 632,000 |
| Issuance of common stock and warrants (unaudited) | 1,683,640 | 1,684 | 653,781 | — | 655,465 |
| Compensation expense credit relating to option issuances (unaudited) | — | — | 298,198 | — | 298,198 |
| Net loss (unaudited) | — | — | — | (2,212,262) | (2,212,262) |
| Balance at September 30, 2006 (unaudited) | <u>20,894,757</u> | <u>\$20,895</u> | <u>\$12,059,700</u> | <u>\$(10,935,624)</u> | <u>\$ 1,144,971</u> |

See accompanying notes.

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Oragenics, Inc.

Statements of Cash Flows

| | Year ended December 31, | | Nine months ended September 30, | |
|---|-------------------------|---------------------|---------------------------------|--------------------|
| | 2005 | 2004 | 2006 | 2005 |
| | | | <i>(unaudited)</i> | |
| Operating activities | | | | |
| Net loss | \$(3,251,378) | \$(3,077,888) | \$(2,212,262) | \$(2,4489,983) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | |
| Depreciation | 260,636 | 41,987 | 210,899 | 188,014 |
| Gain on sale of property and equipment | — | — | (2,024) | — |
| Stock-based compensation resulting from variable accounting | (385,691) | 156,157 | — | (385,691) |
| Stock-based compensation expense resulting from fair value based method | — | — | 298,198 | — |
| Changes in operating assets and liabilities: | | | | |
| Prepaid expenses and other current assets | (3,151) | (84,258) | (2,639) | (26,246) |
| Accounts payable and accrued expenses | (54,798) | 289,013 | (106,010) | (186,322) |
| Accrued interest | — | (25,582) | — | — |
| Deferred compensation | — | (44,672) | 56,500 | — |
| Net cash used in operating activities | <u>(3,434,382)</u> | <u>(2,745,243)</u> | <u>(1,757,338)</u> | <u>(2,900,228)</u> |
| Investing activities | | | | |
| Purchases of property and equipment | (666,268) | (690,548) | (2,897) | (666,268) |
| Proceeds from sale of property and equipment | — | — | 5,000 | — |
| Net cash (used in) provided by investing activities | <u>(666,268)</u> | <u>(690,548)</u> | <u>2,103</u> | <u>(666,268)</u> |
| Financing activities | | | | |
| Net proceeds from issuance of common stock | 1,372,195 | 3,518,278 | 1,287,465 | 230,453 |
| Proceeds from note payable | 615,192 | — | — | 615,192 |
| Principal payment on note payable | (615,192) | — | — | (93,879) |
| Net cash provided by financing activities | <u>1,372,195</u> | <u>3,518,278</u> | <u>1,287,465</u> | <u>751,766</u> |
| Net increase (decrease) in cash and cash equivalents | (2,728,455) | 82,487 | (467,770) | (2,814,730) |
| Cash and cash equivalents at beginning of period | <u>3,666,244</u> | <u>3,583,757</u> | <u>937,789</u> | <u>3,666,244</u> |
| Cash and cash equivalents at end of period | <u>\$ 937,789</u> | <u>\$ 3,666,244</u> | <u>\$ 470,019</u> | <u>\$ 851,514</u> |
| Supplemental disclosure of cash flow information | | | | |
| Interest Paid | <u>\$ 29,176</u> | <u>\$ 26,024</u> | <u>—</u> | <u>\$ 22,566</u> |

See accompanying notes.

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Oragenics, Inc.

Notes to Financial Statements

December 31, 2005 and September 30, 2006 (unaudited)

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 2005 and the unaudited September 30, 2006 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 \$3,251,378 for the year ended December 31, 2005 and as of that date had an accumulated deficit of \$8,723,362. Cash used in operations for the years ended December 31, 2005 and the nine-month period ended September 30, 2006 was \$3,434,382 and \$1,757,338, respectively, and cash flow from operations was negative throughout 2005 and the nine-month period ended September 30, 2006. The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes the working capital at December 31, 2005 and the nine-month period ended September 30, 2006 will be insufficient to meet the business objectives as presently structured. Management recognizes that the Company must generate additional capital resources or consider modifications to its technology development plans to enable it to continue as a going concern. Management's plans include seeking financing, alliances or other partnership agreements with entities interested in the Company's technologies, or other business transactions that would generate sufficient resources to assure continuation of the Company's operations and research and development programs.

The Company intends to seek additional funding through sublicensing arrangements, joint venturing or partnering, sales of rights to technology, government grants and public or private financings. During 2005 and 2006, the Company conducted private placements to raise capital. The Company's future success depends on its ability to raise capital and ultimately generate revenue and attain profitability. The Company cannot be certain that additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to it or, if available, will be on terms acceptable to the Company. If the Company issues additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of its common stock, and the Company's current stockholders may experience dilution. If the Company is unable to obtain funds when needed or on acceptable terms, the Company may be required to curtail their current development programs, cut operating costs and forego future development and other opportunities. Without sufficient capital to fund their operations, the Company will be unable to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Unaudited Interim Information

The accompanying unaudited condensed financial statements as of September 30, 2006 and for the nine-month periods ended September 30, 2006 and 2005 have been prepared in accordance with accepted accounting principles generally accepted in the United States of America (GAAP) for interim financial information and with the instructions to Form 10-QSB and Article 10 of Regulations S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the financial condition, result of operations and cash flows for the periods presented. The results of operations for the interim period September 30, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006 or any future period.

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Oragenics, Inc.

Notes to Financial Statements (continued)

1. Organization and Significant Accounting Policies (continued)

Unaudited Interim Information (continued)

These financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2005 which is included in our Annual Report on Form 10-KSB/A filed with the Securities and Exchange Commission on March 23, 2006. In that report the Company disclosed that it expects to incur substantial expenditures to further develop each of its technologies. It further stated that it believed its working capital will be insufficient to meet the business objectives as presently structured and without sufficient capital to fund its operations, the Company will be unable to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Concentrations of Credit Risk

The Company's cash and cash equivalents are deposited in a financial institution and consist of demand deposits and overnight repurchase agreement investments and at times deposits are in excess of federally insured limits.

Use of Estimates

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

Fair Value of Financial Instruments

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

Cash Equivalents

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

Property and Equipment

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

Business Segments

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

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Oragenics, Inc.

Notes to Financial Statements (continued)

1. Organization and Significant Accounting Policies (continued)**Stock-Based Compensation**

In December 2002, the 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. 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. It also entails a pro forma presentation for comparative prior periods shown disclosing the effect of the new method had it been adopted earlier when the Company employed the use of the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*. The following table provides the required pro forma disclosure for the years ended December 31, 2005 and 2004 and nine months ended September 30, 2005:

| | <u>Years ended December 31</u> | | <u>Nine months ended</u> |
|---|--------------------------------|-----------------------|---|
| | <u>2005</u> | <u>2004</u> | <u>September 30,</u> <u>2005</u> <u>(unaudited)</u> |
| Net loss, as reported | \$ (3,251,378) | \$ (3,077,888) | \$ (2,489,983) |
| Effect of stock-based employee compensation expense (credit) included in reported in net loss | (385,691) | 156,157 | (385,691) |
| Total stock-based employee compensation expense determined under fair value based method for all awards | <u>(200,233)</u> | <u>(152,545)</u> | <u>(194,241)</u> |
| Pro forma net loss | <u>\$ (3,837,302)</u> | <u>\$ (3,074,276)</u> | <u>\$ (3,069,915)</u> |
| Loss per share: | | | |
| Basic and diluted – as reported | \$ (0.22) | \$ (0.22) | \$ (0.17) |
| Basic and diluted – pro forma | \$ (0.25) | \$ (0.22) | \$ (0.21) |
| Shares used to compute basic and diluted net loss per share | 15,082,098 | 14,118,129 | 14,856,540 |

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 anti-dilutive. 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 anti-dilutive. Basic and diluted net loss per share amounts are the same for the periods presented. Net loss per share is computed using the weighted average number of shares of common stock outstanding.

Revenue Recognition

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

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Oragenics, Inc.

Notes to Financial Statements (continued)

1. Organization and Significant Accounting Policies (continued)

Impairment of Long-Lived Assets

The Company reviews their long-lived assets for impairment and reduces the carrying value to fair value whenever events or changes in circumstances indicate that the carrying value may not be recoverable. There were no impairment losses recorded during the years ended December 31, 2005 and 2004 and the nine-months ended September 30, 2006 and 2005.

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.

Recently Issued Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 123 (revised 2004) *Share Based Payment* ("Statement 123(R)"), a revision of FASB Statement No. 123 *Accounting for Stock Based Compensation* ("Statement 123 (R)") supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees* which allowed companies to use the intrinsic value method of valuing share-based payment transactions and amends FAS Statement No. 95, *Statement of Cash Flows*. Statement 123(R) which we have adopted in the first quarter of 2006, is generally similar to Statement 123; however, it requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. Thus, pro forma disclosure will no longer be an alternative to financial statement recognition for new stock option grants and unvested stock option grants prior to adoption of FAS 123 (R).

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Oragenics, Inc.

Notes to Financial Statements (continued)

2. Property and Equipment

Property and equipment, net consists of the following as of December 31, 2005 and September 30, 2006:

| | <u>December 31, 2005</u> | <u>September 30, 2006</u> |
|-------------------------------|--------------------------|---------------------------|
| Leasehold improvements | \$ 876,343 | \$ 875,272 |
| Laboratory equipment | 481,606 | 481,606 |
| Office and computer equipment | 55,107 | 55,107 |
| | <u>1,413,056</u> | <u>1,411,985</u> |
| Accumulated depreciation | <u>(316,492)</u> | <u>(526,399)</u> |
| | <u>\$ 1,096,564</u> | <u>\$ 885,586</u> |

Depreciation expense for 2005 and 2004 was \$260,636 and \$41,987, respectively and for the nine-month period ended September 30, 2006 and 2005 was \$210,899 and \$188,014, respectively

3. Related Party Transactions

At December 31, 2005 and September 30, 2006, \$55,000 was owed and included in accounts payable and accrued expenses for consulting services provided by a stockholder of the Company in prior years. No interest is being accrued on this outstanding debt.

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

In July 2005, the Company entered into a severance agreement with its former Chief Executive Officer (CEO) agreeing to continue payments of \$15,000 per month for one year post separation from employment with the Company. The agreement requires the former CEO to be available as a consultant to management. In the fourth quarter of 2005, \$40,500 of these payments were deferred and included in accounts payable and accrued expenses at December 31, 2005. Beginning January 1, 2006, the Company continued to defer 50% of the payments due to the former CEO. Interest is not being accrued on the deferred amounts.

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

As of September 30, 2006, fees of \$34,000 to the Board of Directors and Audit Committee have been deferred. On September 7, 2006, the Board of Directors and the Compensation Committee approved stock option grants to non-employee directors in lieu of future cash fees for Board and Committee services.

4. Business Loan Agreement

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

4. Business Loan Agreement (continued)

working capital not be lower than \$350,000. The bank also amended the debt-to-equity covenant whereby debt could not be greater than 56% of stockholders' equity. Thus, the Company was in compliance with the loan covenants throughout the term of the loan. The Company incurred interest of \$29,176 during 2005.

5. Stockholders' Equity

Common Stock

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

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

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

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

5. Stockholders' Equity (continued)

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

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

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

Stock Compensation Plan

The Company's 2002 Stock Option and Incentive Plan (the Plan) was adopted by the Board of Directors (the Board). The purpose is to advance the interests of the Company by affording certain employees and directors of the Company and key consultants and advisors an opportunity to acquire or increase their proprietary interests in the Company. The Plan authorizes the grant of stock options (incentive and non-statutory), stock appreciation rights and restricted stock. As of December 31, 2005 and September 30, 2006, the Company had not awarded stock appreciation rights or restricted stock under the Plan. The Company has reserved an aggregate of 3,000,000 shares of common stock for grants under the Plan, of which 1,685,000 shares are available for future grants as of September 30, 2006 and 1,740,000 shares as of December 31, 2005. The exercise price of each option shall be determined by the Board and an option's maximum term is ten years.

In September 2002, the Company issued 195,000 options that were re-priced upon the change in the initial public offering price. As a result, these options were subjected to variable accounting treatment. In accordance with Financial Accounting Standards Board Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation* (FIN 44), stock options must be accounted for as variable under such circumstances. Variable accounting requires companies to re-measure compensation costs for the variable options until the options are exercised, cancelled, or forfeited without replacement. Compensation is dependent on fluctuations in the quoted stock prices for the Company's common stock. Such compensation costs will be recognized over a three-year vesting schedule until the options are fully vested, exercised, cancelled, or forfeited, after which time the compensation will be recognized immediately at each reporting period. During 2005, the Company recognized a credit to compensation expense of \$385,691 as a result of the decline in the fair market value of the Company's common stock below the price of \$1.25 at the IPO. During the nine-month period ended September 30, 2006, the Company recognized \$298,198 as stock option compensation expense.

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Oragenics, Inc.

Notes to Financial Statements (continued)

5. Stockholders' Equity (continued)

A summary of the status of the Company's outstanding stock options as of December 31, 2005 and September 30, 2006 and changes during the periods ending on those dates is presented below:

| | <u>Options</u> | <u>Option Price Per Share</u> | <u>Weighted Average Exercise Price</u> |
|-----------------------------------|------------------|---------------------------------------|--|
| Outstanding at January 1, 2005 | 1,070,000 | \$1.25 – 4.25 | \$ 2.52 |
| Forfeited | (392,000) | 1.25 – 3.30 | 2.25 |
| Granted | <u>582,000</u> | 0.53 – 2.25 | 1.00 |
| Outstanding at December 31, 2005 | 1,260,000 | 0.53 – 4.25 | \$ 1.90 |
| Forfeited | (475,000) | 1.25 – 4.00 | 2.15 |
| Granted | <u>530,000</u> | 0.53 – 0.74 | 0.67 |
| Exercisable at September 30, 2006 | <u>1,315,000</u> | <u>\$0.53 – 4.25</u> | <u>\$ 1.32</u> |

The range of exercise price is \$0.53 to \$4.25 per share. The weighted-average per option fair value of options granted during 2005 was \$0.62 and the weighted average remaining contractual life of those options is 4.3 years. Options vest over a period of three to four years from respective grant dates and the options expire 5 years after the date of grant. The fair value of these options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions: weighted average risk-free interest rate of 2.38%; dividend yields of 0%; weighted-average volatility factors of the expected market price of the Company's common stock of 53.8%; and an expected life of the option of four years.

6. Licenses

The Company has two license agreements with the University of Florida Research Foundation, Inc. ("UFRF") for their technologies. The Company issued 599,940 shares of common stock as partial consideration. Beginning in 2004, the license agreements provide for, among other things, the Company to make minimum annual research expenditures of \$1,000,000 and to adhere to specific milestones. Beginning in 2005, the Company is required to pay minimum royalties on product sales of \$50,000 annually per agreement. If the Company fails to perform certain of its obligations, UFRF may terminate the license agreements.

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

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Oragenics, Inc.

Notes to Financial Statements (continued)

7. Retirement Plan

In January 2004, the Company established a defined contribution retirement plan, replacing the previous plan that had been established in 2001. The new plan covers all employees and provides for a Company match of up to 3% of all employee contributions to the plan. During 2005 and 2004, employee contributions were limited to \$10,000 and \$9,000, respectively, except for individuals 50 years or older for which the contribution limitations were \$12,000 and \$10,500, respectively. Total matching contributions made by the Company in 2005 and 2004 and the nine-month period ended September 30, 2006 and 2005 were \$31,895, \$28,315, \$5,418 and \$25,732, respectively.

8. Income Taxes

At December 31, 2005, the Company had temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and their respective income tax bases, as measured by enacted state and federal tax rates, as follows:

| | |
|---------------------------------|--------------|
| Deferred tax assets: | |
| Net operating loss carryforward | \$ 3,170,707 |
| Consulting services | 57,010 |
| Non qualified stock options | 20,320 |
| Tax credits | 195,326 |
| Total deferred tax assets | 3,443,363 |
| Less valuation allowance | (3,443,363) |
| Total net deferred taxes | \$ — |

The following is a reconciliation of tax computed at the statutory federal rate to the income tax benefit in the statements of operations for the years ended December 31, 2005 and 2004:

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

SFAS No. 109, *Accounting for Income Taxes*, requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all of the evidence, both positive and negative, management has

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Oragenics, Inc.

Notes to Financial Statements (continued)

8. Income Taxes (continued)

determined that a valuation allowance of \$3,443,363 at December 31, 2005 is necessary to reduce the deferred tax assets to the amount that will more likely than not be realized. The change in the valuation allowance for the year ended December 31, 2005 and 2004 was \$1,387,567 and \$1,178,040, respectively. At December 31, 2005, the Company has available net operating loss carryforwards of approximately \$8,426,000 that begin to expire in 2021. The Company also has a research and development credit carryforward of \$195,326 that is available to reduce future tax liabilities through 2025.

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

9. Commitments and Contingencies

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

The new facility is being leased from a real estate developer for a term of five years subject to renewal provisions that include 3% increases in lease payments. This operating lease agreement required the Company to pay a deposit of \$6,400 and provides for monthly lease payments of \$6,793, exclusive of utilities, insurance, sales taxes and real estate taxes. Total rent expense under this lease was \$81,653 and \$10,184 for the years ended December 31, 2005 and 2004, and for the nine-month period of September 2006 and 2005 was \$62,479 and \$61,240, respectively. In addition, the Company has entered into certain operating leases for office equipment.

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

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

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Oragenics, Inc.

Notes to Financial Statements (continued)

10. Unaudited Quarterly Financial Information

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

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

| | 2006 | | |
|--------------------------|------------|------------|------------|
| | First | Second | Third |
| Total operating expenses | \$ 865,131 | \$ 801,831 | \$ 634,132 |
| Net loss | (856,389) | (796,713) | (559,160) |
| Loss per share: | | | |
| Basic and Diluted | \$ (0.05) | \$ (0.04) | \$ (0.03) |

Oragenics, Inc.

2006

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. This prospectus may only be used where it is legal to sell these securities. The information contained in this prospectus may only be accurate on the date of this prospectus.

PART II. INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 24. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

As provided in our bylaws and under Florida law, our directors shall not be personally liable to our company or any other person for monetary damages for breach of duty of care or any other duty owed to our company as a director, unless the breach of or failure to perform those duties constitutes:

- a violation of criminal law, unless the director had reasonable cause to believe his conduct was lawful, or had no reasonable cause to believe his conduct was unlawful;
- a transaction from which the director received an improper personal benefit, directly or indirectly;
- in a proceeding by or in the right of our company or a stockholder, an act or omission which involves a conscious disregard for the best interests of our company or which involves willful misconduct;
- in a proceeding by or in the right of someone other than our company or a stockholder, an act of recklessness or an act or omission which was committed in bad faith or with malicious purpose or in a manner exhibiting wanton and willful disregard of human rights, safety, or property; or
- a distribution made in violation of Florida law.

Our bylaws provide that we are required to indemnify any director, officer, employee or agent made a party to a proceeding because he is or was our director, officer, employee or agent against liability incurred in the proceeding if he acted in good faith and in a manner the director reasonably believed to be in or not opposed to our best interests and, in the case of any criminal proceeding, he had no reasonable cause to believe his conduct was unlawful.

Our bylaws and Florida law also provide that we shall indemnify a director, officer, employee or agent who has been successful on the merits or otherwise in the defense of any proceeding to which he was a party, or in defense of any claim, issue or matter therein, because he is or was a director, officer, employee or agent of our company against expenses actually and reasonably incurred by him in connection with such defense.

ITEM 25. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

The estimated expenses of this offering, all of which are to be paid by the registrant, are as follows:

| | |
|---|------------------|
| SEC Registration Fee | \$ 1,364* |
| American Stock Exchange Additional Listing Fees | 45,000* |
| Accounting Fees and Expenses | 25,000 |
| Legal Fees and Expenses | 40,000 |
| Transfer Agent Fees | — |
| Miscellaneous Expenses | 8,636 |
| TOTAL | \$120,000 |

* Previously paid

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ITEM 26. RECENT SALES OF UNREGISTERED SECURITIES

During the past three years, we have sold the following shares of common stock which were not registered under the Securities Act of 1933, as amended.

On June 24, 2003, we completed an initial public offering (IPO), pursuant to which we sold 2,400,000 units at a price of \$1.25 per unit. Each unit consisted of one share of common stock, one half of one non-transferable Series A Common Stock Purchase Warrant and one half of one non-transferable Series B Common Stock Purchase Warrant. One whole Series A warrant was exercisable on or before December 24, 2003 to acquire one share of common stock at a price of \$2.00 per share. All Series A warrants were exercised on or prior to December 24, 2003 providing proceeds of \$2,400,000 and resulting in the issuance of 1,200,000 shares of our common stock. One whole Series B warrant was exercisable on or before March 24, 2004 to acquire one share of common stock at a price of \$3.00 per share. A total of 995,400 Series B warrants were exercised on or before March 24, 2004 providing proceeds of \$2,986,200 and resulting in the issuance of 985,650 shares of our common stock. The remaining 204,600 Series B warrants expired unexercised on March 24, 2004.

Between June 24, 2003 and June 24, 2005, we issued a total 500,000 shares of common stock upon the exercise of outstanding warrants at an exercise price of \$1.25 per share. These warrants were originally acquired by the underwriters of our initial public offering, Haywood Securities, Inc., in connection with the consummation of our offering and were subject to expiration unless exercised on or before June 24, 2005.

On November 30, 2004 we issued a total of 250,000 shares of our common stock at \$2.75 per share and warrants to purchase 162,500 shares of our common stock in a private placement to three accredited investors (The Arbitrage Fund, Mark Campbell and The Living Trust of Harold Richard Grisham) and a placement agent. We received gross proceeds of \$687,500 in the private placement and incurred costs of approximately \$142,500 resulting in net proceeds of approximately \$545,000.

On May 23, 2005 we issued 315,421 shares to Fusion Capital Fund II, LLC as payment of a commitment fee in connection with a common stock purchase agreement entered into between us and Fusion Capital.

On August 16, 2005, we entered into a consulting agreement for financial public relations services with Investor Awareness, Inc. The terms of that agreement provided that we pay \$10,000 per month plus out-of-pocket expenses and that we issue a common stock purchase warrant for 35,000 shares that has an exercise price of \$1.59 and a term of three years. In November 2005, we suspended the continuance of the consulting agreement.

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

On March 11, 2006, we issued a total of 1,500,000 shares of our common stock and warrants to purchase 1,500,000 shares of our common stock in a private placement to accredited investors. We received gross proceeds of \$600,000 in the private placement and incurred estimated costs of \$75,696 resulting in net proceeds of approximately \$524,304. 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.

On April 26, 2006, we issued 10,250 shares to Westrock Advisors, Inc. in connection with the partial exercise of warrants at \$0.40 per share.

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On May 24, 2006, we issued 6,356 common shares to Westrock Advisors, Inc. in connection with the partial exercise of warrants at \$0.40 per share.

On June 6, 2006, we issued 60,000 shares to Westrock Advisors, Inc. in connection with the partial exercise of warrants at \$0.60 per share.

On June 26, 2006 we issued 35,000 shares to Westrock Advisors, Inc. in connection with the partial exercise of warrants at \$.060 per share.

On June 28, 2006, we issued 300,000 shares at \$0.60 per share to Brian McAlister in connection with the full exercise of warrants previously issued in connection with private placement transaction.

On June 29, 2006, we amended the warrant with the Arbitrage Fund which was to revise the exercise price from \$2.75 to \$0.60. On June 30, 2006 we issued 85,000 shares at \$0.60 per share to the Arbitrage Fund in connection with the exercise of the warrants previously issued in connection with a private placement transaction.

On June 29, 2006, we issued 250,000 shares at \$0.60 per share to the Arbitrage Fund in connection with the full exercise of warrants previously issued in connection with a private placement transaction.

On June 29, 2006 and December 5, 2006 we issued 300,000 shares and 700,000, respectively at \$0.60 per share to George Hawes, a Director, in connection with the exercise of warrants previously issued in connection with a private placement transaction.

On July 20, 2006 we issued 18,394 shares to Westrock Advisors, Inc. in connection with the partial exercise of warrants at \$.060 per share.

On November 17, 2006 we acquired the outstanding stock of iviGene Corporation in exchange for 185,186 aggregate shares of our common stock to the holders of iviGene Corporation, which included one of our directors, who received 20,480 shares.

We issued the above restricted securities to the named individuals and entities pursuant to exemptions under the Securities Act of 1933.

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ITEM 27. EXHIBITS.

The following exhibits are filed as part of this registration statement, pursuant to Item 601 of Regulation S-B.

| <u>Exhibit Number</u> | <u>Exhibit Description</u> | <u>Form</u> | <u>File No</u> | <u>Exhibit</u> | <u>Filing Date</u> | <u>Filed Herewith</u> |
|-----------------------|--|-------------|----------------|----------------|--------------------|-----------------------|
| 3.1 | Amended and Restated Articles of Incorporation | SB-2 | 333-100568 | 3.3 | 10/16/02 | |
| 3.2 | Bylaws | SB-2 | 333-100568 | 3.2 | 10/16/02 | |
| 4.1 | Specimen Stock Certificate | SB-2 | 333-100568 | 4.1 | 10/16/02 | |
| 4.2 | Form of November 2004 private placement warrant | 10-KSB | 000-50614 | 4.3 | 03/14/05 | |
| 4.3 | Form of November 2004 private placement Subscription Agreement (including registration rights) | 10-KSB | 000-50614 | 4.4 | 03/14/05 | |
| 4.4 | Warrant Amendment Agreement (including form of replacement warrant) between the Company and The Arbitrage Fund, Mark Campbell, The Harold T. Grisham Living Trust and Westminster Securities dated May 31, 2005 to November 2004 warrant | SB-2 | 333-125660 | 4.5 | 6/23/05 | |
| 4.5 | Common Stock Purchase Agreement with Fusion Capital Fund II, LLC, dated as of May 23, 2005 | 8-K | 000-50614 | 4.5 | 05/23/05 | |
| 4.6 | Registration Rights Agreement with Fusion Capital Fund II, LLC, dated as of May 23, 2005 | 8-K | 000-50614 | 4.6 | 05/23/05 | |
| 4.7 | Securities Purchase Agreement, dated November 20, 2005, among the purchasers and Oragenics, Inc. | S-3 | 333-131015 | 4.2 | 01/13/06 | |
| 4.8 | Registration Rights Agreement dated November 20, 2005, among the investors and Oragenics, Inc. | S-3 | 333-131015 | 4.3 | 01/13/06 | |
| 4.9 | Specimen private placement December 2005 warrant certificate | S-3 | 333-131015 | 4.4 | 01/13/06 | |
| 4.10 | 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-1 | 333-125660 | 4.10 | 12/05/06 | |
| 5.1 | Opinion of Shumaker, Loop & Kendrick, LLP | | | | | X |
| 10.1 | License Agreement between the Company and the University of Florida Research Foundation, Inc. effective August 4, 1998 for Replacement Therapy for Dental Caries (the "Replacement Therapy License Agreement") | SB-2 | 333-100568 | 10.1 | 10/16/02 | |
| 10.2 | First Amendment to Replacement Therapy License Agreement dated September 15, 2000 | SB-2 | 333-100568 | 10.2 | 10/16/02 | |
| 10.3 | Second Amendment to Replacement Therapy License Agreement dated June 2002 | SB-2 | 333-100568 | 10.3 | 10/16/02 | |
| 10.4 | Third Amendment to Replacement Therapy License Agreement dated September 25, 2002 | SB-2 | 333-100568 | 10.4 | 10/16/02 | |
| 10.5 | Fourth Amendment to Replacement Therapy License Agreement and Antimicrobial Polypeptide License Agreement dated March 2003 | SB-2/A-3 | 333-100568 | 10.36 | 4/9/03 | |

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| Exhibit Number | Exhibit Description | Form | File No | Exhibit | Filing Date | Filed Herewith |
|-----------------------|--|--------------|----------------|----------------|--------------------|-----------------------|
| 10.6 | License Agreement between the Company and the University of Florida Research Foundation, Inc. effective June 22, 2000 (the "Antimicrobial Polypeptide License Agreement") | SB-2 | 333-100568 | 10.5 | 10/16/02 | |
| 10.7 | First Amendment to the Antimicrobial Polypeptide License Agreement dated September 15, 2000 | SB-2 | 333-100568 | 10.6 | 10/16/02 | |
| 10.8 | Second Amendment to the Antimicrobial Polypeptide License Agreement dated June 10, 2002 | SB-2 | 333-100568 | 10.7 | 10/16/02 | |
| 10.9 | Third Amendment to the Antimicrobial Polypeptide License Agreement dated September 25, 2002 | | | | | |
| 10.10+ | Amended and Restated 2002 Stock Option and Incentive Plan | 10-QSB/ A | 001-32188 | 10.1 | 9/29/06 | |
| 10.11 | Proprietary Information Agreements between ourselves, Robert Zahradnik, Howard Kuramitsu, and Steven Projan | SB-2 | 333-100568 | 99.23 | 10/16/02 | |
| 10.12* | Proprietary Information and Invention Agreement between the Company and Jeffrey D. Hillman | SB-2 | 333-100568 | 99.4 | 10/16/02 | |
| 10.13* | Employment agreement of Jeffrey Hillman | 10-KSB | 000-50614 | 10.43 | 3/17/04 | |
| 10.14 | Lease Agreement between the Company and Hawley-Wiggins LLC dated January 28, 2004; Subordination Agreement dated April 14, 2004; and First Amendment dated November 15, 2004 | 10-KSB | 001-32188 | 10.46 | 03/14/05 | |
| 10.15 | Agreement of Separation and Release between the Company and Mento S. Sophonis | 10-QSB | 001-32188 | 10.1 | 08/11/05 | |
| 10.16 | Employment Letter of Robert Zahradnik | 10-QSB | 001-32188 | 10.2 | 08/11/05 | |
| 16.0 | Letter regarding change in certifying accountant | 8-K | 001-32188 | 16.0 | 08/29/05 | |
| 23.1 | Consent of Kirkland Russ Murphy & Tapp, PA | | | | | X |
| 23.2 | Consent of Ernst & Young LLP | | | | | X |
| 24 | Power of Attorney (contained in signature page of earlier filing) | SB-2/A-1 | 333-125660 | N/A | 12/05/06 | |

* management contract

+ compensatory plan or arrangement

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ITEM 28. UNDERTAKINGS.

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
 - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
 - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
 - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the registration statement is on Form S-3 and the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To file a post-effective amendment to remove from registration any of the securities which remain unsold at the end of the offering.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 (the "Act") may be permitted to directors, officers and controlling persons of the small business issuer pursuant to the foregoing provisions, or otherwise, the small business issuer has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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SIGNATURES

In accordance with the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing of this post-effective amendment No.2 to the Form SB-2 Registration Statement and has duly caused this amended registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Alachua, Florida, on this 19th day of December, 2006.

ORAGENICS, INC.

BY: /s/ Robert T. Zahradnik

Robert T. Zahradnik, President, Chief Executive Officer, Secretary and Treasurer

BY: /s/ Robert T. Zahradnik

Robert T. Zahradnik, Interim Chief Financial Officer and Principal Accounting Officer

Pursuant to the requirements of the Securities Act of 1933, this post-effective amendment No.2 to Form SB-2 Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

| <u>Signature</u> | <u>Title</u> | <u>Date</u> |
|---|---|-------------------|
| <u>/s/ Robert T. Zahradnik</u> Robert T. Zahradnik | President, Principal Executive Officer, Secretary, Treasurer, Interim Chief Financial Officer and Principal Accounting Officer and a Member of the Board of Directors | December 19, 2006 |
| <u>/s/ David J. Gury*</u> David J. Gury | Chairman of the Board of Directors | December 19, 2006 |
| <u>/s/ George T. Hawes*</u> George T. Hawes | Member of the Board of Directors | December 19, 2006 |
| <u>/s/ Jeffrey D. Hillman*</u> Jeffrey D. Hillman | Chief Scientific Officer Member of the Board of Directors | December 19, 2006 |
| <u>*/s/ Robert T. Zahradnik</u> Robert T. Zahradnik, As Attorney-in-Fact | | |

SHUMAKER, LOOP & KENDRICK, LLP
ATTORNEYS AT LAW

BANK OF AMERICA PLAZA, SUITE 2800
101 EAST KENNEDY BOULEVARD
TAMPA, FLORIDA 33602
(813) 229-7600
FAX (813) 229-1660

MAILING ADDRESS:
POST OFFICE BOX 172609
TAMPA, FLORIDA 33672-0609

December 19, 2006

Oragenics, Inc.
12085 Research Drive
Alachua, Florida 32615

Re: Form SB-2 Registration Statement

Ladies and Gentlemen:

You have requested our opinion with respect to certain matters in connection with the filing by Oragenics, Inc., a Florida corporation (the "Company") of a Registration Statement on Form SB-2 (the "Registration Statement") filed with the Securities and Exchange Commission (the "Commission") pursuant to the Securities Act of 1933, as amended (the "Act"), covering the offering for sale by Fusion Capital Fund II, LLC of up to 4,109,689 shares of common stock, par value \$.001 per share (the "Securities"), comprised of 315,421 shares (the "Issued Shares") of common stock which are issued and outstanding and 3,794,268 shares (the "Purchase Shares") of common stock issuable pursuant to the Common Stock Purchase Agreement, dated as of May 23, 2005 by and between you and Fusion Capital Fund II, LLC (the "Purchase Agreement").

In connection with this opinion, we have examined and relied upon the Company's Articles of Incorporation, as amended, the Company's Bylaws, the Purchase Agreement, and Registration Statement and related prospectus originals or copies certified or otherwise identified to our satisfaction of all such corporate records of the Company and such other instruments and other certificates of public officials, officers and representatives of the Company and such other persons, and we have made such investigations of law, as we have deemed appropriate as a basis for the opinions expressed below.

In arriving at the opinions expressed below, we have assumed the authenticity of all documents submitted to us as originals and the conformity to the originals of all documents submitted to us as copies. In addition, we have assumed and have not verified the accuracy as to factual matters of each document we have reviewed.

Based on the foregoing, and in reliance thereon subject to the further assumptions and qualifications set forth below, we are of the opinion that (i) Issued Shares are validly issued, fully paid and non-assessable, (ii) the Purchase Shares, when issued and paid for in accordance with the terms of the Purchase Agreement, will be validly issued, fully paid and non-assessable.

The foregoing opinion is limited to the Business Corporation Act of the State of Florida

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement and to the reference to this firm under the heading "Legal Matters" in the Registration Statement and the related prospectus included in the Registration Statement. In giving such consent, we do not thereby admit that we are "experts" within the meaning of the Act or the rules and regulations of the Commission issued thereunder with respect to any part of the Registration Statement, including this exhibit.

Very truly yours,

/s/ Shumaker, Loop & Kendrick, LLP
SHUMAKER, LOOP & KENDRICK, LLP

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" in the Registration Statement (Form SB-2 No. 333-125660) and the related Prospectus of Orogenics, Inc. for the registration of up to 4,109,689 shares of its common stock and to the incorporation by reference therein of our report dated February 15, 2006, except for Note 11 as to which the date is March 6, 2006 with respect to the financial statements of Orogenics, Inc. included in its Annual Report (Form 10-KSB) for the year ended December 31, 2005, filed with the Securities and Exchange Commission.

/s/ Kirkland Russ Murphy & Tapp, PA

Certified Public Accountants

Clearwater, Florida

December 18, 2006

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated January 28, 2005 with respect to the financial statements of Oragenics, Inc. included in the Registration Statement (Post-Effective Amendment No. 2 to Form SB-No. 333-125660) and related Prospectus of Oragenics, Inc. for the registration of 4,109,689 shares of its common stock.

/s/ Ernst & Young LLP

Certified Public Accountants

Tampa, Florida

December 18, 2006

SHUMAKER, LOOP & KENDRICK, LLP
ATTORNEYS AT LAW

BANK OF AMERICA PLAZA, SUITE 2800
101 EAST KENNEDY BOULEVARD
TAMPA, FLORIDA 33602
(813) 229-7600
FAX (813) 229-1660

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POST OFFICE BOX 172609
TAMPA, FLORIDA 33672-0609

December 19, 2006

Jeffrey Riedler, Assistant Director
United States Securities and Exchange Commission
450 Fifth Street, N.W.
Washington, DC 20549

Re: Oragenics, Inc.
Post-Effective Amendment No. 1 to Form SB-2 Registration Statement
Filed December 5, 2006
File No. 333-125660

Dear Mr. Riedler:

On behalf of Oragenics, Inc. (the "Company"), set forth below are responses to the Staff of the Division of Corporation Finance's comment letter dated December 12, 2006, with respect to Oragenics' Amendment No. 1 to Form SB-2 Registration Statement (333-125660). For your convenience, the Staff's comments are set forth in bold and followed by our response.

Comments

- 1. Please revise your registration statement to identify and provide the signature of the controller or principal accounting officer.**

Response: The registration statement has been revised to indicate that our Interim Chief Financial Officer, Robert T. Zahradnik, has also signed in his capacity as the Company's principal accounting officer.

* * * * *

Should you have any questions or clarifications of the matters raised in this letter please contact me at (813) 227-2226.

Sincerely,

/s/ Darrell C. Smith
Darrell C. Smith

cc: Robert Zahradnik, President and Chief Executive Officer