Prospectus

## **ORAGENICS, INC.**

#### 9,200,000

#### Shares of common stock,

This prospectus covers up to 9,200,000 shares of our common stock, \$0.001 par value per share, of which 4,600,000 of the shares are currently issued and outstanding and 4,600,000 of the shares are issuable upon exercise of outstanding warrants, which may be offered for resale by the selling shareholders named in this prospectus and the persons to whom such selling shareholders may transfer their shares. We do not know if any or all of the warrants will be exercised or if any or all of the shares will be resold. No securities are being offered or sold by us pursuant to this prospectus. The selling shareholders acquired the common stock and warrants to purchase common stock in transactions that were exempt from the registration requirements of federal and state securities laws. (See page 18 under the heading "Selling Shareholders.") Our filing of the registration statement, of which this prospectus is a part, is intended to satisfy our obligations to the selling shareholders identified in this prospectus to register for resale shares issued to them.

Pursuant to this prospectus, the selling shareholders may sell some or all of the shares they hold through ordinary brokerage transactions, directly to market makers of our shares, or through any of the other means described in the "Plan of Distribution" section of this prospectus, beginning on page 20. Except for the exercise of warrants, the selling shareholders, and not us, will receive all of the proceeds from any sales of the shares, less any brokerage or other expenses of the sale incurred by them.

We will pay all registration expenses including, without limitation, all Securities and Exchange Commission ("SEC") and blue sky registration and filing fees, printing expenses, transfer agents' and registrars' fees, and the fees and disbursements of our outside counsel in connection with this offering, but the selling shareholders will pay all selling expenses including, without limitation, any underwriters' or brokers' fees or discounts relating to the shares registered hereby, or the fees or expenses of separate counsel to the selling shareholders.

Each selling shareholder and any broker executing selling orders on behalf of the selling shareholders, may be deemed to be an "underwriter" as such term is defined in the Securities Act of 1933, and any commissions paid or discounts or concessions allowed to any such person and any profits received on resale of the securities offered hereby may be deemed to be underwriting compensation under the Securities Act.

Our common stock is listed on the American Stock Exchange with the ticker symbol "ONI." On September 11, 2007, the closing price of our common stock on the American Stock Exchange was \$0.50 per share. Our principal executive offices are located at 13700 Progress Boulevard, Alachua, FL. 32615, and our telephone number is (386) 418-4018.

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.

Investing in our common stock involves a high degree of risk. Please carefully consider the "<u>Risk Factors</u>" beginning on page 6 of this prospectus.

The date of this prospectus is September 26, 2007.

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#### **About This Prospectus**

The selling shareholders named in this prospectus may sell up to 9,200,000 shares of our common stock, of which 4,600,000 of the shares are currently issued and outstanding and 4,600,000 of the shares are issuable upon exercise of outstanding warrants. This prospectus provides you with a general description of the common stock the selling shareholders may offer. You should read this prospectus as well as additional information described under "Where You Can Find More Information" and "Information Incorporated by Reference."

You should rely only on the information contained or incorporated by reference in this prospectus. Neither we nor the selling shareholders have authorized anyone to provide you with different information. This prospectus is not an offer to sell, nor is it a solicitation of an offer to buy, these securities in any state where the offer or sale 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 page. Our business, financial condition, results of operations and prospects may have changed since that date.

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#### PROSPECTUS SUMMARY

This summary highlights selected information from this prospectus and should be read together with the more detailed information and financial data and statements contained elsewhere and incorporated by reference in this prospectus. You should read the entire prospectus carefully, especially the discussion of the risks of purchasing our securities in "Risk Factors" on page 6.

#### 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 and acquired by us. Our strategy is to inlicense, internally discover or acquired 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.

Although we recently closed on a \$1,171,591 private placement that is described below, we are in need of substantial additional funds in order to continue the development of our technologies. We are continuing to seek additional funding. 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. As we move into more advanced stages concerning our products and their testing, our monthly expenses and use of cash are 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 remaining working capital at June 30, 2007 was \$1,740 and together with the net proceeds from the August 7, 2007 financing described below, our funds are sufficient to enable us to continue to operate through the fourth 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<sup>™</sup> and MU 1140<sup>™</sup> (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.

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

On June 15, 2007, Dr. Ronald P. Evens was appointed to the Company's Board of Directors. Our Board of Directors currently consists of four members of which two are independent. On July 2, 2007, AMEX notified the Company that it had completed its review and determined that the Company's compliance plan makes a reasonable

demonstration of the Company's ability to regain compliance with the continued listing standards by the end of the plan period, October 27, 2008 and is therefore continuing the Company's listing pursuant to an extension.

On August 7, 2007, our Securities Purchase Agreement with accredited investors, including our new director, Dr. Ronald P. Evens, became binding and we closed on \$1,171,591 in equity based financing. We issued a total of 4,600,000 shares of restricted common stock in the private placement. The shares were sold to accredited investors at \$0.25 per share, except that per AMEX requirements, Dr. Evens acquired his shares at \$0.44 per share, which was the closing share price on August 7, 2007. Each participating investor, including Dr. Evens, also received warrants to purchase shares of common stock at the price of \$0.58 per share. One warrant was issued for each share of common stock issued for a total of up to 4,600,000 additional shares of restricted common stock that may be acquired upon exercise of the warrants. The warrants become exercisable in six months and expire after one year from the date of issuance. The private placement offering and sale of the common stock and warrants was made in reliance upon the exemption from registration provided by Section 4(2) of the Securities Ace of 1933 as a transaction by the issuer not involving a public offering. We intend to use the net proceeds of the private placement, including any proceeds from exercise of the warrants, for working capital and general corporate purposes. While management is encouraged by the aforementioned financing, the proceeds are insufficient, alone, to regain final compliance with AMEX listing requirements. We have until October 27, 2008 to regain AMEX compliance but there can be no assurance that we will be able to do so.

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

**SMaRT Replacement Therapy**<sup>TM</sup> 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<sup>TM</sup> 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, closed the clinical sites, and discussed with the FDA our problems with patient enrollment and how we could modify our protocol to allow us to move forward in our clinical trials. A formal re-submission of an amended protocol was filed with the FDA on March 9, 2006. We addressed additional protocol changes suggested by the FDA and filed a second re-submission July 20, 2006. Based on further suggestions by the FDA for protocol changes made on September 29, 2006, we filed a third re-submission in early February 2007. We received a clinical hold letter from the FDA on June 14, 2007, and met with the clinical hold oversight committee of the FDA on June 21, 2007, to discuss the status of our IND submission and the remaining clinical hold issues. The Company filed a fourth re-submission on July 6, 2007 as a Complete Response to Clinical Hold, which also covered the remaining clinical hold issues. Oragenics was notified by the FDA on August 9, 2007, that it's IND submission remains on clinical hold. The Company anticipates filing a fifth resubmission by the end of September 2007 that addresses the two remaining clinical hold issues. 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<sup>TM</sup> in a manner that is satisfactory to the FDA. Should the FDA approve our re-submitted protocol, we estimate the cost in the second half of 2007 will be approximately \$300,000 subject to available funding, with an additional \$150,000 scheduled for the first quarter 2008, in order to complete the proposed clinical trial.

**MU 1140<sup>TM</sup>** (Mutacin 1140) is a highly potent bactericidal peptide that is produced by our strain of *Streptococcus mutans*. We developed a proprietary fermentation-based manufacturing process for MU 1140<sup>TM</sup> 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. In parallel, we are

working with our proprietary DPOLT<sup>TM</sup> synthetic chemistry technology to develop a more cost effective method for producing sufficient quantities of MU1140<sup>TM</sup> to complete large scale animal toxicity studies and provide clinical trail material for the proposed human studies that are part of our IND application to the FDA. During the second quarter of 2006, we completed two significant preclinical studies and demonstrated that MU 1140<sup>TM</sup> is effective in an animal infection model against *Staphylococcus aureus*, and is also effective in the laboratory against a number of clinically important Gram-positive bacteria that include *Enterococcus faecalis, Streptococcus pneumoniae, Clostridium difficile* and *Listeria monocytogenes*. In the third quarter of 2007, two additional preclinical studies were completed. These studies demonstrated that MU1140<sup>TM</sup> is effective in a second animal infection model against *Staphylococcus aureus*, and is also effective in the laboratory against pathogenic bacteria that are resistant to a variety of antibiotics, including all vancomycin-resistant strains of enterococcu *aureus*. If we are able to secure adequate funding, we plan to continue to perform preclinical testing including more detailed animal safety and efficacy studies using MU 1140<sup>TM</sup>.

**Probiora3<sup>TM</sup> (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. 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 an appropriate partner, we may achieve commercialization of our probiotic product (Probiora3<sup>TM</sup>) in these markets in first half of 2008. Two sets of subjects completed our Probiora3<sup>TM</sup> human study, and we believe the results confirmed that the product is safe for human use and demonstrated a substantial effect of Probiora3<sup>TM</sup> in reducing the levels of specific disease-causing bacteria in the mouths of young, healthy adult subjects. We are continuing our efforts to seek regional and international partners for market opportunities in the oral care and/or food and nutritional supplement industries to determine interest and deal structure preferences for the rights to the Probiora3<sup>TM</sup> technology.

**IVIAT<sup>TM</sup>** and **CMAT<sup>TM</sup>** 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 infectious diseases, 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. On April 3, 2007 we were notified that the National Institute of Science and the National Cancer Institute has awarded a SBIR grant to support our research efforts to identify unique proteins that are expressed when normal, health bowel cells become cancerous. This six month NCI Phase I grant for approximately \$100,000 started May 1, 2007 and will be completed October 31, 2007.

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

**DPOLT<sup>TM</sup>** (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<sup>TM</sup>, 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 (NSF) to establish proof-of-principal for DPOLT<sup>TM</sup> 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. The SBIR grant funds have been fully utilized and the Company filed a Phase 2 SBIR grant application on July 31, 2007 with NSF for \$500,000 to continue the development of this technology. There can be no assurance that the grant application will be approved and a grant awarded to us. Longer term, we have identified approximately two dozen bioactive peptides that would represent candidates for analog synthesis by DPOLT<sup>TM</sup>, for potentially improved stability or bioavailability. We filed a U.S. patent application in May 2006, covering the DPOLT<sup>TM</sup> technology.

#### **Business Objectives and Milestones**

The specific goal of our business is to successfully develop, clinically test and obtain FDA approval for sales of healthcare 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<sup>TM</sup>

Initiate second Phase I clinical safety trial.

#### **МU 1140<sup>тм</sup>**

- Complete preclinical studies, including animal toxicity and efficacy, required for an investigational new drug application (IND) submission.
- Submit an investigational new drug application to the FDA.

#### DPOLTTM

- Pursue proof-of-principle by chemically synthesizing a selected lantibiotic.
- Pursue scale-up with MU1140<sup>™</sup> for use in late-stage preclinical studies and in clinical trials.

#### Probiora3<sup>TM</sup>

Partner with one or more oral care or food and nutritional supplement manufacturers or distributors.

#### LPT3-04<sup>тм</sup>

- Initiate human safety and effectiveness study.
- Pursue partner for further development and commercialization.

#### **IVIAT<sup>TM</sup>**

• Validate gene markers for Mycobacteriam tuberculosis.

#### СМАТтм

· Complete proof-of-principle by identifying novel biomarkers in colorectal cancer model.

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<sup>™</sup> and MU 1140<sup>™</sup> technologies. 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 4730 S.W. 103 Way, Gainesville, Florida 32608. Our telephone number is (386) 418-4018. Our corporate website is at <u>www.oragenics.com</u>. 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. 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 shareholders.

#### **RISK FACTORS**

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

#### **Risks Associated with Our Company**

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

We do not have sufficient capital to sustain our operations beyond the fourth 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 weight loss agent and development of our technologies and products;
- We will have to lay-off our personnel;
- We could be unable to continue to make public filings;
- We will be de-listed from the American Stock Exchange; and
- Our licenses for our SMaRT Replacement Therapy<sup>™</sup> technology and MU 1140<sup>™</sup> technology could be terminated which would significantly harm our business.

At June 30, 2007 and December 31, 2006, we had working capital of approximately \$1,740 and \$453,576, respectively. The independent registered public accounting firm's report as of and for the year ended December 31, 2006, includes an explanatory paragraph to their audit opinion stating that our recurring losses from operations and limited working capital raise substantial doubt about our ability to continue as a going concern. We have an operating cash flow deficit of \$1,004,487 for the six months ended June 30, 2007 and have sustained operating cash flow deficit of \$2,224,538 in 2006.

#### 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<sup>TM</sup>, Probiora<sup>3TM</sup>, MU 1140<sup>TM</sup>, LPT3-04<sup>TM</sup> and other technologies we either license or own. No assurances can be given when this will occur or that we will ever be profitable.

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

We hold our replacement therapy and Mutacin 1140 technologies under licenses from the University of Florida Research Foundation, Inc. Under the terms of the licenses, we must spend at least \$1 million per year on development of those technologies before the first commercial sale of products derived from those technologies. In addition, we must pay \$25,000 per quarter as minimum royalties to the University of Florida Research Foundation, Inc. under our license agreements. If we do not, our licenses on these technologies could be terminated. We also

hold a license for our IVIAT and CMAT technologies from iviGene Corporation, which required us to either fund two full time resources or invest \$200,000 annually toward development of these technologies. Until commercial sales of any developed products take place, we will not be earning revenues from the sale of products and will, therefore, have to raise the money we must spend on development of our technologies by other means, such as the sale of our common stock. There is no assurance we will be able to raise the financing necessary to meet our obligations under our licenses. If we cannot, we may lose our licenses to these technologies and have to cease operations.

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

#### We must spend at least \$1 million annually on development of our SMaRT Replacement Therapy<sup>TM</sup> and MU 1140<sup>TM</sup> 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<sup>TM</sup> and MU 1140<sup>TM</sup> 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<sup>TM</sup> technology and our MU 1140<sup>TM</sup> 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<sup>TM</sup> 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<sup>™</sup> technology has been granted clearance to begin Phase 1 human clinical trials by the FDA. Clinical trials on our SMaRT Replacement Therapy<sup>™</sup> are expected to take several years to fully complete. Our other drug technologies have not been cleared for testing in humans. Our drug technologies have not been cleared for marketing by the FDA or foreign regulatory authorities and they will not be able to be commercially distributed in the United States or any international markets until such clearances are obtained. Before regulatory approvals can be obtained, our drug technologies will be subject to extensive preclinical and clinical testing. These processes are lengthy and expensive. We cannot assure that such trials will demonstrate the safety or effectiveness of our drug technologies. There is a possibility that our drug 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<sup>™</sup> or fail to obtain FDA clearance for our other drug technologies, we may have to cease operations.

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

All of our product candidates are in the early development stage. Although we have current data which indicates the promise of the concept of our SMaRT Replacement Therapy<sup>TM</sup>, Probiora3<sup>TM</sup>, MU 1140<sup>TM</sup> and LPT3-04<sup>TM</sup> 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<sup>TM</sup>, Probiora3<sup>TM</sup>, MU 1140<sup>TM</sup> and LPT3-04<sup>TM</sup> technologies are based may also fail due to flaws or inaccuracies on which the data are based, or because the data are totally or partially incorrect, or not predictive of future results. If our science proves to be flawed, incorrect or otherwise fails, we will not be able to create a marketable product or generate revenues and we may have to cease operations.

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

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

## Each of the technologies we are developing toward the goal of 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, 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<sup>TM</sup> technology will be less effective in humans than it has been shown to be in animals. It is possible our MU 1140<sup>TM</sup> (Mutacin 1140) technology will be shown to be ineffective or harmful in humans. If any of these technologies are shown to be ineffective or harmful in humans, we will be unable to generate revenues from them, and we may have to cease operations.

To date the testing of our SMaRT Replacement Therapy<sup>TM</sup> 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<sup>TM</sup> 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 (MU 1140<sup>TM</sup>) 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 fermentation-based 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 may 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. We are also attempting to develop our proprietary DPOLT<sup>™</sup> synthetic chemistry technology in order to evaluate the possibility of making large-scale batches of MU1140<sup>™</sup> using this process. However, if we are not able to optimize either of these methodologies, we will be unable to generate revenues from this technology and we may have to cease operations.

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

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

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

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

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

perceived defects in the design of the clinical trials and changes in regulatory policy during the period of product development. Any delays in, or termination of, our clinical trials will materially and adversely affect our development and commercialization timelines, which would adversely affect our business and cause our stock price to decline and may cause us to cease operations.

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

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

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

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

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

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

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

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

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

#### 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 are to be exported may not approve them for import.

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

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

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

The commercial success of our SMaRT Replacement Therapy<sup>TM</sup>, Probiora3<sup>TM</sup>, MU 1140<sup>TM</sup>, LPT3-04<sup>TM</sup> 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 demonstrate positive outcomes and reduced utilization of other products or services as well as cost data which show that treatment costs using the new product are equal to or less than what is currently covered for other products. If we are unable to obtain favorable third party reimbursement and patients are unwilling or unable to pay for our products out-of-pocket, it could limit our revenue and harm our business.

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

We are evaluating our internal controls in order to allow management to report on, and our independent registered public accounting firm to attest to, our internal controls, as required by Section 404 of the Sarbanes-Oxley Act of 2002. We may encounter unexpected delays in implementing the requirements relating to internal controls, therefore, we cannot be certain about the timing of completion of our evaluation, testing and remediation actions or the impact that these activities will have on our operations. We also expect to incur additional expenses and diversion of management's time as a result of performing the system and process evaluation, testing and remediation required in order to comply with the management certification and auditor attestation requirements.

We are a small company with limited resources that will make it difficult for us to comply with the requirements of Section 404 in a timely fashion. If we are not able to comply with the requirements set forth in Section 404, we might be subject to sanctions or investigation by regulatory authorities or delisted. 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**

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

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

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

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

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

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

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

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



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

The market price of our common stock has been and is expected to continue to be highly volatile. Factors, including announcements of technological innovations by us or other companies, regulatory matters, new or existing products or procedures, concerns about our financial position, operating results, litigation, government regulation, developments or disputes relating to agreements, patents or proprietary rights, may have a significant impact on the market price of our stock. In addition, potential dilutive effects of future sales of shares of common stock by us and by stockholders, including Fusion Capital, upon the exercise 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 September 2007 our stock price has fluctuated from \$5.00 to \$0.32 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 September 14, 2007, there were 28,002,443 shares of our common stock outstanding, with another 1,577,500 shares of common stock issuable upon the exercise of warrants to investors, and an additional 1,560,000 shares available for issuance under our stock option plans. The issuance of 3,000,000 shares of our stock underlying stock options is covered by an S-8 registration statement we filed with the SEC and may be resold into the market. We have filed registration statements covering the resale of restricted common stock acquired from us in private placements and the shares of common stock able to be acquired upon the exercise of warrants issued in connection with such private placements. In addition, the shares of restricted common stock sold in private placements that are held by non-affiliates for two years may be resold into the market under Rule 144(k). Sales of the shares pursuant to the registration statements or Rule 144 (k) could cause the market price of our common stock to drop significantly.

#### **Risk Factors Relating to this Offering**

The sale of shares by the selling stockholders as contemplated by the registration statement filed by us may encourage our other shareholders to sell their stock and have an adverse impact on the market price of our common stock and the issuance of shares upon exercise of the warrants will result in dilution to our existing shareholders.

The sale of our common stock by the selling stockholders named in the registration statement we filed as contemplated thereby will increase the number of our publicly traded shares, which could depress the market price of our common stock. Moreover, the mere prospect of resales by the selling stockholders as contemplated by the registration statement could depress the market price for our common stock. The issuance of any shares pursuant to any exercise of the warrants 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.

#### SPECIAL NOTE REGARDING 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 future financing plans, (b) our anticipated needs for working capital, (c) our projected sales and profitability, (d) our growth strategies and (e) anticipated trends in our industry. Forward-looking statements, which involve assumptions and describe our future plans, strategies, and expectations, are generally identifiable by use of the words "may," "will," "should," "expect," "anticipate," "estimate," "believe," "intend," or "project" or the negative of these words or other variations on these words or comparable terminology. This information may involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from the future results, performance, or achievements expressed or implied by any forward-looking statements 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.

#### **USE OF PROCEEDS**

We will not receive any proceeds from the resale of the common stock by the selling shareholders including the resale of any common shares that the warrant holders acquire upon exercise of the warrants. If the warrants for which the 4,600,000 shares that can be acquired upon exercise are covered by this registration statement are exercised in full, we would receive additional proceeds of \$2,668,000. It is uncertain when, if ever, we will receive any proceeds from the exercise of the warrants.

#### SELLING SHAREHOLDERS

The following table presents information regarding the selling shareholders. Other than as set forth below, neither the selling shareholders 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 28,002,443 shares issued and outstanding at September 14, 2007. The percentage of shares beneficially owned after the offering assumes the resale by the selling shareholder of all of the shares covered by this registration statement, including the shares able to be acquired upon the exercise of the warrants and the retention of all shares beneficially owned prior to the offering.

Selling	Number of Shares of Common Stock Beneficially Owned Prior to the	Number of Shares Issuable Upon the Exercise of Warrants outstanding prior to the	Total Number of Securities Beneficially Owned Prior to the	Percentage of Shares Beneficially Owned Prior to the	Total Number of Securities to be sold in the	Number of Shares Beneficially Owned After the	Percentage of Shares Beneficially Owned After the
Stockholders	Offering	Offering(1)	Offering(1)	Offering (1)	Offering(1)	Offering	Offering
George T. Hawes (2)	4,688,267	1,687,500	6,375,767	21.5%	2,200,00	4,175,767	14.35%
Meghan McAlister (3)	600,000	600,000	1,200,000	4.2%	1,200,000	0	*
Kelly Leaird (4)	804,240	686,364	1,490,604	5.2%	1,372,728	117,876	*
D.A.W Investments (5)	650,000	400,000	1,050,000	3.7%	800,000	250,000	*
William F. Matlack (6)	412,500	325,000	737,500	2.6%	400,000	337,500	1.20%
Cleo Christine Allen (7)	408,000	500,000	908,000	3.2%	800,000	108,000	*
Bernadette Berry (8)	408,500	400,000	808,500	2.8%	800,000	8,500	*
Cristina Hawes-Mohr (9)	200,000	300,000	500,000	1.8%	400,000	100,000	*
Roger Goodwin (10)	287,500	200,000	487,500	1.7%	400,000	87,500	*
William Radvak (11)	200,000	200,000	400,000	1.4%	400,000	0	*
Ronald P. Evens (12)	113,636	113,636	227,272	*	227,272	0	*
Kathleen Hawes (13)	100,000	100,000	200,000	*	200,000	0	*
	8,872,643	5,512,500	14,385,143	49.6%	9,200,000	5,185,143	

<sup>\*</sup> less than one percent

(2) George T. Hawes served on our Board of Directors from December 19, 2005 until his resignation on May 1, 2007. The shares being registered hereby include 1,100,000 shares of common stock and 1,100,000 shares of common stock able to be acquired upon the exercise of warrants at \$0.58 per share. Included in the number of shares issuable upon the exercise of warrants outstanding prior to the offering, are 587,500 shares issuable upon the exercise of warrants at \$0.60 per share which expire on March 6, 2008.

<sup>(1)</sup> Although the warrants issued by us in connection with the private placement transaction, discussed below, are not currently exercisable because they do not vest until six months after the private placement transaction, the shares able to be acquired upon exercise of such warrants have been included in the table as being beneficially owned. In calculating amounts beneficially owned prior to and after the offering the exercise in full of all outstanding warrants is assumed.

- (3) The shares being registered hereby include 600,000 shares of common stock and 600,000 shares of common stock able to be acquired upon the exercise of warrants at \$0.58 per share. Of the shares not included in this registration statement, 600,000 shares are issuable upon the exercise of warrants at \$0.60 per share by March 6, 2008.
- (4) The shares being registered hereby include 686,364 shares of common stock and 686,364 shares of common stock able to be acquired upon the exercise of warrants at \$0.58 per share.
- (5) The shares being registered hereby include 400,000 shares of common stock and 400,000 shares of common stock able to be acquired upon the exercise of warrants at \$0.58 per share.
- (6) The shares being registered hereby include 200,000 shares of common stock and 200,000 shares of common stock able to be acquired upon the exercise of warrants at \$0.58 per share. Included in the number of shares issuable upon the exercise of warrants outstanding prior to the offering, are 125,000 shares issuable upon the exercise of warrants at \$0.60 per share which expire on March 6, 2008.
- (7) The shares being registered hereby include 400, 000 shares of common stock and 400, 000 shares of common stock able to be acquired upon the exercise of warrants at \$0.58 per share. Included in the number of shares issuable upon the exercise of warrants outstanding prior to the offering, are 100,000 shares issuable upon the exercise of warrants at \$0.60 per share which expire on March 6, 2008.
- (8) The shares being registered hereby include 400,000 shares of common stock and 400,000 shares of common stock able to be acquired upon the exercise of warrants at \$0.58 per share.
- (9) The shares being registered hereby include 200, 000 shares of common stock and 200, 000 shares of common stock able to be acquired upon the exercise of warrants at \$0.58 per share. Included in the number of shares issuable upon the exercise of warrants outstanding prior to the offering, are 100,000 shares issuable upon the exercise of warrants at \$0.60 per share which expire on March 6, 2008.
- (10) The shares being registered hereby include 200,000 shares of common stock and 200,000 shares of common stock able to be acquired upon the exercise of warrants at \$0.58 per share.
- (11) The shares being registered hereby include 200,000 shares of common stock and 200,000 shares of common stock able to be acquired upon the exercise of at \$0.58 per share.
- (12) Dr. Evens is a director and has served on our Board of Directors since June 15, 2007. The shares being registered hereby include 113,636 of common stock which were purchased at market value of \$0.44 and 113,636 shares of common stock to be acquired upon exercise of warrants at \$0.58 per share. Excluded from Dr. Evens ownership of common stock and warrants is 65,000 shares issuable upon the exercise of options at \$0.53 per share he received upon becoming a member of our Board.
- (13) The shares being registered hereby include 100,000 shares of common stock and 100,000 shares of common stock able to be acquired upon the exercise of warrants at \$0.58 per share. Ms. Hawes is the spouse of George Hawes.

#### **Private Placement Transaction**

On August 7, 2007, our Securities Purchase Agreement with accredited investors, including our new director, Dr. Ronald P. Evens, became binding and we closed on \$1,171,591 in equity based financing. We issued a total of 4,600,000 shares of restricted common stock in the private placement. The shares were sold to accredited investors at \$0.25 per share, except that per AMEX requirements, Dr. Evens acquired his shares at \$0.44 per share, which was the closing share price on August 7, 2007. Each participating investor, including Dr. Evens, also received warrants to purchase shares of common stock at the price of \$0.58 per share. One warrant was issued for each share of common stock issued for a total of up to 4,600,000 shares that may be acquired upon exercise of the warrants.

The warrants become exercisable in six months and expire August 8, 2008 which is one year from the date of issuance. The private placement offering and sale of the common stock and warrants was made in reliance upon the exemption from registration provided by Section 4(2) of the Securities Ace of 1933 as a transaction by the issuer not involving a public offering. We incurred estimated costs of approximately \$75,000 in the private placement transaction resulting in net proceeds of approximately \$1,096,591. We intend to use the net proceeds of the private placement, including any proceeds from exercise of the warrants, for working capital and general corporate purposes. While management is encouraged by the aforementioned financing, the proceeds are insufficient, alone, to regain final compliance with AMEX listing requirements. We have until October 27, 2008 to regain AMEX compliance but there can be no assurance that we will be able to do so.

In connection with the Securities Purchase Agreement we also entered into a Registration Rights Agreement with each of the accredited investors. The Registration Rights Agreement requires that we file this registration statement covering the resale of the shares of the common stock issued and the shares able to be acquired upon exercise of the warrants.

#### PLAN OF DISTRIBUTION

We are registering the shares of common stock and the shares of common stock issuable upon exercise of the warrants to permit the resale of these shares of common stock by the holders from time to time after the date of this prospectus. The selling shareholders and any of their pledgees, assignees, donees and successors-in-interest may, from time to time, sell any or all of their resale shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling shareholder may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker dealer solicits purchasers;
- block trades in which the broker dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker dealer as principal and resale by the broker dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the date of this prospectus;
- broker dealers may agree with the selling shareholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise; or
- any other method permitted pursuant to applicable law.

The selling shareholders may also sell shares under Rule 144 under the Securities Act of 1933, as amended (the "Securities Act"), if available, rather than under this prospectus.

Broker dealers engaged by the selling shareholders may arrange for other brokers dealers to participate in sales. Broker dealers may receive commissions or discounts from the selling shareholders (or, if any broker dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. Each selling shareholder does not expect these commissions and discounts relating to the sale of shares to exceed the amount that is customary in the types of transactions involved.

In connection with the sale of our common stock or interests therein, the selling shareholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling shareholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling shareholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling shareholders and any broker dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling shareholder has informed the Company that it does not have any agreement or understanding, directly or indirectly, with any person to distribute the Common Stock.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the shares. The Company has agreed to indemnify the selling shareholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because selling shareholders may be deemed to be "underwriters" within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. Each selling shareholder has advised us that they have not entered into any agreements, understandings or arrangements with any underwriter or broker-dealer regarding the sale of the resale shares. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling shareholders.

We agreed to keep the registration statement of which this prospectus is part effective until the earlier of (i) the date on which the shares may be resold by the selling shareholders without volume restrictions pursuant to Rule 144(k) or (ii) all of the shares have been sold pursuant to the registration statement of which this prospectus is part or Rule 144 under the Securities Act or any other Rule of similar effect. The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to our common stock for a period of two business days prior to the commencement of the distribution. In addition, the selling shareholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of our common stock by the selling shareholders or any other person. We will make copies of this prospectus available to the selling shareholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

#### LEGAL MATTERS

Certain legal matters with respect to the securities offered through this prospectus will be passed upon for us by Shumaker, Loop & Kendrick, LLP.

#### EXPERTS

The financial statements of Oragenics, Inc. as of December 31, 2006 and for the years ended December 31, 2005 and 2006, appearing in Oragenics, Inc.'s Annual Report (Form 10-KSB) for the year ended December 31, 2006, and incorporated by reference in this Prospectus and Registration Statement, have been audited by Kirkland Russ Murphy & Tapp, PA, 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 incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

#### INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to "incorporate by reference" into this prospectus information we file with them, which means that we are disclosing important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede previously filed information, including information contained in this document. We incorporate by reference the documents listed below and any future filings we will make with the SEC, including filings after the date of the initial registration statement and prior to effectiveness of the registration statement, under Sections 13 (a), (c), 14 or 15(d) of the Securities and Exchange Act of 1934, as amended, until this offering has been completed:

- Our Annual Report on Form 10-KSB for the year ended December 31, 2006 filed on March 23, 2007.
- Our Definitive Proxy Statement, filed on April 27, 2007.
- Our Quarterly Reports on Form 10-QSB for the quarter ending March 31, 2007 and June 30, 2007 filed May 11, 2007 and August 13, 2007, respectively.
- Our Current Reports on Form 8-K filed on January 16, 2007, February 15, 2007, April 27, 2007, May 2, 2007, May 7, 2007, June 6, 2007 and June 20, 2007.
- The description of our common stock contained in the registration statement on Form 8-A No. 001-32188 filed with the SEC on May 19, 2004 under Section 12(b) of the Exchange Act, including any amendment or report filed for the purpose of updating such description.

You may obtain free copies of these filings and other documents incorporated by reference in this prospectus by requesting them in writing or by telephone from us at the following address:

Oragenics, Inc. 13700 Progress Boulevard Alachua, Florida 32615 Attention: Chief Financial Officer (386) 418-4018 X232

If you request any incorporated documents from us, we will mail them to you by first-class mail, or another equally prompt means, within one business day after we receive your request.

#### WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission (the "Commission") a registration statement on Form S-3 under the Securities Act relating to the shares of common stock that may be offered by the selling stockholders. This prospectus is included as a part of that registration statement and we have omitted from this prospectus additional information contained in the registration statement as provided by the rules and regulations of the SEC. For further information about us and the securities offered in this prospectus, you should review the registration statement and information incorporated by reference therein.

We file annual, quarterly and current reports, proxy statements and other information with the Commission under the Securities Exchange Act of 1934, as amended ("Exchange Act"). You may read and copy this information at the following location of the Commission:

Public Reference Room 100 F Street, N.E., Room 1580 Washington, D.C. 20549

You may also obtain copies of this information by mail from the Public Reference Room of the Commission, 100 F Street, N.E., Room 1580, Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the Public Reference Room by calling the Commission at 1-800-SEC-0330.

The Commission also maintains a website that contains reports, proxy statements and other information about issuers, like us, who file electronically with the Commission. Our SEC filings are also available to you free of charge at the SEC's web site. The address of that site is <u>http://www.sec.gov</u>.

#### 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.