

PROSPECTUS

# ORAGENICS, INC.

## 4,109,689 Shares of Common Stock

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

Our common stock is quoted on the American Stock Exchange under the symbol "ONI." On June 15, 2007, the last reported sale price for our common stock as reported on the American Stock Exchange was \$0.53 per share.

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**Investing in the common stock involves certain risks. See "[Risk Factors](#)" beginning on page 4 for a discussion of these risks.**

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

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**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.**

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The date of this Prospectus is July 2, 2007.

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

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

## PROSPECTUS SUMMARY

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

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

We are in need of substantial additional funds in order to continue the development of our technologies. We are continuing to seek additional funding. We currently do not have any commitments for funding or other strategic options pending and there can be no assurances that we will be able to obtain funding or implement any strategic options in the future. Since the fourth quarter 2005, we deferred partial payments to our Chief Executive Officer and President, Chief Scientific Officer, Board of Directors and Audit Committee members, and our former chief executive officer and president. Through employee attrition we have reduced our full time staff even though we have hired one R&D employee as a Senior Research Chemist. As we move into more advanced stages concerning our products and their testing, our monthly 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 March 31, 2007 was \$468,697 and is insufficient to enable us to continue to operate through the third quarter of 2007. While we believe additional capital may become available through grants or through possible future exercises of outstanding warrants, there can be no assurance of the same. In the event adequate capital is not raised we would likely need to cease all operations until we are able to raise additional capital. We have a contractual obligation to pay a minimum royalty of \$25,000 quarterly and spend or cause to be spent an aggregate of \$1,000,000 annually toward research, development and regulatory prosecution, in order to maintain our license with the University of Florida Research Foundation, Inc. for SMaRT Replacement Therapy™ and MU 1140™ (Mutacin 1140) technologies. While we believe we have met our obligations under the license agreement to date, if we are unable to make future payments, our license could be terminated which will substantially diminish the value of our company.

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. The Warning Letter provided that we had until August 2, 2007 to regain compliance. We submitted a plan on May 24, 2007 to AMEX for regaining compliance with all of the continued listing standards, which included our expectation of appointing an independent director within sixty days to fill the vacancy left by Mr. Hawes' departure. 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. With the appointment of Dr. Evens to the Board, the Company believes it is now in compliance with AMEX's listing standards regarding the number of independent directors.

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

**SMaRT Replacement Therapy™** is a single, painless one time topical treatment that has the potential to offer lifelong protection against dental caries (tooth decay). The therapy is based on genetically altering the bacterium, *Streptococcus mutans* (*S. mutans*), which is the primary etiologic agent in tooth decay. We are in Phase I clinical trials and expect to partner with a major healthcare products or pharmaceutical company prior to initiating Phase III clinical trials.

**MU 1140™ (Mutacin 1140)** is a highly potent bactericidal peptide that is produced by our strain of *Streptococcus mutans*. We developed a proprietary manufacturing process for MU 1140™ and are now refining the process so that sufficient quantities can be produced to allow us to conduct preclinical studies needed to enable the filing of an Investigational New Drug (IND) application.

**Probiora3™ (Probiotics)** consists of 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.

**IVIAT™ and CMAT™** are technologies that enable the simple, fast identification of novel and potentially important gene targets associated with the natural onset and progression of infections, cancers and other diseases in humans and other living organisms, including plants.

**LPT3-04™** 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™ is orally available and we believe it has an excellent safety and tolerability profile.

**DPOLT™** (Differentially Protected Orthogonal Lantionine Technology) is a solid phase peptide synthesis platform technology that has broad application for the cost-effective manufacture of a number of commercially important bioactive peptides, including our lead antibiotic, MU1140™.

## **Business Objectives**

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.

## **About Us**

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

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### **The Offering**

We entered into a common stock purchase agreement with Fusion Capital Fund II, LLC (Fusion Capital) on May 23, 2005, pursuant to which Fusion Capital agreed, under certain conditions, to purchase on each trading day \$15,000 of our common stock up to an aggregate of \$9.0 million over a 30 month period. In our discretion, we may elect to sell more of our common stock to Fusion Capital than the minimum daily amount if our share price is \$2.20 or higher. The purchase price of the shares of common stock will be based upon the future market price of the common stock without any fixed discount to the market price. Fusion Capital does not have the right or the obligation to purchase shares of our common stock in the event that the price of our common stock is less than \$0.75.

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

As of May 15, 2007, there were 23,202,443 shares outstanding, including the 315,421 shares that we issued to Fusion Capital as compensation for its purchase commitment, but excluding the 3,794,268 shares offered by Fusion Capital pursuant to this prospectus which it has not yet purchased from us. If all of the 3,794,268 shares (which are presently not outstanding) included in the shares offered by this prospectus were issued and outstanding as of the date hereof, they would represent 14.05% of the total common stock outstanding (including the 3,794,268 in the shares outstanding.)

## RISK FACTORS

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

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

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

We do not have sufficient capital to sustain our operations through the third 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™ technology and MU 1140™ technology could be terminated which would significantly harm our business.

At March 31, 2007 and December 31, 2006, we had working capital of approximately \$468,697 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 \$410,533 for the three months ended March 31, 2007 and have sustained operating cash flow deficits of \$2,224,538 in 2006 and \$3,434,382 in 2005. Our ability to obtain additional funding will determine our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

We have yet to establish any history of profitable operations. Our limited revenues to date have not been related to the commercialization or licensing of our products and have not been sufficient to sustain our operations. We expect that our revenues will not be sufficient to sustain our operations for the foreseeable future. Our profitability will require the successful commercialization of our SMaRT Replacement Therapy™, Probiora3™, MU 1140™, LPT3-04™ and other technologies we either license or own. No assurances can be given when this will occur or that we will ever be profitable.

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

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

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

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

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

In the event that we decide to issue more than approximately 2,900,000 shares, we would first be required to seek stockholder approval in order to be in compliance with American Stock Exchange rules. We have issued 315,421 shares to Fusion Capital as a commitment fee and 205,732 shares pursuant to the common stock purchase agreement and accordingly may issue up to 2,378,847 shares to Fusion Capital before we would be required to seek stockholder approval in order to be in compliance with American Stock Exchange rules. Assuming a minimum purchase price of \$0.75 per share and the purchase by Fusion Capital of 2,378,847 shares under the common stock purchase agreement, proceeds to us would only be \$1,784,135, unless we elect to sell more than 2,378,847 shares to Fusion Capital, which we have the right, but not the obligation, to do.

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

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

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

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

Only our SMaRT Replacement Therapy™ technology has been granted clearance to begin Phase 1 human clinical trials by the FDA. Clinical trials on our SMaRT Replacement Therapy™ are expected to take several years to fully complete. Our other new drug technologies have not been cleared for testing in humans. Our new 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 new drug technologies will be subject to extensive preclinical and clinical testing. These processes are lengthy and expensive. We cannot assure that such trials will

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demonstrate the safety or effectiveness of our technologies. There is a possibility that our technologies may be found to be unsafe or ineffective or otherwise fail to satisfy regulatory requirements. If we are unable to resolve the FDA's concerns, we will not be able to proceed further to obtain regulatory approval for that technology. If we fail to maintain regulatory clearance for our SMaRT Replacement Therapy™ or fail to obtain FDA clearance for our other new 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™, Probiora3™ and MU 1140™ and LPT3-04™ technologies, we can offer you no assurance that the technologies will be effective at a level sufficient to support a profitable business venture. If they are not, we will be unable to create marketable products, we will not generate revenues from our operations, and we may have to cease operations. The science on which our SMaRT Replacement Therapy™, Probiora3™ and MU 1140™ and LPT3-04™ technologies are based may also fail due to flaws or inaccuracies on which the data are based, or because the data are totally or partially incorrect, or not predictive of future results. If our science proves to be flawed, incorrect or otherwise fails, we will not be able to create a marketable product or generate revenues and we may have to cease operations.

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

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

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

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

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

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



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We have no “key man” life insurance policies. We have an employment agreement with Dr. Hillman, which automatically renews for one-year terms unless 90 days written notice is given by either party.

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

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

To date the testing of our SMaRT Replacement Therapy™ technology has been undertaken solely in animals and a limited number of humans. Studies have proven our genetically altered strain of *S. mutans* to be effective in preventing tooth decay in animals. It is possible that our strain of *S. mutans* will be shown to be less effective in preventing tooth decay in humans in clinical trials. If our SMaRT Replacement Therapy™ technology is shown to be ineffective in preventing tooth decay in humans, we will be unable to commercialize and generate revenues from this technology. To date the testing of the antibiotic substance, Mutacin 1140 has been undertaken solely in the laboratory and in animals. We have not yet conducted human studies of Mutacin 1140. It is possible that when these studies are conducted, they will show that Mutacin 1140 is ineffective or harmful. If Mutacin 1140 is shown to be ineffective or harmful, we will be unable to commercialize it and generate revenues from sales of Mutacin 1140. If we are unable to generate revenues from our technologies, we may have to cease operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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From time to time, legislative or regulatory proposals are introduced that could alter the review and approval process relating to our technologies. It is possible that the FDA will issue additional regulations further restricting the sale of our proposed drug 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 drug products based on our technologies, or to produce, market, and distribute such products if approved.

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

The commercial success of our SMaRT Replacement Therapy™, ProBiora3™, MU 1140™, LPT3-04™ and other technologies will depend in part on government and public acceptance of their production, distribution and use. Biotechnology has enjoyed and continues to enjoy substantial support from the scientific community, regulatory agencies and many governmental officials in the United States and around the world. Future scientific developments, media coverage and political events may diminish such support. Public attitudes may be influenced by claims that health products based on biotechnology are unsafe for consumption or pose unknown risks to the environment or to traditional social or economic practices. Securing governmental approvals for, and consumer confidence in, such products poses numerous challenges, particularly outside the United States. The market success of technologies developed through biotechnology such as ours could be delayed or impaired in certain geographical areas because of such factors. Products based on our technologies may compete with a number of traditional dental therapies and drugs manufactured and marketed by major pharmaceutical companies and other biotechnology companies. Market acceptance of products based on our technologies will depend on a number of factors including potential advantage over alternative treatment methods. We can offer you no assurance that dentists, physicians, patients or the medical and dental communities in general will accept and utilize products developed from our technologies. If they do not, we may be unable to generate sufficient revenues from our technologies, which may cause us to have to cease operations.

***We may be exposed to product liability claims 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 new drug products based on our technologies, it could limit our revenue.***

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

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

We are evaluating our internal controls in order to allow management to report on, and our independent registered public accounting firm to attest to, our internal controls, as required by Section 404 of the Sarbanes-Oxley

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

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

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

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

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

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

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

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

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

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

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

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

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

Historically, the daily trading volume of our common stock has been relatively low. We cannot guarantee that an active public market for our common stock will be sustained or that the average trading volume will remain at present levels or increase. In addition, the stock market in general, has experienced significant price and volume fluctuations. Volatility in the market price for particular companies has often been unrelated or disproportionate to the operating performance of those companies. Broad market factors may seriously harm the market price of our common stock, regardless of our operating performance. In addition, securities class action litigation has often been initiated following periods of volatility in the market price of a company's securities. A securities class action suit against us could result in substantial costs, potential liabilities, and the diversion of management's attention and resources. Since our initial public offering in June 2003 and through June 2007 our stock price has fluctuated from \$5.00 to \$0.34 per share. To the extent our stock price fluctuates and/or remains low, it could impair our ability to raise capital through the offering of additional equity securities.

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

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur. In addition, these factors could make it more difficult for us to raise funds through future offerings of common stock. As of May 15, 2007, there were 23,202,443 shares of our common stock outstanding, with another 1,577,500 shares of common stock issuable upon exercise of warrants to investors, 1,330,000 shares issuable upon exercise of options issued and an additional 1,670,000 shares available for issuance under our stock option plans. The issuance of 1,000,000 shares of our stock underlying these options is covered by an S-8 registration statement we filed with the SEC and may be resold into the market following exercise. The shares of common stock held in escrow pursuant to Canadian law and underwriter requirements in connection with our initial public offering pursuant to escrow agreements were released as of June 30, 2006 and the escrow arrangement was concluded in accordance with its terms. Released shares may be resold into the market under Rule 144. This could cause the market price of our common stock to drop significantly.

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

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

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. The Warning Letter provided that we had until August 2, 2007 to regain compliance. We submitted a plan on May 24, 2007 to AMEX for regaining compliance with all of the continued listing standards, which included our expectation of appointing an independent director within sixty days to fill the vacancy left by Mr. Hawes’ departure. 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. With the appointment of Dr. Evens to the Board, the Company believes it is now in compliance with AMEX’s listing standards regarding the number of independent directors.

There can be no assurance that we will be able to locate and appoint an independent director candidate to replace Mr. Hawes within the time period provided by AMEX. If we do not regain compliance with the AMEX listing standards, we will be subject to delisting proceedings.

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

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- that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

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

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

### **FORWARD-LOOKING STATEMENTS**

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



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**USE OF PROCEEDS**

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

**MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS**

Our common stock began trading on the American Stock Exchange under the symbol ONI on May 20, 2004. The following sets forth the high and low sales prices for the common stock on the American Stock Exchange for each quarter in the last two fiscal years.

Period	2007		2006		2005	
	High	Low	High	Low	High	Low
First quarter	\$1.20	\$0.73	\$0.61	\$0.34	\$4.00	\$1.59
Second quarter			\$1.50	\$0.48	\$2.40	\$1.59
Third quarter			\$0.91	\$0.57	\$1.85	\$1.15
Fourth quarter			\$1.45	\$0.60	\$1.00	\$0.40

On June 15, 2007, the closing bid price of the common stock, as reported by the American Stock Exchange, was \$0.53. As of April 12, 2007, there were approximately 41 registered holders of our common stock according to our transfer agent. The number of record holders does not reflect the number of beneficial owners of the common stock for whom shares are held by banks, brokerage firms and others.

**Dividends**

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

## THE FUSION CAPITAL FUND TRANSACTION

### General

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

To date Fusion Capital acquired an aggregate of 205,732 shares from us and we received proceeds of approximately \$200,000. Fusion Capital is offering for sale up to 4,109,689 shares of our common stock consisting of (i) 315,421 shares that we previously issued to Fusion Capital in connection with its purchase commitment, and (ii) up to 3,794,268 shares, which represents the balance of up to 4,000,000 shares we originally were authorized to sell to Fusion Capital. If all of such 4,109,689 shares were issued and outstanding as of the date hereof, the 4,109,689 shares would represent 15.0% of our total outstanding common stock. The number of shares ultimately offered for sale by Fusion Capital is dependent upon the number of shares purchased by Fusion Capital under the common stock purchase agreement.

### Purchase Of Shares Under The Common Stock Purchase Agreement

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

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

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

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

<u>Assumed Average Purchase Price</u>	<u>Number of Shares to be Issued if Full Purchase</u>	<u>Percentage of Outstanding After Giving Effect to the Issuance to Fusion Capital<sup>(1)</sup></u>	<u>Proceeds from the Sale of Shares to Fusion Capital Under the Common Stock Purchase Agreement</u>
\$0.75	4,000,000 <sup>(2)</sup>	14.7%	\$ 3,000,000
\$1.00	4,000,000	14.7%	\$ 4,000,000
\$2.00	4,000,000	14.7%	\$ 8,000,000
\$3.00	3,000,000	11.0%	\$ 9,000,000
\$4.00	2,250,000	8.3%	\$ 9,000,000

- (1) Based on 23,202,443 shares outstanding as of May 15, 2007 which includes the 315,421 commitment fee shares we issued to Fusion Capital together with the number of shares issuable at the corresponding assumed purchase price set forth in the adjacent column in this calculation.
- (2) The closing sale price of our common stock on May 15, 2007 was \$0.51. At the time we entered into the common stock purchase agreement, we authorized the sale to Fusion Capital of up to 4,000,000 shares of our common stock of which 205,732 have been sold to Fusion Capital. We estimate that we will issue no more than 4,000,000 shares to Fusion Capital under the common stock purchase agreement (exclusive of the 315,421 shares issued to Fusion Capital as the commitment fee). We have the right to terminate the agreement without any payment or liability to Fusion Capital at any time, including in the event that more than 4,000,000 shares are issuable to Fusion Capital under the common stock purchase agreement

### **Minimum Purchase Price**

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

### **Our Right To Suspend Purchases**

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

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### **Our Right To Increase and Decrease the Amount to be Purchased**

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

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

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

### **Events of Default**

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

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

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

### **Our Termination Rights**

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

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

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

### **No Short-Selling or Hedging by Fusion Capital**

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

### **Commitment Shares Issued to Fusion Capital**

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

### **No Variable Priced Financings**

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

## MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

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

### Overview

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

We are in need of substantial additional funds in order to continue the development of our technologies. We are continuing to seek additional funding. We currently do not have any commitments for funding or other strategic options pending and there can be no assurances that we will be able to obtain funding or implement any strategic options in the future. Since the fourth quarter 2005, we deferred partial payments to our Chief Executive Officer and President, Chief Scientific Officer, Board of Directors and Audit Committee members, and our former chief executive officer and president. Through employee attrition we have reduced our full time staff even though we have hired one R&D employee as a Senior Research Chemist. As we move into more advanced stages concerning our products and their testing, our monthly 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 March 31, 2007 was \$468,697 and is insufficient to enable us to continue to operate through the third quarter of 2007. While we believe additional capital may become available through grants or through possible future exercises of outstanding warrants, there can be no assurance of the same. In the event adequate capital is not raised we would likely need to cease all operations until we are able to raise additional capital. We have a contractual obligation to pay a minimum royalty of \$25,000 quarterly and spend or cause to be spent an aggregate of \$1,000,000 annually toward research, development and regulatory prosecution, in order to maintain our license with the University of Florida Research Foundation, Inc. for SMaRT Replacement Therapy™ and MU 1140™ (Mutacin 1140) technologies. While we believe we have met our obligations under the license agreement to date, if we are unable to make future payments, our license could be terminated which will substantially diminish the value of our company.

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. The Warning Letter provided that we had until August 2, 2007 to regain compliance. We submitted a plan on May 24, 2007 to AMEX for regaining compliance with all of the continued listing standards, which included our expectation of appointing an independent director within sixty days to fill the vacancy left by Mr. Hawes' departure. 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. With the appointment of Dr. Evens to the Board, the Company believes it is now in compliance with AMEX's listing standards regarding the number of independent directors.

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

**SMaRT Replacement Therapy™** is a single, painless one time topical treatment that has the potential to offer lifelong protection against dental caries (tooth decay). The therapy is based on genetically altering the bacterium, *Streptococcus mutans* (*S. mutans*), which is the primary etiologic agent in tooth decay. Present in the normal flora of the mouth, *Streptococcus mutans* converts dietary sugar to lactic acid; the lactic acid, in turn, causes the erosion of tooth enamel that results in the destruction of the tooth surface and eventually the entire tooth. SMaRT Replacement Therapy™ permanently replaces resident acid producing *Streptococcus mutans* with a patented genetically engineered strain of *Streptococcus mutans* that does not produce lactic acid. Applied topically to tooth surfaces with a swab, the therapy requires only one application. We have begun Phase I clinical trials and expect to partner with a major healthcare products or pharmaceutical company prior to initiating Phase III clinical trials. To facilitate further patient recruitment in our Phase I clinical trial, we opened an additional clinical site in June 2005, however, we had very limited patient enrollment through December 31, 2005 due to the rigorous requirements for enrollment imposed upon us by the FDA. In January 2006, we concluded this study, 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 do not anticipate instituting a second Phase I clinical study until such time as the FDA approves our protocol changes for the study. We remain committed to complete the human safety study of SMaRT Replacement Therapy™ in a manner that is satisfactory to the FDA. Should the FDA approve our re-submitted protocol, we estimate the cost in the third quarter of 2007 will be approximately \$500,000 subject to available funding.

**MU 1140™ (Mutacin 1140)** is a highly potent bactericidal peptide that is produced by our strain of *Streptococcus mutans*. We developed a proprietary manufacturing process for MU 1140™ and are now refining the process so that sufficient quantities can be produced to allow us to conduct preclinical studies needed to enable the filing of an Investigational New Drug (IND) application. During the second quarter of 2006, we completed a significant preclinical study and demonstrated that MU 1140™ is effective in an animal infection model against *Staphylococcus aureus*. 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™.

**Probiora3™ (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™) in these markets in first half of 2008. Two sets of subjects completed our Probiora3™ human study, and we believe the results confirmed that the product is safe for human use and demonstrated a substantial effect of Probiora3™ in reducing the levels of specific disease-causing bacteria in the mouths of young, healthy adult subjects. We are continuing our efforts to seek 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™ technology.

**IVIAT™ and CMAT™** are technologies that enable the simple, fast identification of novel and potentially important gene targets associated with the natural onset and progression of infections, cancers and other diseases in humans and other living organisms, including plants. These technologies offer the potential to generate and develop a number of product candidates for future out-licensing to corporate partners, particularly in the area of cancer and 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

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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 Phase I grant for approximately \$100,000 has a start date of May 1, 2007.

**LPT3-04™** 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™ 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™** (Differentially Protected Orthogonal Lantionine Technology) is a solid phase peptide synthesis platform technology that has broad application for the cost-effective manufacture of a number of commercially important bioactive peptides. Lantibiotics, including our lead antibiotic, MU1140™, are a potentially important class of antibiotics, and constitute a family of polycyclic peptides that are produced by bacteria, and are highly modified structurally. Many strains of medically important bacteria have become increasingly resistant to currently marketed antibiotics. Attempts to study lantibiotics for their potential usefulness as therapeutic agents have been hindered by difficulties in producing sufficiently pure material, in amounts adequate for preclinical testing. In July 2006, the Company was awarded a \$100,000 SBIR (Small Business Innovation Research) grant from the National Science Foundation to establish proof-of-principal for DPOLT™ and to eventually synthesize a number of novel lantibiotic analogs that may be effective in treating various infections, including ones caused by drug resistant bacteria. Longer term, we have identified approximately two dozen bioactive peptides that would represent candidates for analog synthesis by DPOLT™, for potentially improved stability or bioavailability. We filed a U.S. patent application in May 2006, covering the DPOLT™ technology.

### **Business Objectives and Milestones**

The specific goal of our business is to successfully develop, clinically test and obtain FDA approval for sales of 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™**

- Initiate second Phase I clinical safety trial.

#### **MU 1140™**

- 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.



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### **Probiora3™**

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

### **LPT3-04™**

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

### **DPOLT™**

- Pursue proof-of-principle by chemically synthesizing a selected lantibiotic.

### **IVIAT™**

- Validate gene markers for *Mycobacterium tuberculosis*.

### **CMAT™**

- 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™ and MU 1140™ 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.

### **Critical Accounting Policies**

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

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### **New Accounting Pronouncements**

In June 2006, the FASB issued FASB Interpretation No. 48, “*Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statements No. 109*” (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing a two-step method of first evaluating whether a tax position has met a more likely than not recognition threshold and second, measuring that tax position to determine the amount of benefit to be recognized in the financial statements. FIN 48 provides guidance on the presentation of such positions within a classified statement of financial position as well as on derecognition, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 was adopted by the Company effective January 1, 2007. Initial analyses indicate that the adoptions of this statement will not likely have a material effect on the Company’s future reported financial position or results of operations. As a result of the implementation of FIN 48, the Company did not recognize a change in its tax liabilities or assets as of March 31, 2007.

In September 2006, the FASB issued SFAS No. 157, “*Fair Value Measurements*”. The objective of SFAS 157 is to clarify the definition of fair value, establish a framework for measuring fair value and expand the disclosures on fair value measurements. The provisions of SFAS 157 are effective for fair value measurements made in fiscal years beginning after November 15, 2007. The adoption of this statement is not expected to have a material effect on the Company’s future reported financial position or results of operations.

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[Table of Contents](#)**Results of Operations**

	Three Months Ended	
	March 31	
	2007	2006
Revenue	\$ 33,088	\$ —
Operating expenses:		
Research and development	366,258	500,285
General and administration	217,812	364,846
Total operating expenses	584,070	865,131
Loss from operations	(550,982)	(865,131)
Other income (expense):		
Interest income	9,826	7,359
Interest expense	—	(641)
Gain on sale of property and equipment	—	2,024
Total other income, net	9,826	8,742
Net loss	\$ (541,156)	\$ (856,389)

  

	Years ended December 31	
	2006	2005
Revenue	\$ 66,176	\$ —
Operating expenses:		
Research and development	2,023,896	2,097,223
General and administration	1,004,099	1,166,854
Total operating expenses	3,027,995	3,264,077
Loss from operations	(2,961,819)	(3,264,077)
Other income (expense):		
Interest income	24,931	41,875
Interest expense	(855)	(29,176)
Gain on sale of property and equipment	2,024	—
Total other income (expense), net	26,100	12,699
Net loss	\$ (2,935,719)	\$ (3,251,378)

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### ***For the Three Months Ended March 31, 2007 and 2006***

We had \$33,088 in revenues associated with an SBIR grant in the three months ended March 31, 2007 compared with no revenues in the same period in 2006. Our first quarter operating expenses continue to decrease by 32.5% to \$584,070 in the three months ended March 31, 2007 from \$865,131 in the same period in 2006. Research and development (R&D) expenses decreased 26.8% to \$366,258 in the three months ended March 31, 2007 from \$500,285 in the same period in 2006, reflected mostly by our staffing reductions approximately \$42,350, the decreased use of outside consultants for research and development, clinical trials and contract manufacturing totaling approximately \$18,368, a decrease in stock option expense of approximately \$41,000 and a reduction in our legal and patent expense of approximately \$35,300. Our only R&D expenses that increased were for rent and maintenance by approximately \$4,900. General and administration (G&A) expenses decreased 40.3% to \$217,812 in the three months ended March 31, 2007 from \$364,846 in the same period in 2006, reflecting the reduction in our staffing and the use of outside consultants approximately \$88,000, the decrease in stock option expense of approximately \$23,100, and the reduction of legal and accounting expenses of approximately \$26,800. In addition, our Board of Directors fees were reduced by approximately \$11,350 since we granted stock options in lieu of Board fees as of September 2006. The only G&A expenses to increase were rent, advertising and travel by approximately \$2,100.

Interest income increased 33.5% to \$9,826 in the three months ended March 31, 2007 from \$7,359 during the same period in 2006, reflecting the higher average cash balances maintained during most of the quarterly period in 2007. We had no interest expense in 2007 compared to an interest expense of \$641 in the first three months of 2006 that was a carryover from a note payable that was repaid in December 2005.

We incurred net losses of \$541,156 and \$856,389 during the three months ended March 31, 2007 and 2006, respectively. The decrease in our net loss of \$315,233 was principally caused by the reduction in staffing and the decreased use of outside professional consultants totaling approximately \$148,700, the reduction of stock option expenses due to forfeitures of approximately \$64,100 and reductions in legal and accounting fees of approximately \$62,100. The only expenses that increased from the same quarter in 2006, were rent and advertising, travel and maintenance, approximately \$7,000.

### ***For the Years Ended December 31, 2006 and 2005***

We had \$66,176 in revenue in the year ended December 31, 2006 as compared to none in 2005. This is a result of having a Small Business Innovation Research (SBIR) grant for our DPOLT™ technology. Our operating expenses decreased 7% to \$3,027,995 for the year ended December 31, 2006 from \$3,264,077 in 2005. Research and development expenses decreased 3.5% to \$2,023,896 in 2006 from \$2,097,223 in 2005, reflecting the reduction in research staff and their associated expenses and the fewer use of outside consultants of approximately \$763,950. This was offset by the increase of stock option compensation expense of approximately \$348,170, legal and patent expense of approximately \$251,795, depreciation expense of approximately \$21,800, the expenses for repairs and maintenance of our lab equipment of approximately \$37,700 and the increase of clinical trials expense of approximately \$14,000. We also increased our international Science Advisory Board therefore generating an increase in fees of approximately \$17,000. General and administration expenses decreased 13.4% to \$1,004,099 in 2006 from \$1,166,854 in 2005, reflected by our staff lay-offs and the associated expense and the use of fewer outside consultants was approximately \$236,900, lower professional fees and stock expense of \$116,500, lower banking and finance fees associated with financings ventures and a decrease in Board expense of approximately \$13,600. This decrease was offset by our stock option compensation expense of approximately \$278,900 and promotional and investor relations expense of approximately \$44,000.

Interest income decreased 40.5% to \$24,931 in the year ended December 31, 2006 from \$41,875 in the year ended December 31, 2005, which was a result of lower average cash balances maintained in 2006. Interest expense decreased to \$855 in 2006 from \$29,176 in 2005 reflects the total payment on our equipment loan in 2005.

Our net loss decreased 9.7% to \$2,935,719 in the year ended December 31, 2006 from \$3,251,378 in 2005. The decrease in our net loss was principally caused by our significant cut-backs in personnel and the reduction in the use of outside consultants, offset by the increase in our stock option compensation expenses, and our legal and patent expenses.

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### **Liquidity and Capital Resources**

Since our inception, we have funded our operations through the sale of equity securities in private placements and our initial public offering, the sale of equity securities and warrants in private placements, debt financings and grants.

Our operating activities used cash of \$410,533 for the three months ended March 31, 2007 and \$740,022 for the three months ended March 31, 2006. Our working capital was \$468,697 as of March 31, 2007. Cash used by operations in the three months ended March 31, 2007 resulted primarily from our net loss from operations of \$541,156. Our operating activities used cash of \$2,224,538 for the year ended December 31, 2006 and \$3,434,382 for the year ended December 31, 2005. Our working capital was \$453,576 as of December 31, 2006. Cash used by operations in the year ended December 31, 2006 resulted primarily from operating losses from operations of \$2,935,719.

No cash was provided by our investing activities for the three months ended March 31, 2007. We do not anticipate any significant spending on additional property and equipment during the remainder of 2007. Our investing activities used cash of \$7,011 for the year ended December 31, 2006 as a result from the sale of property and for the acquisition of laboratory equipment. We do not anticipate any significant spending on additional property and equipment during 2007.

Our financing activities for the three months ended March 31, 2007 provided net cash of \$459,067, which consists of \$472,500 in gross proceeds from the exercise of 787,500 warrants at \$0.60 per share. We intend to use the net proceeds for working capital and general corporate purposes. Our financing activities provided \$2,001,038 in cash for the year ended December 31, 2006, which came from four sources. In the first quarter of 2006, we issued common stock and warrants in a private placement in March 2006 that provided gross proceeds of \$600,000. Common stock warrants issued in connection with two private placements in November 2004 and December 2005 were exercised during 2006 providing funds of approximately \$1,427,000. In the second and third quarter of 2006, we issued common stock under our agreement with Fusion Capital that provided funds of \$164,999. In the fourth quarter of 2006, we issued common stock of \$200,000 in the acquisition of iviGene Corporation. Additional details of these financings are provided below:

**Private Placement, March 2006** - On March 6, 2006, we issued a total of 1,500,000 shares of our common stock and warrants to purchase 1,500,000 shares of our common stock in a private placement to accredited investors. The issuance of the shares of common stock and warrants was made pursuant to the exemptions from registration provided by Section 4(2) of the Securities Act and Regulation D promulgated thereunder. We received gross proceeds of \$600,000 in the private placement and incurred estimated costs of approximately \$75,000 resulting in net proceeds of approximately \$525,000. We intend to use the net proceeds of the private placement, including any proceeds we may receive from exercise of the warrants, for working capital and general corporate purposes. There was no underwriter or placement agent associated with this transaction. Each warrant is exercisable on or before February 8, 2008 to acquire one share of common stock at a price of \$0.60 per share. Pursuant to the terms of a registration rights agreement, dated January 6, 2006, the Company agreed to file a registration statement with the Securities and Exchange Commission covering the resale of the acquired shares in the private placement and the shares able to be acquired upon exercise of the warrants within 45 of days of the closing of the transaction.

**Private Placement, December 2005** - On December 14, 2005, we issued a total of 2,937,500 shares of our common stock and warrants to purchase 2,937,500 shares of our common stock in a private placement to accredited investors. The issuance of the shares of common stock and warrants was made pursuant to the exemptions from registration provided by Section 4(2) of the Securities Act and Regulation D promulgated thereunder. We received gross proceeds of \$1,175,000 in the private placement and incurred estimated costs of approximately \$70,000 resulting in net proceeds of approximately \$1,105,000. We intend to use the net

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proceeds of the private placement, including any proceeds we may receive from exercise of the warrants, for working capital and general corporate purposes. The warrants representing shares of common stock were exercisable by the accredited investors at any time over a two-year period at an exercise price of \$0.60 per share. Pursuant to the terms of a registration rights agreement, dated December 14, 2005, the Company agreed to file a registration statement with the Securities and Exchange Commission covering the resale of the acquired shares and the shares able to be acquired upon exercise of the warrants. The Company filed a registration statement on January 13, 2006 and it was declared effective on January 27, 2006. On January 16, 2007, we called all outstanding warrants associated with our December 2005 private financing event. A total of 1,387,500 warrants were exercised that provided \$832,500 in funds for the Company which is expected to result in the Company having sufficient funding to last through the third quarter 2007.

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

**Private Placement, November 2004** - November 30, 2004, we issued a total of 250,000 shares of our common stock and warrants to purchase 162,500 shares of our common stock in a private placement to three accredited investors and a placement agent. During the second quarter, 85,000 warrants were exercised which provided \$51,000 in funds.

During the remainder of 2007 provided adequate additional funding is obtained, we expect to spend approximately \$1,400,000 to maintain our operations and research and development, approximately \$150,000 to perform additional studies on Probiora3™ and MU1140™ and approximately \$500,000 to continue our Phase I SMaRT Replacement Therapy Clinical trial.

Our business is based on commercializing entirely new and unique technologies, and our current business plan contains a variety of assumptions and expectations that are subject to uncertainty, including assumptions and expectations about manufacturing capabilities, clinical testing cost and pricing, continuing technological improvements, strategic licensing relationships and other relevant matters. These assumptions take into account recent financings, as well as expected but currently unidentified additional financings. We have experienced losses from operations during the last two fiscal years and have an accumulated deficit of \$11,659,081 and \$12,200,237 as of December 31, 2006 and March 31, 2007, respectively. Cash used in operations for the three months ended March 31, 2007 and the twelve months of 2006 and 2005 was \$410,533, \$2,224,513 and \$3,434,382, respectively. At December 31, 2006, our principal source of liquidity was \$707,278 of cash and cash equivalents and at March 31, 2007 was \$749,733 of cash and cash equivalents. These operating results occurred while developing and attempting to commercialize and manufacture products from entirely new and unique technologies. Our business plan requires significant spending related primarily to clinical testing expenditures, as well as conducting basic research. These factors place a

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significant strain on our limited financial resources and adversely affect our ability to continue as a going concern. Our ultimate success depends on our ability to continue to raise capital for our operations.

Because of our limited available financial resources, we have continued to adopt several approaches to reduce expenditures by reducing our matching contributions for the employee retirement plan, appreciably reducing travel and other operating costs, decreasing the use of outside consultants and delaying the production of additional supplies of our SMaRT Replacement Therapy™ technology to be used in later clinical studies. As of March 31, 2007, salary payments of \$26,250 each to Jeffrey D. Hillman, our Chief Scientific Officer, and Robert T. Zahradnik, our President and Chief Executive Officer and 2005 and 2006 fees of \$34,000 to the Board of Directors and Audit Committee have been deferred. These salary payments and meeting fees were agreed to be deferred until such time as we obtain sufficient funding that payment can be made. There is no time period on the payment of the deferred amounts concerning our officers and directors. As of March 31, 2007, per our oral agreement with our former chief executive officer, we have deferred \$23,000 in severance. As part of this oral agreement, we are currently paying \$7,500 per month which is one half of the monthly amount due of \$15,000 under the separation agreement. These payments are to be concluded in July of 2007. The deferrals of payments to our former chief executive officer, current officers and directors, do not reduce our expenses, but serve to preserve our limited cash resources to the extent necessary to maintain our operations.

Our capital requirements for 2007 will depend on numerous factors, including the success of our research and development, the resources we devote to develop and support our technologies and the success of pursuing strategic licensing and funded product development relationships with external partners. Subject to our ability to raise additional capital, we expect to need to incur substantial expenditures to further develop each of our technologies including continued increases in costs related to research, preclinical testing and clinical studies, as well as significant costs associated with being a public company. Our working capital at March 31, 2007 is not adequate to meet our business objectives as presently structured. We will require substantial funds to conduct research and development and preclinical and Phase I clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase II and III clinical testing and manufacture and marketing of any products that are approved for commercial sale. We recognize that we must generate additional capital resources to enable us to continue as a going concern. Our plans include seeking financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to assure continuation of our operations and research and development programs.

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

To date, we have not obtained financing sufficient to fully support our plans going forward. Until such time as additional financing for our operations is obtained, we expect to continue to need to curtail our spending. While we continue to focus on completing the Phase I clinical trial for our SMaRT Replacement Therapy™ technology, conducting additional studies for our MU 1140™ antibiotic technology and Probiora3™, and developing strategic partners for Probiora3™, we do not have sufficient capital resources to complete these projects. As we move into more advanced stages concerning our products and their testing and development our use of cash is likely to increase accordingly. Our available working capital at March 31, 2007 and December 31, 2006 is \$468,697 \$453,576, respectively (which includes proceeds from warrants being exercised) is insufficient to enable us to continue to operate after the third quarter of 2007. While we believe additional capital may become available based upon the SBIR grant, possibly through our arrangement with Fusion Capital or through possible future exercises of outstanding warrants, there can be no assurance of the same. In the event adequate capital is not raised we will be unable to continue as a going concern and will have to cease operations.

## BUSINESS

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

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

### Our Technologies

#### SMaRT Replacement Therapy™

**SMaRT Replacement Therapy™** is a single, painless one time topical treatment that has the potential to offer lifelong protection against dental caries (tooth decay). Dental caries is a worldwide epidemic that affects the majority of populations in industrialized and developing countries. According to the World Health Organization, tooth decay is the most prevalent infectious disease, affecting approximately 5 billion people. Much of the tooth decay in low-income countries remains untreated until the teeth are extracted.

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

Our replacement therapy technology is based on genetically altering the bacterium, *Streptococcus mutans* (*S. mutans*), which is the primary etiologic agent in tooth decay and employs a genetically modified strain of *Streptococcus mutans* that does not produce lactic acid. When applied to the teeth, this non acid-producing organism displaces and permanently replaces the indigenous acid-producing strains of *Streptococcus mutans*, thereby potentially providing lifelong protection against most forms of tooth decay.

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

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



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### **Technical Background**

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

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

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

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

### **Regulatory Status**

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

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

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

We began our initial study in May 2005; however, during the remainder of 2005 we were unable to enroll a sufficient number of qualified subjects into our study. This initial study was expected to be conducted in eleven couples and an additional four unattached males at Hill Top Research in West Palm Beach, Florida and would look

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at the safety of Replacement Therapy and the potential for horizontal transmission of the Replacement Therapy organism to the non-treated member of each couple. All of the participants in the trial, according to the FDA approved protocol, were required to be without teeth, with full sets of dentures, and under the age of 55. The study required four days of pretreatment with an antibacterial rinse (chlorhexidine) to kill resident *S. mutans* in each participant's mouth. Male study subjects were to receive Replacement Therapy. The non-treated member of each couple was to be tested repeatedly to see if there was any horizontal transmission of the Replacement Therapy organism from one person to another. The investigators were to determine the genetic stability of the Replacement Therapy organism over time. Seven days after treatment, the subjects were to undergo an eradication phase of the study for one month, using the same antibacterial rinse and the withholding of a D-alanine amino acid supplement that the Replacement Therapy organism requires for its survival. Finally, the protocol required investigators to subsequently follow each study participant for three months to ensure that the eradication was effective.

On December 2, 2005, due to the enrollment of only one subject in our initial clinical study, we re-submitted a new protocol to the FDA that was less restrictive. In January 2006, we held discussions with the FDA about our problems with patient enrollment and how we could modify our protocol. The critical changes to the study are that it will be conducted in 10 patients who have teeth and the patients will be quarantined to a hospital-type setting for up to 12 days with a 2 month follow-up phase. We concluded the initial study and submitted additional proposed changes in the trial to the FDA in March 2006. We addressed additional protocol changes suggested by the FDA and filed a second re-submission July 2006. Additional protocol changes were suggested by the FDA on September 29, 2006. Protocol changes from FDA were addressed in our third re-submission submitted in February 2007. We believe these changes, if approved in a timely manner by the FDA, will allow the Company to complete the enrollment of patients and thereby complete the study by the end of 2007. We do not anticipate instituting a second Phase I clinical study until such time as the FDA approves our protocol changes for the study.

### **Preclinical Studies**

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

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

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

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

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

- Does not cause significant tooth decay in the animal test subjects;
- Persistently and preemptively colonizes the tooth surfaces of the animal test subjects;

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

### ***Intellectual Property***

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

Under the terms of the license, we have entered into an Equity Agreement with the University of Florida Research Foundation, Inc. under which we issued 599,940 shares of our common stock as partial consideration for the license. We are obligated to pay 5% of the selling price of any products developed from the licensed technology to the University of Florida Research Foundation, Inc. and, if we sublicense the license, we are obligated to pay 20% of all amounts received from the sublicensee. On December 31, 2006 and each year thereafter we are obligated to make a minimum royalty payment of \$50,000 for replacement therapy and \$50,000 for Mutacin 1140, for an aggregate of \$100,000 which is required to be paid in equal quarterly installments of \$25,000. We spent in excess of \$1,000,000 in each of 2006 and 2005 which were the minimum amounts required under our license in order to maintain it. In each future calendar year and in addition to the royalty payment obligations, we are obligated to spend, or cause to be spent, an aggregate of \$1,000,000 on the research, development and regulatory prosecution of our replacement therapy and Mutacin 1140 technologies combined, until a product which is covered wholly or partially by the claims of the patent, or is manufactured using a process which is covered wholly or partially by the claims of the patent, is sold commercially. If we fail to make these minimum expenditures, the University of Florida Research Foundation, Inc. may terminate our license.

We must also pay all patent costs and expenses incurred by the University of Florida Research Foundation, Inc. for the preparation, filing, prosecution, issuance and maintenance of the patent. In 2003, upon our having received external funding exceeding \$1 million, we reimbursed the university \$100,000 of the initial \$105,000 they paid for patent prosecution. We have agreed to indemnify and hold the University of Florida Research Foundation, Inc. harmless from any damages caused as a result of the production, manufacture, sale, use, lease, consumption or advertisement of the product. Further, we are required to maintain liability insurance coverage appropriate to the risk involved in marketing the products, for which we obtained liability insurance in the amount of \$2,000,000 that expires in August, 2007. There is no assurance that we can obtain continued coverage on reasonable terms.

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

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

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

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

### ***Market Opportunity***

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

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

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

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

### ***Competition***

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

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

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

### **MU 1140™ (Mutacin 1140)**

**MU 1140™ (Mutacin 1140)** is a novel antibiotic that has broad-spectrum antimicrobial activity against essentially all Gram-positive bacteria including methicillin-resistant *Staphylococcus aureus*. The antibiotic currently is in preclinical stages of development. Most clinical isolates of *Streptococcus mutans* secrete peptides, called mutacins, which exhibit antimicrobial activity against closely related streptococcal species and other Gram-positive bacteria. Research suggests that these mutacins play a key role in enabling *Streptococcus mutans* to effectively colonize the oral cavity.

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

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

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

#### ***Preclinical Studies***

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

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

During the second quarter of 2006, we completed a significant preclinical study and demonstrated that MU 1140™ is effective in an animal infection model against *Staphylococcus aureus*. We plan to continue to perform *in vitro* antimicrobial susceptibility and toxicity testing as well as more detailed animal safety and efficacy studies using MU 1140™.

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### ***Regulatory Status***

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

### ***Intellectual Property***

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

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

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

### ***Market Opportunity***

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

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

### ***Competition***

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

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

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

### **Probiora3™ (Probiotics)**

Our oral rinse probiotics' technology (**Probiora3™**) employs three natural strains of beneficial bacteria which promote oral health and inhibit the growth of harmful bacteria that cause periodontal disease and tooth decay. Probiotics are live microorganisms that confer a health benefit to their host when administered in adequate amounts. In probiotic therapy, beneficial microorganisms are colonized in areas normally colonized by pathogens. By being better adapted to their ecosystem than the pathogens, these beneficial bacteria crowd out harmful bacteria and inhibit colonization and growth of the disease-causing pathogens. Examples of common probiotic applications are the use of yogurt containing live cultures to improve digestion, immune system response, and vaginal and urinary tract health

The oral cavity provides an ecological niche for 400-500 bacterial species, some of which are responsible for periodontal disease (gum disease) and dental caries (tooth decay). Of all of the bacteria normally residing in a person's mouth, only about half a dozen are the primary cause of periodontal disease and dental caries.

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

Through our research, we have developed a probiotic product (**Probiora3™**) containing three natural strains of beneficial bacteria that promote oral health and provide significant protection against the causative organisms of periodontal disease and dental caries. The three bacterial strains are *Streptococcus oralis* and *Streptococcus uberis* for the maintenance of periodontal health and *Streptococcus rattus* for the maintenance of dental health.

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

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

#### ***Preclinical Studies***

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

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

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

### ***Clinical Studies***

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

### ***Regulatory Status***

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

### ***Intellectual Property***

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

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

Manufacturing methods used to produce probiotic strains are the standard fermentation methods which involve culturing bacteria in large vessels and harvesting them when mature by centrifuge or filtration. These methods are relatively commonplace and readily available within the probiotics industry. We intend to seek one or more strategic partners for the manufacturing, marketing and distribution of our oral probiotic technology. Companies have indicated their intent to enter into licenses discussions with us. We are continuing to pursue potential regional and international partners in the oral care and/or food and nutritional supplement industries for the rights to the Probiora3™ technology.

### ***Market Opportunity***

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



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### **Competition**

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

### **IVIAT™ and CMAT™**

**IVIAT™ and CMAT™** are technologies that enable the simple, fast identification of novel and potentially important gene targets associated with the natural onset and progression of infections, cancers and other diseases in humans and other living organisms, including plants. On November 17, 2006, we acquired 100% of the outstanding capital stock of iviGene Corporation, in exchange for 185,186 shares of our common stock. Following this transaction, iviGene Corporation will be dissolved and its assets, which primarily consisted of one patent and two additional patent filings (patents pending) will be assigned to Oragenics. It's two novel technologies enable the simple, fast identification of novel and potentially important gene targets associated with the natural onset and progression of cancers and other diseases in humans and other living organisms, including plants. 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.

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

### **Technical Background**

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

### **Intellectual Property**

Since our acquisition of iviGene Corporation on November 17, 2006, we own the exclusive worldwide rights to these broad platform technologies in the areas of cancer and infectious diseases, as well as agricultural and other non-human uses. We believe that these proprietary technologies will position us to create significant future opportunities for Oragenics.

In December 2006 we filed a U.S. patent application covering a collection of 44 genes of *Mycobacterium tuberculosis* that are specifically induced during active infection of human patients. We believe the identification of these gene targets, utilizing IVIAT™, offers potential new tuberculosis (TB) diagnostic test to meet a critical need and could potentially serve as a basis for an effective new vaccine against tuberculosis infection.

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### **LPT3-04™**

In April 2006, we filed a U.S. patent application to protect our intellectual property rights to a small molecule weight management agent and its analogs, which we refer to as LPT3-04™. As a natural substance, LPT3-04™ is orally available and we believe it has an excellent safety and tolerability profile. While we are optimistic about the future prospects for this small molecule, we are in mid-to-late discovery stage of this research and development. There can be no assurance that a patent will be issued or that new technology will be successfully developed by us. Although we intend to continue our development efforts regarding this technology 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 management field.

### **DPOLT™**

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

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

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

### **General**

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

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

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

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

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### **Clinical Trials**

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

#### **Phase I**

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

#### **Phase II**

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

#### **Phase III**

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

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

### **Pharmaceutical Development**

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

### **New Drug Application**

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

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### **Post Marketing Surveys**

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

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

### **Competition**

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

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

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

### **Research and Development Costs**

We have spent \$2,023,896 and \$2,097,223 on research and development of our technologies in 2006 and 2005, respectively. For the three months period ended March 31, 2007 and 2006 our research and development expense was \$366,258 and \$500,285, respectively.

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

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

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**Our Employees**

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

**Description of Property**

Our administrative office and laboratory facilities are located at 13700 Progress Boulevard, Alachua, Florida 32615. We began leasing this property pursuant to a five-year operating lease in November 2004. The facility is approximately 5,300 square feet of which approximately 60% is laboratory space and the remainder is office space and common areas. The twelve months rental for 2006 was approximately \$84,130, net of insurance, taxes and utilities that are paid by us. Lease payments escalate by 3% annually. We paid approximately \$12,000 in 2005 and none in 2006 for leasehold improvements. These 2005 improvements included equipping the building with sufficient air-handling and building laboratory stations. We also spent approximately \$12,000 and \$653,000 in 2006 and 2005, respectively, for laboratory equipment to outfit our facility. We believe our facilities are sufficient for our current needs and do not expect significant purchases of property in 2007.

**LEGAL PROCEEDINGS**

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

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### MANAGEMENT

The following table and text set forth the names and ages of all directors and executive officers of our company as of May 15, 2007. The Board of Directors is comprised of only one class. All of the directors will serve until the next annual meeting of stockholders and until their successors are elected and qualified, or until their earlier death, retirement, resignation or removal. There are no family relationships between or among the directors, executive officers or persons nominated or charged by our company to become directors or executive officers. Executive officers serve at the discretion of the Board of Directors, and are appointed to serve by the Board of Directors. Also provided herein are brief descriptions of the business experience of each director and executive officer during the past five years and an indication of directorships held by each director in other companies subject to the reporting requirements under the federal securities laws.

<u>Name</u>	<u>Age</u>	<u>Position</u>
David J. Gury	68	Chairman of the Board
Ronald P. Evens	53	Director
Jeffrey D. Hillman	58	Director, Chief Scientific Officer
Robert T. Zahradnik	62	Director, Chief Executive Officer, President and , Treasurer
Dorothy J. Delfino	60	Chief Financial Officer and Secretary

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

**Ronald P. Evens. Dr. Evens** has served as Director as of June 15, 2007. He is currently President and CEO of MAPS 4 Biotec, a biotechnology consulting company in Jacksonville, Florida, and is Clinical Professor, University of Florida, College of Pharmacy. Prior to that, Dr. Evens has had a distinguished industrial career, including thirteen years at Amgen, a leading human therapeutics biotechnology company, where he served as Senior Director and Head of Professional Services. Prior to that, he spent six years at Bristol-Myers, a global pharmaceutical company, where he was Associate Director, Clinical Research & Medical Services. He has written/edited the book, "Drug & Biological Development, From Molecule to Product & Beyond" (Springer, 2007), and has served on twelve professional and medical Boards of Directors or Advisory Boards.

**Jeffrey D. Hillman.** Dr. Hillman has been our Chief Scientific Officer since November 1996 and served as Chairman of the Board of Directors from November 1996 to December 2004. From November 1991, Dr. Hillman has been a Professor in the College of Dentistry at the University of Florida in Gainesville, Florida. However, Dr. Hillman has been on leave from the University of Florida, since February 2001, in order to develop our technologies. Dr. Hillman received undergraduate training at the University of Chicago (Phi Beta Kappa), and his D.M.D. degree (cum Laude) from the Harvard School of Dental Medicine and his Ph.D. from Harvard University Medical School. He has authored or co-authored more than 100 publications and textbook chapters on subjects related to infectious diseases, including the etiology and prevention. He has also worked extensively in the area of novel antibiotics. He is the inventor or co-inventor of Orogenics' technologies, including the platform technologies to identify targets for the development of new vaccines and diagnostic tests for a wide variety of infectious diseases and cancer.

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**Robert T. Zahradnik.** Dr. Zahradnik has been our President and Chief Executive Officer since September 2005. In addition in the past Dr. Zahradnik serves as our Treasurer. Dr. Zahradnik has served as a member of our Board of Directors since November 1996, except for the period between July 2005 and January 2006. During that period Dr. Zahradnik resigned from the Board so we would satisfy regulatory requirements with regards to independent directors. Dr. Zahradnik was appointed back on the Board to fill the vacancy left by our former chief executive officer and director. From July 2000 until its merger with Orogenics in November 2006, Dr. Zahradnik was a Director of IviGene Corporation, Alachua, Florida. IviGene was engaged in the business of developing vaccines and therapeutics. From September 1999 to June 2005, Dr. Zahradnik was general manager of ProHealth, Inc., Batesville, Arkansas. ProHealth, Inc. is a manufacturer of nutritional supplements and household and skin care products. From February 1993 to June 2005, Dr. Zahradnik was a partner and general manager of Professional Dental Technologies and Therapeutics, Batesville, Arkansas, an oral pharmaceutical manufacturer. From February 1986 until June 2003, Dr. Zahradnik has been the Chief Executive Officer and Chairman of the Board of Directors of Advanced Clinical Technologies, Inc., Medfield, Massachusetts, a medical diagnostic manufacturer and technical consulting firm. Dr. Zahradnik is a graduate of Penn State University with a Bachelor of Science degree in Chemistry and Boston University with a PhD in Physical Chemistry. Dr. Zahradnik's spouse, Joann Zahradnik, also provides services to us from time to time as an independent contractor.

**Dorothy Jean (Dotti) Delfino.** Ms. Delfino was appointed on June 1, 2007 to be an Officer of the Company. Ms. Delfino has been approved by the Board as the Company's Chief Financial Officer and Secretary. She brings to Orogenics broad management experience from several venues of public and university research and development platforms. Ms. Delfino joined the Company in May 2006 as the Corporate Controller. Prior to joining the Company, Ms. Delfino worked for a private accounting practice, providing tax and accounting services. Previously, from May 2000 to December 2004, she was part of senior management at the University of Florida. She held positions ranging from financial manager for one of the seventeen colleges, budget officer of the University's Physical Plant Division and associate director at one of the College of Engineering's research centers. Prior to joining the University of Florida, Ms. Delfino held management positions with several national engineering consulting firms. She holds a Masters in Accounting from the University of Florida and a Masters of Information Science from the University of Hawaii.

On May 1, 2007, one of our independent directors, Mr. Hawes, resigned from the Company's Board of Directors.

### **Scientific Advisory Board (SAB)**

Our international Scientific Advisory Board (SAB) is composed of dentists and scientist with expertise related to our technologies. They advise our management team on matters including product development and clinical trials. The five-member Board does not meet formally during the year. Dr. Raman Bedi, Chairman and Senior Consultant contacts the other members for discussion on special issues as needed. As compensation, the Chairman has been provided a one-time stock option grant and the other four members are compensated in the amount of \$5,000 annually. Currently, our SAB members are:

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

**Dr. Ayyaz Khan** is the most senior dental advisor to the Health Ministry in Pakistan. He is currently the Head of the Department of Oral Health Sciences at the Shaikh Zayed Medical Institute in Lahore, Pakistan. He is also a Research Fellow at the University of Buffalo; the National Coordinator, Oral Health for a Joint WHO/Government of Pakistan

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Program; and the Principal Research Officer with the Pakistan Medical Research Council. He has been the Convener of the Expert Panel on Oral Health and a member of the Technical Advisory Committee of the Pakistan Medical Research Council for four consecutive three year terms. He is the past Chair of the International Dental Federation's (FDI) World Dental Development Health Promotion Committee which is responsible for the management of the World Dental Development Fund.

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

**Dr. Hari Parkash** is one of the most senior dental advisors to the federal government of India and is currently the Director for ITS Center Dental Studies and Research, Ghaziabad, (U.P.) India and serves as an adjunct professor at the School of Dental Medicine at the University of Pennsylvania. Dr. Parkash has served as the Chairman of the Hospital Management Board and Chief of the Centre for Dental Education & Research, All India Institute of Medical Sciences, New Delhi; Project Director, National Oral Health Care Program of India, Ministry of Health and Family Welfare; President, IDA Delhi State Branch; Past President, Indian Dental Association-HO; Past President, Int. Coll. of Dent. (India & Sri Lanka Sect.); Past President, Faculty Association of AIIMS; Past President, Indian Prosthodontic Society, and received the Pierre Fauchard Academy International Certificate of Merit for 2002 for his contributions in the field of dentistry. He has been conferred Honorary Fellowship of the Institute of Maxillofacial Prosthetics and Technologists, UK.

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

### **SAB Independent Consultants**

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

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

### **Corporate Governance Meetings of the Board of Directors and Committees**

The property, affairs and business of the Company are under the general management of our Board of Directors as provided by the laws of the State of Florida and our Bylaws. The Board of Directors conducts its business through meetings of the full Board and through committees of the Board, and the Board of Directors has appointed standing Audit and Compensation Committees of the Board of Directors. The Board of Directors does not have a separate nominating committee. The entire Board functions as the Company's nominating committee. The Board currently consists of three members with one vacancy due to the recent resignation of one of our



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independent directors, Mr. George Hawes. The Board has adopted the definition of “independence” as described under the Sarbanes-Oxley Act of 2002 (“Sarbanes-Oxley”) Section 301, Rule 10A-3 under the Securities Exchange Act of 1934 (the “Exchange Act”) and the rules of the American Stock Exchange. The Board periodically reviews the size of the Board and recommends any changes it determines to be appropriate given the needs of the Company. Under the Company’s Bylaws, the number of members on the Board may be increased or decreased by resolution of the Board.

In March 2004, the Board adopted a Corporate Governance Policy. The Board reviews this policy annually to ensure the Company’s policies and practices are in line with the standards suggested by various groups or authorities active in corporate governance as well as practices of other comparable public companies.

The Audit Committee and Compensation Committees currently consists solely of Mr. Gury. Mr. Gury serves as Chairman of the Audit Committee and Mr. Gury meets the definition of being “independent” as defined under the Sarbanes-Oxley Act of 2002 and under the applicable American Stock Exchange listing standards.

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. The Warning Letter provided that we had until August 2, 2007 to regain compliance. We submitted a plan on May 24, 2007 to AMEX for regaining compliance with all of the continued listing standards, which included our expectation of appointing an independent director within sixty days to fill the vacancy left by Mr. Hawes’ departure. 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. With the appointment of Dr. Evens to the Board, the Company believes it is now in compliance with AMEX’s listing standards regarding the number of independent directors.

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**EXECUTIVE COMPENSATION**

The following table sets forth the aggregate compensation in 2005 and 2006 for services in all capacities paid or accrued by the Company to our Principal Executive Officer and our next most highly compensated officer who earned more than \$100,000 in total salary and bonus during the fiscal year ended December 31, 2006 (the “Named Executive Officers”).

**Summary Compensation Table**

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Option Awards (\$) (2)</u>	<u>All Other Compensation (\$) (3)</u>	<u>Total (\$)</u>
Robert T. Zahradnik (1)	2006	\$180,000	\$ 2,535	\$ 1,800	\$184,335
CEO, President, Secretary, Treasurer and Interim Financial Officer	2005	90,000	0	1,463	91,463
Jeffrey D. Hillman (1)	2006	180,000	2,535	1,800	184,335
Chief Scientific Officer	2005	180,000	0	4,613	184,613
<b>Former Officers</b>					
Paul A. Hassie, (4)	2006	55,093	0	546	55,639
CFO, Secretary & Treasurer	2005	135,000	0	4,050	139,050

- (1) During October and November 2005, Dr. Zahradnik and Dr. Hillman orally agreed to an indefinite deferral of \$26,250 each in salary. These amounts remained deferred and unpaid as of December 31, 2005 and 2006. The amounts reflected in the table as salary for the 2005 period include the deferred amounts for each of these individuals.
- (2) On September 7, 2006, the Board of Directors and the Compensation Committee approved stock option grants to Drs. Zahradnik and Hillman to each acquire 75,000 shares of our common stock. These were vested in equal amounts and have an exercise price of \$0.74 per share, which was the fair market value of common stock on the date of the grant. The amounts reflected in the table with respect to these awards represent the 2006 compensation expense associated with such grants. The Company uses a Black-Scholes option-pricing model to estimate the fair value of the stock option grant. The use of a valuation model requires the Company to make certain assumptions with respect to selected model inputs. The average expected life is based on the contractual term of the option and on the simplified approach provided by SAB 107. The risk-free interest rate is based on the U.S. Treasury zero-coupon issues equal to the expected life assumed at the date of the grant. No amounts were shown for 2005, as the Company was not subject to SFAS 123(R).
- (3) The Company’s 401(k) retirement plan requires the Company to match employee contributions up to the first 3% of compensation earned and amounts presented represent the Company’s matching contribution.
- (4) On May 5, 2006 Paul Hassie resigned his position as CFO, Secretary and Treasurer. His salary for this period was below \$100,000. All of his stock options have been forfeited.

**Employment Contracts and Change in Control Arrangements**

Dr. Robert Zahradnik, our President and CEO does not have an employment agreement with us, but in his offer letter he is to be compensated at the rate of \$180,000 per annum, receive 20 days accumulating vacation/sick leave annually and be provided the same employee benefit package available to all employees. Dr. Zahradnik has also signed our Company’s non-disclosure and non-compete agreements. Our employment arrangement with Dr. Zahradnik is “at will” and may be terminated upon 30 days written notice by either Dr. Zahradnik or us.

We have an employment agreement with Jeffrey D. Hillman, our Chief Scientific Officer. His agreement is for three years and provides for automatic one-year extensions after December 31, 2007. Under the terms of our

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employment agreement with Dr. Hillman, we are obligated to pay initial compensation of \$180,000. He is also eligible for participation in incentive bonus compensation plans. The employment agreement also provides for other benefits including the right to participate in fringe benefit plans, life and disability insurance plans, expense reimbursement and 20 days accumulating vacation/sick leave annually. If Dr Hillman is terminated by the Company without cause (as defined in the agreement) or within twelve months following a change of control (as defined in the agreement), he will be entitled to severance payments, at his then annual base salary and all stock options granted to the executive and any benefits under any benefit plans shall become immediately vested and to the extent applicable, exercisable. The employment agreement also includes non-disclosure and non-compete provisions, as well as salary payments for a three month period in the event of an executive's death or disability during the term of the agreements.

### Outstanding Equity Awards

The following table sets forth information regarding individual grants of options during fiscal 2006 to the Named Executive Officers.

#### OUTSTANDING EQUITY AWARDS AT FISCAL YEAR END OPTION AWARDS

Name	Number of Securities Underlying Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Options Expiration Date
Robert T. Zahradnik CEO, President, Secretary, Treasurer, Interim Chief Financial Officer and Principal Executive Officer	0	75,000	75,000	\$ 0.74	9/8/2011
Jeffrey D. Hillman Chief Scientific Officer	0	75,000	75,000	\$ 0.74	9/8/2011

There were no stock option grants exercised by the Named Executive Officers during the year ended December 31, 2006. No stock awards were given during the fiscal year 2006. We do not have any long-term incentive plans that provide compensation intended to serve as incentives for performance other than our 2002 Stock Incentive Plan.

In September 2006 the Compensation Committee approved the grant of stock options under our Stock Incentive Plan to our Principal Executive Officer and Chief Scientific Officer. These grants were made in connection with the continued services of these officers to us and to provide incentives to each of them to continue their efforts with respect to our objectives. Each stock option grant was for 75,000 shares of our common stock and is exercisable at \$0.74 per share, which was the fair market value of our common stock on the date of grant, September 7, 2006. These stock option grants time vest annually in three equal amounts of 25,000 shares. The Compensation Committee believed that notwithstanding the amount of common stock beneficially owned by these individuals, the awards were necessary and in the best interest of the Company in order to continue to receive the services of these executive officers since no other bonuses or awards were made for these executive officers and no change to the amount of annual salary payable to these executive officers has been made during the past two years.

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**Compensation of Directors**

The following table sets forth the compensation we paid to our non-employee directors in 2006.

**Director Compensation**

<u>Name</u>	<u>Gross Fees Earned or Paid in Cash (\$) (2)</u>	<u>Option Awards (\$ (3)</u>	<u>All Other Compensation (\$ (4)</u>	<u>Total (\$)</u>
David J. Gury	\$ 17,500	\$ 24,000	\$ 0	\$41,500
George Hawes (1)	8,500	20,800	0	29,300
Brian Anderson (5)	8,000	0	0	8,000

- (1) On May 1, 2007, Mr. George Hawes resigned his position on the Board of Directors. We are currently in the process of recruiting a new independent Board member.
- (2) Fees reflected were earned by each Director for Board and Committee meetings up to and including September 7, 2006, however, such amounts were deferred rather than being paid to the directors.
- (3) On September 7, 2006, the Board of Directors and the Compensation Committee approved stock option grants to non-employee directors in lieu of future cash fees for Board and Committee services. Messrs. Gury and Hawes, our non-employee directors at that time received grants of stock options to acquire 75,000 and 65,000 shares of our common stock, respectively. These options were immediately vested and have an exercise price of \$0.74 per share, the fair market value of common stock on the date of the grant. The amounts reflected in the table with respect to these awards represent the 2006 compensation expense associated with such grants. The Company uses a Black-Scholes option-pricing model to estimate the fair value of the stock option grant. The use of a valuation model requires the Company to make certain assumptions with respect to selected model inputs. The average expected life is based on the contractual term of the option and on the simplified approach provided by SAB 107. The risk-free interest rate is based on the U.S. Treasury zero-coupon issues equal to the expected life assumed at the date of the grant. The total number of stock option shares outstanding as of December 31, 2006 for these Directors is as follows: Mr. Gury (180,000) and Mr. Hawes (65,000).
- (4) No other compensation was paid to the Directors except reimbursement for their travel expense to Board meetings.
- (5) Mr. Anderson did not seek re-election to our board in connection with our prior year's annual meeting (2005) and as such his service on our board ended at the prior year's meeting.

Directors who are executive officers of the Company do not receive any compensation for services on our board. Up to September 2006 our non-employee directors were paid as follows: Each Director received \$2,500 for each Board meeting attended up to a maximum of \$10,000 per year; for the Audit Committee, the Chairman received \$2,500 and each Director received \$1,000 for each Committee meeting attended; and no additional compensation was received for attendance at the Compensation Committee meetings. Outside directors are also reimbursed for their expenses associated with travel to and from Board meetings and meetings with management.

Due primarily to conditions existing as a result of our limited operating capital, in September 2006 the Board instituted a new director compensation program. The new director compensation program consisted of a one time option grant to existing non-employee directors in lieu of future meeting fees. The fees previously earned by

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the non-employee directors for attending all Board and Committee meetings through September 2006 were deferred instead of being paid. As a result of the change in director compensation no future meeting fees will be paid to our directors until such time as the director compensation program may be revisited by the board.

### Equity Compensation Plan Information

The Company has reserved an aggregate of 3,000,000 shares of the Company's common stock for issuance pursuant to its 2002 Stock Option and Incentive Plan, amended and restated May 5, 2006. The per share exercise price of each stock option or similar award granted under these plans must be at least equal to the closing fair market value of the stock on the date of grant. The following table represents the number of shares issuable upon exercise and reserved for future issuance under its compensation plans as of December 31, 2006.

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights (a)	Cumulative Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) (c))
<b>Equity compensation plans approved by security holders</b>	<b>1,255,000</b>	<b>\$ 1.90</b>	<b>1,745,000</b>
<b>Equity compensation plans not approved by security holders</b>	52,500(1) 25,000(1) 35,000(2) 762,500(3) 1,500,000(4)	2.75 2.25 1.59 0.60 0.60	— — — — —
<b>Total</b>	<b>3,630,000</b>	<b>\$ 1.10</b>	<b>1,745,000</b>

- (1) Represents 52,500 warrants with an exercise price of \$2.75 per share issued on November 30, 2004, and exercisable for period of four years to investors and the placement agent and 25,000 warrants with an exercise price of \$2.25 per share issued to the placement agent in connection with the private placement of 250,000 shares of common stock for gross proceeds of \$687,500.
- (2) Represents warrants issued to a consultant having provided investor relations services during 2005. Such warrants are exercisable for a period of three years.
- (3) Represents the balance of remaining warrants with an exercise price of \$0.60 per share issued to investors in connection with the private placement of 2,937,500 shares of common stock for gross proceeds of \$1,175,000. As of January 8, 2007, all of these remaining warrants were exercised which provided an additional \$457,500 in proceeds.
- (4) Represents 1,500,000 warrants with an exercise price of \$0.60 per share issued to investors in connection with the private placement of 1,500,000 shares of common stock for gross proceeds of \$600,000. Such warrants are exercisable for a period of two years.

### Stock Option and Compensation Committee Interlocks and Insider Participation

The members of the Compensation Committee were Messrs. Gury and Hawes for the fiscal year 2006. No officer or employee of the Company participated in deliberations of the Compensation Committee concerning executive officer compensation during the year ended December 31, 2006 while serving as an officer or employee.

## CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The Audit Committee of the Board of Directors is responsible for reviewing all transactions between the Company and any officer or Director of the Company or any entity in which an officer or Director has a material interest. Any such transactions must be on terms no less favorable than those that could be obtained on an arms-length basis from independent third parties.

### Agreements regarding iviGene Corporation

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

On November 17, 2006 we acquired the outstanding stock of iviGene Corporation in exchange for 185,186 shares of our common stock to the shareholders of iviGene Corporation, which included one of our directors, who received 20,480 shares. On January 19, 2007 we filed a Form S-3 Registration Statement to register the 185,186 shares for resale in accordance with the registration rights provided to the shareholders of iviGene Corporation in connection with this transaction. Our CEO, President and director, Robert T. Zahradnik, was an officer, director and former shareholder of iviGene. Dr. Zahradnik did not receive any shares of Orogenics common stock or any other consideration in this transaction. IviGene Corporation owned the patent rights to IVIAT™ and CMAT™ that we previously licensed. With this transaction, Orogenics has now acquired all of iviGene's assets, including issued and pending patents. Following the completion of the international patent transfers, iviGene Corporation will be dissolved.

### Consulting Fees

In 2001 and 2002 we incurred consulting fee obligations of \$60,000 and \$15,000, respectively, payable to Dr. Jeffrey Hillman. We paid \$ 20,000 to Dr. Hillman toward this outstanding obligation in January 2005. We still owe a balance of \$55,000 as of December 31, 2006. No interest is being accrued on this outstanding obligation.

### Financing Transaction

On March 6, 2006 in conjunction with a private placement, Directors Hillman, Zahradnik, Gury and Hawes acquired 62,500, 62,500, 62,500 and 587,500 shares respectively from us for payments of \$25,000, \$25,000, \$25,000 and \$235,000. In addition to the shares acquired, each of these individuals received warrants to acquire an equal number of shares at \$0.60 per share. This transaction was approved by our independent director and was consummated at the fair market value of our common stock on the day the agreement was entered into. In connection with the financing transaction these directors acquired registration rights pursuant to a registration rights agreement with us.

### Relationships

Dr. Zahradnik's wife provides administrative services to the Company as an independent contractor on an as-needed basis at an hourly rate. On September 1, 2006 Ms. Zahradnik was granted stock options to acquire 25,000 shares of our common stock at an exercise price of \$0.74 the fair market value of our common stock on such date. The options vest equally over the next three years on the anniversary of the date of grant.

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**SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth certain information with respect to the beneficial ownership of common stock of the Company as of June 15, 2007 by (i) each person who is known by the Company to beneficially own more than five percent of the Common Stock, (ii) each Director of the Company, (iii) each of the executive officers, and (iv) all officers and Directors as a group.

<b>Name and Address of Beneficial Owners (1)</b>	<b>Number of Shares Beneficially Owned</b>	<b>Percentage of Ownership</b>
<b>Directors and Officers</b>		
Jeffrey D. Hillman (2)	4,139,894	17.79%
Robert Zahradnik (3)	887,667	3.81%
David J. Gury (4)	290,400	1.22%
Dorothy J. Delfino (5)	50,000	*
Ronald P. Evens (6)	65,000	*
All Officers and Directors as a Group (5 Persons)	5,432,961	22.95%
<b>Others</b>		
George Hawes (7)	4,240,767	17.63%

\* indicates less than one percent of ownership

- (1) Except as indicated in the footnotes set forth below, the persons named in the table have sole voting and investment power with respect to all shares shown as beneficially owned by them. The numbers of shares shown include shares that are not currently outstanding but which certain shareholders are entitled to acquire or will be entitled to acquire within 60 days upon the exercise of common stock warrants and stock options. Such shares are deemed to be outstanding for the purpose of computing the percentage of common stock owned by the particular shareholder and by the group but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person. The percentage of common stock beneficially owned is based on 23,202,443 shares of common stock outstanding on June 15, 2007. Except as indicated in the table, the business address of all persons named in the table is 13700 Progress Boulevard, Alachua, Florida 32615.
- (2) Represents: 4,056,914 shares held by the 2002 Jeffrey Hillman Trust, 82,980 shares held directly by Jeffrey D. Hillman (which includes the recently acquired 20,480 shares from the iviGene Corp purchase, as well as 62,500 common stock acquired in a private placement), and 62,500 shares of common stock warrants currently exercisable.
- (3) Represents 818,500 shares owned directly and 62,500 common stock warrants and 6,667 stock options currently exercisable within 60 days.
- (4) Represents 400 shares owned by Mr. Gury; 62,500 shares owned by David Gury and Karen Gury Trustees UA April 26, 2004 for the David J. Gury Revocable Trust (the "Trust"); 62,500 common stock warrants currently exercisable held by the Trust; and 165,000 stock options held by Mr. Gury currently exercisable and exercisable within 60 days.
- (5) Represents 50,000 stock options currently exercisable within 60 days.
- (6) Represents 65,000 stock options currently exercisable within 60 days.

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(7) Represents 3,588,267 shares owned 587,500 common stock warrants currently exercisable and 65,000 stock options currently exercisable within 60 days. On May 1, 2007, Mr. Hawes, resigned from the Company's Board of Directors.

## DESCRIPTION OF SECURITIES

### General

We are authorized to issue up to 100,000,000 shares of common stock, \$0.001 par value per share, and 20,000,000 shares of preferred stock, with no par value per share. As of June 15, 2007, 23,202,443 shares of common stock and no shares of preferred stock were issued and outstanding. All of the outstanding capital stock is, and will be, fully paid and non-assessable.

### Common Stock

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

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

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

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

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

### Preferred Stock

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

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



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

### **Options and Warrants**

As of June 15, 2007, 1,560,000 options for shares were outstanding under our approved stock option plans and 1,440,000 shares were available for future grants under our stock option plans. We have also issued warrants in connection with our financing transactions with respect to our common stock totaling 1,577,500 shares. Holders of options and warrants do not have any of the rights or privileges of our stockholders, including voting rights, prior to exercise of the options and warrants. The number of shares of common stock for which these options and warrants are exercisable and the exercise price of these options and warrants are subject to proportional adjustment for stock splits and similar changes affecting our common stock. We have reserved sufficient shares of authorized common stock to cover the issuance of common stock subject to the options and warrants.

### **Registrar and Transfer Agent**

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

### **Registration Rights**

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

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

*iviGene Corporation Acquisition.* In connection with our acquisition of the outstanding capital stock of iviGene Corporation in November 2006, we filed a Form S-3 registration statement on January 19, 2007 to register the resale of our common stock by the former iviGene Corporation shareholders.

## SHARES ELIGIBLE FOR FUTURE SALE

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

### **Sale of Restricted Shares**

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

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

### **Options**

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

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**SELLING STOCKHOLDER**

The following table presents information regarding the selling stockholder. Neither the selling stockholder nor any of its affiliates has held a position or office, or had any other material relationship, with us. Unless otherwise indicated, the percentage of outstanding shares beneficially owned is based on 23,202,443 shares issued and outstanding at May 15, 2007.

<b>Selling Stockholder</b>	<b>Shares Beneficially Owned Before Offering</b>	<b>Percentage of Outstanding Shares Beneficially Owned Before Offering</b>	<b>Shares to be Sold in the Offering</b>	<b>Percentage of Outstanding Shares Beneficially Owned After Offering</b>
Fusion Capital Fund II, LLC (1)	315,421	1.4%	4,109,689	—

- (1) As of the date hereof, 521,153 shares of our common stock have been acquired by Fusion Capital under the common stock purchase agreement. Fusion Capital may acquire up to an additional 3,794,268 shares under the common stock purchase agreement. Percentage of outstanding shares is based on 23,202,443 shares of common stock outstanding as of May 15, 2007, together with such additional 3,794,268 shares of common stock that may be acquired by Fusion Capital from us under the common stock purchase agreement after the date hereof. Fusion Capital may not purchase shares of our common stock under the common stock purchase agreement if Fusion Capital, together with its affiliates, would beneficially own more than 9.9% of our common stock outstanding at the time of the purchase by Fusion Capital. Fusion Capital has the right at any time to sell any shares purchased under the common stock purchase agreement which would allow it to avoid the 9.9% limitation. Therefore, we do not believe that Fusion Capital will ever reach the 9.9% limitation. Steven G. Martin and Joshua B. Scheinfeld, the principals of Fusion Capital, are deemed to be beneficial owners of all of the shares of common stock owned by Fusion Capital. Messrs. Martin and Scheinfeld have shared voting and disposition power over the shares being offered under this prospectus. See “The Fusion Capital Fund Transaction.”

## PLAN OF DISTRIBUTION

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

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

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

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

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

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

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

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

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

## **DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES**

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

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

## **CHANGES IN ACCOUNTANTS**

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

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

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

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

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

## **LEGAL MATTERS**

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

## **EXPERTS**

The financial statements of Oragenics, Inc. as of December 31, 2006 and for the years ended December 31, 2006 and 2005, included in this prospectus, have been audited by Kirkland Russ Murphy & Tapp, P.A., our current independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about Oragenics, Inc.'s ability to continue as a going concern as described in Note 1 to the financial statements). Such financial statements are included herein in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

**WHERE YOU CAN FIND ADDITIONAL INFORMATION**

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

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**FINANCIAL STATEMENTS**

**Orogenics, Inc.**

Financial Statements

Years ended December 31, 2006 and 2005  
and for the three-months ended March 31, 2007 and 2006

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheet of Oragenics, Inc. as of December 31, 2006, and the related statements of operations, stockholders' equity, and cash flows for the years ended December 31, 2006 and 2005. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Oragenics, Inc. as of December 31, 2006, and the results of its operations and its cash flows for the years ended December 31, 2006 and 2005 in conformity with accounting principles generally accepted in the United States of America.

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

February 19, 2007  
/s/ Kirkland Russ Murphy & Tapp, P.A.  
Certified Public Accountants  
Clearwater, Florida



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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

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

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

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

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

February 15, 2006

/s/ Kirkland Russ Murphy & Tapp, P.A.  
Certified Public Accountants  
Clearwater, Florida

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Oragenics, Inc.

Balance Sheets

	<u>December 31,</u> <u>2006</u>	<u>March 31,</u> <u>2007</u> <i>(unaudited)</i>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 707,278	\$ 749,733
Prepaid expenses and other current assets	73,871	81,394
Total current assets	781,149	831,127
Property and equipment, net	824,698	761,571
Total assets	\$ 1,605,847	\$ 1,592,698
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 195,573	\$ 252,930
Deferred compensation	132,000	109,500
Total current liabilities	327,573	362,430
Stockholders' equity:		
Preferred stock, no par value; 20,000,000 shares authorized; None issued and outstanding	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 23,192,443 and 22,404,943 shares issued and outstanding at March 31, 2007 and December 31, 2006, respectively	22,405	23,192
Additional paid in capital	12,914,950	13,407,313
Accumulated deficit	(11,659,081)	(12,200,237)
Total stockholders' equity	1,278,274	1,230,268
Total liabilities and stockholders' equity	\$ 1,605,847	\$ 1,592,698

*See accompanying notes.*

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Oragenics, Inc.

Statements of Operations

	Year ended December 31,		Three months ended March 31,	
	2006	2005	2007	2006
Revenue	\$ 66,176	\$ —	\$ 33,088	\$ —
Operating expenses:				
Research and development	2,023,896	2,097,223	366,258	500,285
General and administration	1,004,099	1,166,854	217,812	364,846
Total operating expenses	3,027,995	3,264,077	584,070	865,131
Loss from operations	(2,961,819)	(3,264,077)	(550,982)	(865,131)
Other income (expense):				
Interest income	24,931	41,875	9,826	7,359
Interest expense	(855)	(29,176)	—	(641)
Gain on sale of property & equipment	2,024	—	—	2,024
Total other income, net	26,100	12,699	9,826	8,742
Net loss	\$ (2,935,719)	\$ (3,251,378)	\$ (541,156)	\$ (856,389)
Basic and diluted net loss per share	\$ (0.15)	\$ (0.22)	\$ (0.03)	\$ (0.05)
Shares used to compute basic and diluted net loss per share	20,038,177	15,082,098	23,127,721	18,562,784

See accompanying notes.

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Oragenics, Inc.

Statements of Changes in Stockholders' Equity (Deficit)

	<u>Common Stock</u>		<u>Additional Paid In Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity (Deficit)</u>
	<u>Shares (#)</u>	<u>Amount</u>			
Balance at December 31, 2005	18,146,117	\$18,146	\$10,476,786	\$ (8,723,362)	\$ 1,771,570
Exercise of common stock warrants	2,390,000	2,390	1,424,610	—	1,427,000
Issuance of common stock and warrants	1,683,640	1,684	572,354	—	574,038
Acquisition of iviGene Corporation	185,186	185	199,815	—	200,000
Compensation expense relating to option issuances	—	—	241,385	—	241,385
Net loss	—	—	—	(2,935,719)	(2,935,719)
Balance at December 31, 2006	22,404,943	\$22,405	\$12,914,950	\$(11,659,081)	\$ 1,278,274
Exercise of common stock warrants (unaudited)	787,500	787	458,280	—	459,067
Compensation expense relating to option issuances	—	—	34,083	—	34,083
Net loss (unaudited)	—	—	—	(541,156)	(541,156)
Balance at March 31, 2007 (unaudited)	<u>23,192,443</u>	<u>\$23,192</u>	<u>\$13,407,313</u>	<u>\$ 12,200,237</u>	<u>\$ 1,230,268</u>

See accompanying notes.

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## Oragenics, Inc.

## Statements of Cash Flows

	Year ended December 31,		Three months ended March 31,	
	2006	2005	2007	2006
			<i>(unaudited)</i>	
<b>Operating activities</b>				
Net loss	\$(2,935,719)	\$(3,251,378)	\$ (541,156)	\$ (856,389)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	280,901	260,636	69,206	70,765
Stock-based compensation (credit) expense	241,385	(385,691)	34,083	98,199
Patents acquired from iviGene Corp	200,000	—	—	—
Gain on sale of asset	(2,024)	—	—	(2,024)
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	38,176	(3,151)	(7,523)	(44,098)
Accounts payable and accrued expenses	(86,257)	(54,798)	57,357	(28,975)
Deferred compensation	39,000	—	(22,500)	22,500
Net cash used in operating activities	(2,224,538)	(3,434,382)	(410,533)	(740,022)
<b>Investing activity</b>				
Purchases of property and equipment	(12,011)	(666,268)	(6,079)	(1,540)
Proceeds from sale of property and equipment	5,000	—	—	5,000
Net cash provided by (used in) by investing activity	(7,011)	(666,268)	(6,079)	3,460
<b>Financing activities</b>				
Net proceeds from issuance of common stock	2,001,038	1,372,195	459,067	524,304
Net proceeds from bank loan	—	615,192	—	—
Repayment of bank loan principal	—	(615,192)	—	—
Net cash provided by financing activities	2,001,038	1,372,195	459,067	524,304
Net increase (decrease) in cash and cash equivalents	(230,511)	(2,728,455)	42,455	(212,258)
Cash and cash equivalents at beginning of year	937,789	3,666,244	707,278	937,789
Cash and cash equivalents at end of year	\$ 707,278	\$ 937,789	\$ 749,733	\$ 725,531
<b>Supplemental disclosure of cash flow information</b>				
Non-cash acquisition of iviGene Corporation	200,000	—	—	—
Interest Paid	\$ 855	\$ 29,176	\$ —	\$ —

See accompanying notes.

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Oragenics, Inc.

Notes to Financial Statements

December 31, 2006 and March 31, 2007 (unaudited)

**1. Organization and Significant Accounting Policies**

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

**Basis of Presentation**

The accompanying 2006 and the unaudited March 31, 2007 financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) including the assumption of a going concern basis which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company incurred a net loss of \$2,935,719 for the year ended December 31, 2006 and as of that date had an accumulated deficit of \$11,659,081. Cash used in operations for the years ended December 31, 2006 and the three-month period ended March 31, 2007 was \$2,224,538 and \$410,533, respectively, and cash flow from operations was negative throughout 2006 and the three-month period ended March 31, 2007. The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes the working capital at December 31, 2006 and the three-month period ended March 31, 2007 will be insufficient to meet the business objectives as presently structured. Management recognizes that the Company must generate additional capital resources or consider modifications to its technology development plans to enable it to continue as a going concern. Management's plans include seeking financing, alliances or other partnership agreements with entities interested in the Company's technologies, or other business transactions that would generate sufficient resources to assure continuation of the Company's operations and research and development programs.

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

**Unaudited Interim Information**

The accompanying unaudited condensed financial statements as of March 31, 2007 and for the three-month periods ended March 31, 2007 and 2006 have been prepared in accordance with accepted accounting principles generally accepted in the United States of America (GAAP) for interim financial information and with the instructions to Form 10-QSB and Article 10 of Regulations S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the financial condition, result of operations and cash flows for the periods presented. The results of operations for the interim period March 31, 2007 are not necessarily indicative of the results that may be expected for the year ending December 31, 2007 or any future period.

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Oragenics, Inc.

Notes to Financial Statements (continued)

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

**Unaudited Interim Information (continued)**

These financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2006 which is included in our Annual Report on Form 10-KSB filed with the Securities and Exchange Commission on March 22, 2007. In that report the Company disclosed that it expects to incur substantial expenditures to further develop each of its technologies. It further stated that it believed its working capital will be insufficient to meet the business objectives as presently structured and without sufficient capital to fund its operations, the Company will be unable to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Concentrations of Credit Risk**

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

**Use of Estimates**

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

**Fair Value of Financial Instruments**

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

**Cash Equivalents**

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

**Property and Equipment**

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

**Business Segments**

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

## Oragenics, Inc.

## Notes to Financial Statements (continued)

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

In December 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation - Transition and Disclosure (FAS 148). FAS 148 amends an earlier standard on accounting for stock-based compensation, Accounting for Stock-Based Compensation (FAS 123), to provide alternative methods of transition to the fair value based method of accounting for stock-based employee compensation which is required beginning January 1, 2006. In December 2004, FASB issued FASB Statement No. 123 (revised 2004), *Share-Based Payment* ("Statement 123(R)"), a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Statement 123(R), which we have adopted in the first quarter of 2006, is generally similar to Statement 123; however, it requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. The Company has elected to adopt the Modified Prospective Method. This method requires the Company to prospectively expense all new grants and unvested pre-adoption grants. It also entails a pro forma presentation for comparative prior periods shown disclosing the effect of the new method had it been adopted earlier when the Company employed the use of the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*. The following table provides the required pro forma disclosure for the year ended December 31, 2005:

	<u>Year Ended December 31</u> <u>2005</u>
Net loss, as reported	\$ (3,251,378)
Effect of stock-based employee compensation expense (credit) included in reported net loss	(385,691)
Total stock-based employee compensation expense determined under fair value based method For all awards	<u>(200,233)</u>
Pro forma net loss	<u>\$ (3,837,302)</u>
Loss per share:	
Basic and diluted – as reported	\$ (0.22)
Basic and diluted – pro forma	\$ (0.25)
Shares used to compute basic and diluted net loss per share	15,082,098

**Net Loss Per Share**

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



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Oragenics, Inc.

Notes to Financial Statements (continued)

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

**Revenue Recognition**

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

**Impairment of Long-Lived Assets**

The Company periodically reviews their long-lived assets for impairment and reduces the carrying value to fair value whenever events or changes in circumstances indicate that the carrying value may not be recoverable. There were no impairment losses recorded during the years ended December 31, 2006 and 2005 and the three-months ended March 31, 2007 and 2006.

**Research and Development Expenses**

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

**Income Taxes**

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rate is recognized in operations in the period that includes the enactment date. Deferred tax assets are reduced to estimated amounts expected to be realized by the use of a valuation allowance.

**Recently Issued Accounting Pronouncements**

In September 2006, the FASB issued SFAS No. 157, "*Fair Value Measurements*". The objective of SFAS 157 is to clarify the definition of fair value, establishes a framework for measuring fair value and expands the disclosures on fair value measurements. The provisions of SFAS 157 are effective for fair value measurements made in fiscal years beginning after November 15, 2007. The adoption of this statement is not expected to have a material effect on the Company's future reported financial position or results of operations.

**2. Property and Equipment, net**

Property and equipment, net consists of the following as of December 31, 2006 and March 31, 2007:

	<u>December 31, 2006</u>	<u>March 31, 2007</u>
Laboratory equipment	\$ 884,387	\$ 890,465
Leasehold improvements	481,606	481,606
Office and computer equipment	<u>55,106</u>	<u>55,106</u>
	1,421,099	1,427,177
Accumulated depreciation and amortization	<u>(596,401)</u>	<u>(665,606)</u>
	<u>\$ 824,698</u>	<u>\$ 761,571</u>

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Oragenics, Inc.

Notes to Financial Statements (continued)

**2. Property and Equipment, net (continued)**

Depreciation and amortization expense for 2006 and 2005 was \$280,901 and \$260,636, respectively and for the three-month period ended March 31, 2007 and 2006 was \$69,206 and \$70,765, respectively.

**3. Related Party Transactions**

At December 31, 2006 and March 31, 2007, \$52,500 was owed to President and CEO, Robert T. Zahradnik and to the CSO, Jeffrey D. Hillman and included in accounts payable and accrued expenses for consulting services in 2005. No interest is being accrued on this outstanding debt.

In July 2005, the Company entered into a severance agreement with its former Chief Executive Officer (CEO) agreeing to continue payments of \$15,000 per month for one year post separation from employment with the Company. The agreement requires the former CEO to be available as a consultant to management. As of March 31, 2007, the Company has paid \$157,000 as severance pay and has a balance of \$23,000 remaining at the rate of \$7,500 per month. Interest is not being accrued on the deferred amounts

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

**4. Business Loan Agreement**

None during the fiscal year 2006 or as of March 31, 2007.

**5. Stockholders' Equity**

**Common Stock**

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

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

Oragenics, Inc.

Notes to Financial Statements (continued)

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

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

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

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

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

**Stock Compensation Plan**

The Company's 2002 Stock Option and Incentive Plan (the Plan) was adopted by the Board of Directors (the Board). The purpose is to advance the interests of the Company by affording certain employees and directors of the Company and key consultants and advisors an opportunity to acquire or increase their proprietary interests in the

Company. The Plan authorizes the grant of stock options (incentive and non-statutory), stock appreciation rights and restricted stock. As of December 31, 2006, the Company had not awarded stock appreciation rights or restricted stock under the Plan. The Company has reserved an aggregate of 3,000,000 shares of common stock for grants under the Plan, of which 1,745,000 shares are available for future grants as of December 31, 2006 and 1,740,000 shares as of December 31, 2005. The exercise price of each option shall be determined by the Board and an option's maximum term is ten years.

In September 2002, the Company issued 195,000 options that were re-priced upon the change in the initial public offering price. As a result, these options were subjected to variable accounting treatment. In accordance with Financial Accounting Standards Board Interpretation No. 44, *Accounting for Certain Transactions Involving Stock*

## Oragenics, Inc.

## Notes to Financial Statements (continued)

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

*Compensation* (FIN 44), stock options must be accounted for as variable under such circumstances. Variable Oragenics, Inc. accounting requires companies to re-measure compensation costs for the variable options until the options are exercised, cancelled, or forfeited without replacement. Compensation is dependent on fluctuations in the quoted stock prices for the Company's common stock. Such compensation costs will be recognized over a three-year vesting schedule until the options are fully vested, exercised, cancelled, or forfeited, after which time the compensation will be recognized immediately at each reporting period. In 2005, we had a stock option compensation credit of \$385,691 based on FAS 123. As of 2006, the Company recognized a stock compensation expense of \$241,385 based on FAS 123 (R). A summary of the status of the Company's outstanding stock options as of December 31, 2006 and March 31, 2007 and changes during the periods ending on those dates is presented below:

	<u>Options (#)</u>	<u>Option Price Per Share (\$)</u>	<u>Weighted Average Exercise Price (\$)</u>
Outstanding at December 31, 2005	1,260,000	\$ 0.53 – 4.25	\$ 1.90
Forfeited	(535,000)	0.59 – 4.00	2.15
Granted	530,000	0.53 – 0.74	0.67
Outstanding at December 31, 2006	1,255,000	\$ 0.53 – 4.25	\$ 1.90
Forfeited	—	—	—
Granted	—	—	—
Exercisable at March 31, 2007	<u>1,255,000</u>	<u>\$ 0.53 – 4.25</u>	<u>\$ 1.90</u>

The range of exercise price is \$0.53 to \$4.25 per share. The weighted-average per option fair value of options granted during 2006 was \$0.67 and the weighted average remaining contractual life of those options is 4.3 years. Options vest over a period of three to four years from respective grant dates and the options expire 5 years after the date of grant. The fair value of these options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions: weighted average risk-free interest rate of 2.38%; dividend yields of 0%; weighted-average volatility factors of the expected market price of the Company's common stock of 53.8%; and an expected life of the option of four years.

**6. Licenses**

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

In February 2004, the Company licensed from iviGene Corporation (iviGene), a company whose major shareholders also own a significant number of shares of the Company's common stock, applications of two novel technologies referred to as IVIAT™ and CMAT™. On November 17, 2006 we acquired the outstanding stock of iviGene Corporation

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Oragenics, Inc.

Notes to Financial Statements (continued)

**6. Licenses (continued)**

in exchange for 185,186 shares of our common stock to the holders of iviGene Corporation, which included one of our directors, who received 20,480 shares. Following the consummation of this transaction, iviGene Corporation will be dissolved and as a result, Oragenics will acquire all of iviGene's assets, including issued and pending patents to two broad based platform technologies. These technologies are capable of identifying gene and protein biomarkers for application to the improve diagnosis and treatment of a wide range of infectious diseases and cancers. Besides human diseases, other potential applications for these technologies include animal disease, industrial and marine biofilm formation and plant diseases.

**7. Retirement Plan**

In January 2004, the Company established a defined contribution retirement plan, replacing the previous plan that had been established in 2001. The new plan covers all employees and provides for a Company match of up to 3% of all employee contributions to the plan. During 2006 and 2005, employee contributions were limited to \$15,000 and \$14,000, respectively, except for individuals 50 years or older for which the contribution limitations were \$20,000 and \$18,000, respectively. Total matching contributions made by the Company in 2006 and 2005 and March 31, 2007 were \$6,409, \$31,895 and \$1,263, respectively.

**8. Income Taxes**

At December 31, 2006, the Company had temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and their respective income tax bases, as measured by enacted state and federal tax rates, as follows:

Deferred tax assets:	
Net operating loss carryforward	\$ 4,217,956
Compensation to Directors & Offices and consulting services	14,676
Tax credits	252,817
Total deferred tax assets	4,485,449
Less valuation allowance	(4,485,449)
Total net deferred taxes	\$ —

The following is a reconciliation of tax computed at the statutory federal rate to the income tax benefit in the statements of operations for the years ended December 31, 2006 and 2005:

	Year ended December 31	
	2006	2005
Income tax benefit computed at statutory federal rate of 34%	\$ (998,144)	\$(1,105,469)
State income tax benefits, net of federal expense/benefit	(106,567)	(118,025)
Change in valuation allowance	1,042,086	1,387,567
Non-deductible expenses	91,198	(98,021)
Research and development credit	(40,792)	(66,052)
Other	12,219	—
Total	\$ —	\$ —

Oragenics, Inc.

Notes to Financial Statements (continued)

**8. Income Taxes (continued)**

SFAS No. 109, *Accounting for Income Taxes*, requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all of the evidence, both positive and negative, management has determined that a valuation allowance of \$4,485,449 at December 31, 2006 is necessary to reduce the deferred tax assets to the amount that will more likely than not be realized. The change in the valuation allowance for the year ended December 31, 2006 was \$1,042,086. At December 31, 2006, the Company has available net operating loss carryforwards of approximately \$11,209,026 that begin to expire in 2021. The Company also has a research and development credit carryforward of \$252,817 that is available to reduce future tax liabilities through 2026.

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

In June 2006, the FASB issued FASB Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statements No. 109*" (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing a two-step method of first evaluating whether a tax position has met a more likely than not recognition threshold and second, measuring that tax position to determine the amount of benefit to be recognized in the financial statements. FIN 48 provides guidance on the presentation of such positions within a classified statement of financial position as well as on derecognition, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 was adopted by the Company effective January 1, 2007. Initial analyses indicate that the adoption of this statement will not likely have a material effect on the Company's future reported financial position or results of operations. As a result of the implementation of FIN 48, the Company did not recognize a change in its tax liabilities or assets as of March 31, 2007.

**9. Commitments and Contingencies**

The Company's facility is being leased from a real estate developer for a term of five years subject to renewal provisions that include 3% increases in lease payments. This operating lease agreement required the Company to pay a deposit of \$6,400 and provides for monthly lease payments of \$6,793, exclusive of utilities, insurance, sales taxes and real estate taxes. Total rent expense under this lease was \$84,131 and \$81,653 for the years ended December 31, 2006 and 2005, respectively. In addition, the Company has entered into operating leases for office equipment.

Future annual minimum payments under all non-cancelable operating leases are approximately as follows:

Year ended:	
2007	88,900
2008	91,400
2009	91,600
Thereafter	—
	<u>\$271,900</u>

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Oragenics, Inc.

Notes to Financial Statements (continued)

**10. Unaudited Quarterly Financial Information**

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

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

	2007			
	First	Second	Third	Fourth
Revenue	\$ 33,088	—	—	—
Total operating expenses	(584,070)	—	—	—
Net loss	(550,982)	—	—	—
Loss per share:				
Basic and Diluted	\$ (0.03)	—	—	—

**11. Subsequent Event**

We have filed an 8-K on January 16, 2007 as a result of the early termination of warrants and notification of the early acceleration to the warrant holders in connection with our December 2005 private financing. All the outstanding warrants associated with this resulting issuance of 1,387,500 shares of common stock provided \$832,500 in proceeds. Approximately half of this amount (\$375,000) was included in the reported working capital as of December 31, 2006. When considered with the additional proceeds of \$457,500 that was received in January 2007, our current available working capital is insufficient to enable us to continue to operate after the third quarter of 2007.

On January 19, 2007, we filed a registration statement on Form S-3 as a post-effective amendment to register 185,186 shares of Oragenics common stock. These shares were issued to the shareholders of iviGene Corporation as a result of our acquisition agreement. On November 17, 2006, we acquired all the stocks and assets of iviGene Corporation in exchange for Oragenics' common stock.

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. The Warning Letter provided that we had until August 2, 2007 to regain compliance. We submitted a plan on May 24, 2007 to AMEX for regaining compliance with all of the continued listing standards, which included our expectation of appointing an independent director within sixty days to fill the vacancy left by Mr. Hawes' departure. 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. With the appointment of Dr. Evens to the Board, the Company believes it is now in compliance with AMEX's listing standards regarding the number of independent directors.

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Oragenics, Inc.

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2006 and 2007

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