# **UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

|   |  | FORM 10-Q  |   |
|---|--|--|---|
| X | QUARTERLY REPORT UNDER S   | SECTION 13 OR 15(d) OF THE S   | SECURITIES EXCHANGE ACT OF  |
|   | For the quarterly period ended March 31                                | , 2008.  |   |
|   |  | OR   |   |
|   | TRANSITION REPORT UNDER S  | SECTION 13 OR 15(d) OF THE E   | EXCHANGE ACT  |
|   | For the transition period fromto                                       |  |   |
|   |  | Commission File Number: 001-32188  |   |
|   |  | RAGENICS, INC  |   |
|   | FLORIDA (State or other jurisdiction of incorporation or organization) |  | 59-3410522<br>(IRS Employer<br>Identification No.)  |
|   |  | 13700 Progress Boulevard<br>Alachua, Florida 32615<br>(Address of principal executive offices) |   |
|   |  | (386) 418-4018<br>(Issuer's telephone number)  |   |
|   |  |  | e Exchange Act during the past 12 months (or subject to such filing requirements for the past |

90 days. Yes ⊠ No □ Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting

company. See the definitions of "large accelerated filer," accelerated filer," "non-accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

| Large accelerated filer | Accelerated filer         |   |
|-------------------------|---------------------------|---|
| Non-accelerated filer   | Smaller reporting company | X |

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  $\square$  No  $\boxtimes$ 

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date:

As of May 1, 2008, there were 32,538,807 shares of Common Stock, \$.001 par value, outstanding.

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# PART I—FINANCIAL INFORMATION

# ITEM 1. FINANCIAL STATEMENTS

# Oragenics, Inc.

# **Balance Sheets**

|  | March 31,<br>2008<br>(Unaudited) | December 31,<br>2007 |
|--|----------------------------------|----------------------|
| Assets   | , i                              |                      |
| Current assets:  |                                  |                      |
| Cash and cash equivalents  | \$ 1,966,877                     | \$ 475,508           |
| Prepaid expenses and other current assets  | 127,148                          | 116,520              |
| Total current assets   | 2,094,025                        | 592,028              |
| Property and equipment, net  | 459,308                          | 559,349              |
| Total assets   | \$ 2,553,333                     | \$ 1,151,377         |
| Liabilities and stockholders' equity   |                                  |                      |
| Current liabilities:   |                                  |                      |
| Accounts payable and accrued expenses  | \$ 337,843                       | \$ 244,994           |
| Deferred compensation  | 60,250                           | 86,500               |
| Total current liabilities  | 398,093                          | 331,494              |
| Stockholders' equity:  |                                  |                      |
| Preferred stock, no par value; 20,000,000 shares authorized; none issued and outstanding at March 31, 2008 and December 31, 2007 | _                                | _                    |
| Common stock, \$0.001 par value; 100,000,000 shares authorized; 32,538,807 and 28,002,443 shares                                 |                                  |                      |
| issued and outstanding at March 31, 2008 and December 31, 2007, respectively   | 32,538                           | 28,002               |
| Additional paid-in-capital   | 16,885,131                       | 14,762,674           |
| Accumulated deficit  | (14,762,429)                     | (13,970,793)         |
| Total stockholders' equity   | 2,155,240                        | 819,883              |
| Total liabilities and stockholders' equity   | \$ 2,553,333                     | \$ 1,151,377         |

The accompanying notes are an integral part of these condensed financial statements.

# Oragenics, Inc.

# Statements of Operations (Unaudited)

|   | Three mon Marci |              |
|---|-----------------|--------------|
|   | 2008            | 2007         |
| Revenue   | \$ 125,000      | \$ 33,088    |
| Operating expenses:   |                 |              |
| Research and development                                    | 478,373         | 366,258      |
| General and administration                                  | 447,722         | 217,812      |
| Total operating expenses                                    | 926,095         | 584,070      |
| Loss from operations  | (801,095)       | (550,982)    |
| Other income:   |                 |              |
| Interest income   | 4,599           | 9,826        |
| Gain on sale of property and equipment                      | 4,860           |              |
| Total other income  | 9,459           | 9,826        |
| Net loss  | \$ (791,636)    | \$ (541,156) |
| Basic and diluted net loss per share                        | \$ (0.03)       | \$ (0.03)    |
| Shares used to compute basic and diluted net loss per share | 29,833,302      | 23,127,721   |

 ${\it The\ accompanying\ notes\ are\ an\ integral\ part\ of\ these\ condensed\ financial\ statements}.$ 

# Oragenics, Inc.

# Statements of Cash Flows (Unaudited)

|   | Three mont   |             |
|---|--------------|-------------|
|   | 2008         | 2007        |
| Operating activities  |              |             |
| Net loss  | \$ (791,636) | \$(514,156) |
| Adjustments to reconcile net loss to net cash used in operating activities: |              |             |
| Depreciation  | 62,649       | 69,206      |
| Stock-based compensation expense resulting from fair value based method     | 130,993      | 34,083      |
| Gain on sale of property and equipment                                      | (4,860)      | _           |
| Changes in operating assets and liabilities:                                |              |             |
| Prepaid expenses and other current assets                                   | (4,374)      | (7,523)     |
| Accounts payable and accrued expenses                                       | 92,849       | 57,357      |
| Deferred compensation   | (26,250)     | (22,500)    |
| Net cash used in operating activities                                       | (531,881)    | (410,533)   |
| Investing activities  |              |             |
| Purchases of property and equipment   | _            | (6,079)     |
| Proceeds from sale of property and equipment                                | 27,250       |             |
| Net cash provided by (used in) investing activities                         | 27,250       | (6,079)     |
| Financing activities  |              |             |
| Net proceeds from issuance of common stock                                  | 1,996,000    | 459,067     |
| Net cash provided by financing activities                                   | 1,996,000    | 459,067     |
| Net increase (decrease) in cash and cash equivalents                        | 1,491,369    | 42,455      |
| Cash and cash equivalents at beginning of period                            | 475,508      | 707,278     |
| Cash and cash equivalents at end of period                                  | \$1,966,877  | \$ 749,733  |

The accompanying notes are an integral part of these condensed financial statements..

#### Oragenics, Inc.

# Notes to Financial Statements (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 general health benefits.

#### Basis of Presentation

The accompanying unaudited condensed financial statements as of March 31, 2008 and December 31, 2007 and for the three months ended March 31, 2008 and 2007 have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation 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, results of operations and cash flows for the periods presented. The results of operations for the interim period March 31, 2008 are not necessarily indicative of the results that may be expected for the year ended December 31, 2008 or any future period.

These financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2007 which is included in our Annual Report on Form 10-KSB filed with the Securities and Exchange Commission on March 18, 2008. 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 believes 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.

#### 2. Net Loss Per Share

Net loss per share is computed using the weighted average number of shares of common stock outstanding. Common equivalent shares from stock options and warrants are excluded as their effect is anti-dilutive.

#### 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.

In September 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. 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, 2008.

#### 4. Fair Value of Financial Instruments

SFAS No. 157, *Fair Value Measurements* ("SFAS 157"), defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 establishes a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value as follows:

- Level 1. Observable inputs such as quoted prices in active markets;
- Level 2. Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3. Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The Company does not have any assets or liabilities measured at fair value on a recurring basis at March 31, 2008. The Company did not have any fair value adjustments for assets and liabilities measured at fair value on a nonrecurring basis during the three months ended March 31, 2008.

# ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

We are a developmental biotechnology company with various products being developed and clinically tested or with established proof of concept. Our aim has been to add value to novel technologies and products sourced from innovative research centers and from internal discovery. The Company has a pipeline which includes platform technologies in antibiotics and diagnostics. Since our 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 agreements and various governmental grants. At this time we have not generated revenues from sales of products.

We are in need of additional funds in order to continue the development of our technologies. 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. As we move into more advanced stages concerning our products and their testing, our monthly expenses and use of cash is likely to increase. Our available working capital at March 31, 2008 is \$1,695,932. We believe this capital is sufficient to enable us to continue to operate through the fourth quarter of 2008. While 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 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.

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

**MU 1140<sup>TM</sup>** is a highly potent bactericidal peptide that is produced by our proprietary strain of *Streptococcus mutans*. We completed development of a fermentation manufacturing process for MU 1140 in the Fall 2007 and have refined the process so that sufficient quantities has been produced to allow us to conduct preclinical studies needed to enable the filing of an Investigational New Drug (IND) application. During 2007, we completed significant preclinical studies including the demonstration that MU 1140 is effective in an animal infection model against *Staphylococcus aureus*. If we are able to secure adequate funding, we plan to continue to perform *in vitro* and animal safety studies using MU 1140<sup>TM</sup> that will provide sufficient information to permit a pre-IND meeting with the U.S. FDA.

**DPOLT<sup>TM</sup>** (Differentially Protected Orthogonal Lantionine Technology) is a solid and/or liquid 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. 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 clinical testing and commercialization. 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 on February 15, 2008, Oragenics was awarded a \$500,000 Phase II NSF SBIR grant to develop a scale-up method for MU 1140-S synthesis and testing as a therapeutic antibacterial agent. The Company was issued a U.S. patent in February 15, 2007, covering the DPOLT technology.

IVIAT<sup>TM</sup> and CMAT<sup>TM</sup> are technologies that enable the simple, fast identification of novel and potentially important gene targets associated with the natural onset and progression of infections, cancers and other diseases in humans and other living organisms, including plants. These technologies offer the potential to generate

and develop a number of product candidates as diagnostics or therapeutics for future out-licensing to corporate partners, particularly in the areas of cancer and infectious diseases. We have received funding under SBIR grants with the National Institutes of Health to develop our biomarker technology and, if more funding becomes available, we will pursue additional research in these areas. We are in collaborations with outside companies and institutes to validate our identified biomarkers for their potential use in diagnostic products.

SMaRT Replacement Therapy<sup>TM</sup> is a single, painless one time topical treatment that has the potential to offer significant 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, S. 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 S. mutans with a patented genetically modified strain of S. mutans that does not produce lactic acid. Applied topically to tooth surfaces with a cotton-tipped swab, the therapy may require 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 II and III clinical trials. In our Phase I clinical trial in 2005, 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 terminated this study and discussed with the FDA our problems with patient enrollment and how we could modify our protocol to allow us to move forward in our clinical trials, A formal re-submission of an amended protocol was filed with the FDA on March 9, 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. Further protocol revisions and requirements in the conduct of the study were designated to be done by the FDA during 2007, which were completed and re-submitted in October 2007. We now have a Phase I protocol approved by the FDA, as of November 2007. We remain committed to complete the human safety study of SMaRT Replacement Therapy by ourselves or through a partner.

**Probiora3**<sup>TM</sup> (**Probiotics**) contains three naturally occurring, live microorganisms that helps maintain dental and oral health when administered to the host in adequate amounts. The use of yogurt containing live *Lactobacillus* cultures is an example of a probiotic application. Because probiotic treatments may be marketed as a cosmetic or as "health supplements" in certain geographic areas without the need for extensive regulatory oversight, we believe that with adequate funding, we may achieve commercialization of our probiotic product (Probiora3) in these markets by the first half of 2009. Two sets of subjects completed our Probiora3 human study in 2006, 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 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. The Company was issued a U.S. patent in November 2, 2006, covering this technology and our intellectual property rights.

LPT3-04<sup>TM</sup> is a small molecule weight management agent for which we were issued a U.S. patent on May 4, 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 in 2008, 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 market.

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

The specific goal of our business is to discover, successfully develop preclinical, and then clinically test 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 through licensing with major pharmaceutical, biotechnology or healthcare product firms for advanced clinical development and commercialization. One

or more strategic partners 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:

#### Antibiotics

#### MU 1140

- Complete preclinical studies, including animal toxicity, activity, and pharmacokinetics, required for an investigational new drug application (IND) submission for MU 1140 native and MU 1140 synthetic.
- Schedule a pre-IND meeting with the FDA for MU 1140 native and / or MU 1140 synthetic.
- Continue discussions with biotechnology and pharmaceutical companies for the licensing of MU 1140 and/or its analogs.

#### Lantibiotics

## **DPOLT**

- Complete proof-of-principle studies.
- Initiate program for the scale-up of DPOLT for lantibiotic production.

#### Biomarkers

#### **IVIAT**

• Validate proprietary gene/protein markers for *Mycobacterium tuberculosis*.

#### **CMAT**

- Complete proof-of-principle in colorectal cancer model.
- Validate the identified biomarkers for colorectal cancer.

#### Oral Health

## **SMaRT Replacement Therapy**

- Initiate second Phase I clinical safety trial.
- Pursue partners for licensing, or further development and commercialization.

#### Probiora3

- Partner with one or more nutritional, oral care, or food manufacturers or distributors.
- Produce scale-up lots and perform all necessary product testing.

Weight Loss and Weight Management

#### LPT3-04

- Conduct human safety and effectiveness study.
- Pursue partners for licensing, or further development and commercialization.

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 expected continued development of our technologies have been extended from those previously indicated from time to time due primarily to our insufficient capital position. The time periods for the expected developments could change in the future depending on the progress of our ability to negotiate a partnering arrangement, as well as our efforts to raise additional capital. We have a contractual obligation to pay a minimum royalty of \$25,000 per quarter and spend or cause to be spent an aggregate of \$1,000,000 per annum toward research, development and regulatory prosecution, in order to maintain our license with the University of Florida Research Foundation, Inc. for our SMaRT Replacement Therapy<sup>TM</sup> and MU 1140<sup>TM</sup> technologies. We believe we have exceeded the \$1,000,000 per annum threshold for research, development and regulatory prosecution. If we are unable to make the minimum royalty payments, our license could be terminated which will substantially diminish the value of our company.

#### **Critical Accounting Policies**

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

#### **New Accounting Pronouncements**

In September 2006, the Financial Accounting Standards Board ("FASB") issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. In February 2008, the FASB deferred the effective date of SFAS 157 until the fiscal year beginning after November 15, 2008 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The partial adoption of SFAS 157 for financial assets and liabilities did not have a material effect on the Company's financial statements. The remaining requirements of SFAS 157 are not expected to have a material effect on the Company's financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ("SFAS 159"), which gives entities the option to measure eligible financial assets, and financial liabilities at fair value on an instrument by instrument basis, that are otherwise not permitted to be accounted for at fair value under other accounting standards. The election to use the fair value option is available when an entity first recognizes a financial asset or financial liability. Subsequent changes in fair value must be recorded in earnings. This statement is effective as of the beginning of a Company's first fiscal year after November 15, 2007. The adoption of SFAS 159 did not have an effect on the Company's financial statements as it did not elect this fair value option.

In June 2007, the FASB ratified Emerging Issues Task Force Issue No. 06-11, *Accounting for Income Tax Benefits of Dividends on Share-Based Payment Awards* ("EITF 06-11"). EITF 06-11 specifies how companies should recognize the income tax benefit received on dividends that are (a) paid to employees holding equity-classified nonvested shares, equity-classified nonvested share units, or equity-classified outstanding share options and (b) charged to retained earnings under SFAS 123(R). The adoption of EITF 06-11 did not have a material impact on the Company's financial statements.

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

In December 2007, the SEC issued Staff Accounting Bulletin No. 110 ("SAB 110"). SAB 110 expresses the views of the staff regarding the use of a "simplified" method, as discussed in SAB No. 107, in developing an estimate of the expected term of "plain vanilla" share options in accordance with SFAS No. 123 (revised 2004). Oragenics' adoption of SAB 110 did not have a material impact on its results of operations or financial condition.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations* ("SFAS 141R"). SFAS 141R establishes principles and requirements for an acquiring entity to recognize and measure in its financial statements the identifiable assets acquired, the liabilities assumed, any noncontrolling interest in the acquired and the goodwill acquired. SFAS 141R expands on required disclosures to improve the statement users' abilities to evaluate the nature and financial effects of business combinations. SFAS 141R is effective for fiscal years beginning after December 15, 2008. The Company adopted SFAS 141R and it did not have a material impact on its financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements—an amendment of ARB No. 51* ("SFAS 160"). SFAS 160 requires that a noncontrolling interest in a subsidiary be reported within equity and the amount of consolidated net income attributable to the noncontrolling interest be identified in the consolidated financial statements. SFAS 160 calls for consistency in the manner of reporting changes in the parent's ownership interest and requires fair value measurement of any noncontrolling equity investment retained in a deconsolidation. SFAS No. 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS No. 160 is effective for fiscal years beginning after December 15, 2008. The Company adopted SFAS 160 and it did not have a material impact on its financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities*—an amendment of FASB Statement No. 133 ("SFAS 161"). This statement amends SFAS No. 133 by requiring enhanced disclosures about an entity's derivative instruments and hedging activities, but does not change SFAS No. 133's scope or accounting. SFAS 161 requires increased qualitative, quantitative and credit-risk disclosures about the entity's derivative instruments and hedging activities. SFAS 161 is effective for fiscal years, and interim periods within those fiscal years, beginning after November 15, 2008, with earlier adoption permitted. The adoption of SFAS 161 by the Company, did not have a material impact it's financial statements.

#### **Results of Operations**

#### Three Months Ended March 31, 2008 and 2007

We had \$125,000 in revenues associated with a two-year NSF SBIR Phase II grant in the three months ended March 31, 2008 compared with \$33,088 in revenues in the same period in 2007. Our first quarter loss from operations expenses increased by 44.4% to \$801,095 in the three months ended March 31, 2008 from \$550,982 in the same period in 2007. Research and development (R&D) expenses increased 30% to \$478,373 in the three months ended March 31, 2008 from \$366,258 in the same period in 2007, reflected mostly by our staffing increase, initial fees for clinical trials, increase in equipment service and stock option expense. General and administration (G&A) expenses increased 105% to \$447,722 in the three months ended March 31, 2008 from \$217,812 in the same period in 2007, reflecting the use of outside consultants for business development to help facilitate our marketing plans for our technology and from stock option expense.

Interest income decreased 53.2% to \$4,599 in the three months ended March 31, 2008 from \$9,826 during the same period in 2007. In addition, the Company sold some excess laboratory equipment for a gain of \$4,860.

We incurred net losses of \$791,636 and \$541,156 during the three months ended March 31, 2008 and 2007, respectively. The increase in our net loss of \$250,480 was principally caused by the use of outside business development consultants and their compensation for stock options granted, initial fees for clinical trials and the hiring of a Sr. Research Chemist.

#### **Liquidity and Capital Resources**

Since our inception, we have funded our operations through the sale of equity securities in private placement and our initial public offering, the sale of equity securities and warrants in private placements, debt financing and grants. So far in 2008, the Company has been awarded a two-year \$500,000 NSF Phase II grant restricted for its DPOLT technology and has completed two security events whereby 4,536,364 warrants were exercised for common stock that provided \$1,996,000 in proceeds.

Our operating activities used cash of \$531,881 for the three months ended March 31, 2008 and \$410,533 for the three months ended March 31, 2007. Our working capital was \$1,695,932 as of March 31, 2008 which includes the restricted NSF grant funds of \$125,000 and the two security events. Cash used by operations in the three months ended March 31, 2008 resulted primarily from our net loss from operations of \$791,636.

Our investing activities increased in cash of \$27,250 for the three months ended March 31, 2008 as a result of the sale of laboratory equipment. The Company sold \$42,250, of which \$15,000 is included in other current assets, in equipment that was no longer in use and will use the proceeds towards the purchase of laboratory equipment in April 2008.

Our financing activities for the three months ended March 31, 2008 provided net cash of \$1,996,000 from the exercise of 4,536,364 warrants at \$0.44 per share and \$125,000 restricted funds from the NSF grant. We intend to use the net proceeds from the exercise of warrants for working capital and general corporate purposes. Additional details of these financings are provided below:

**Private Placement, August, 2007**—On August 7, 2007, we closed on \$1,171,591 in equity based financing. We issued a total of 4,600,000 shares of restricted common stock and warrants to acquire 4,600,000 shares of common stock in a private placement to accredited investors. The shares were sold to accredited investors at \$0.25 per share, except that per AMEX requirements, our former CEO, Dr. Ronald Evens acquired his shares at \$0.44 per share, which was the closing share price on August 7, 2007. Each warrant to purchase shares of common stock is exercisable at the price of \$0.58 per share. The warrants expire on August 8, 2008 (the "August 2007 Warrants"). On January 31, 2008 we amended the August 2007 Warrants, to reduce the exercise price to \$0.44, which was the fair market value on the date of the amendment for a designated period of time (from January 28, 2008 to February 29, 2008) following which the exercise price reverts back to \$0.58. Prior to the expiration of the August 2007 Warrants, 3,386,364 were issued upon exercise at the amended exercise price resulting in additional working capital proceeds to us of \$1,490,000.

**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. 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. 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 (the "March 2006 Warrants"). On January 17, 2008 we amended the March 2006 Warrants. Pursuant to the amendment, the warrant exercise price was reduced to \$0.44, which was the fair market value on the date of the amendment. Prior to the expiration of the March 2006 Warrants, 1,150,000 were issued upon exercise at the amended exercise price resulting in additional working capital proceeds to us of \$506,000. The remaining unexercised March 2006 Warrants expired and are no longer outstanding.

**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. The warrants representing shares of common stock were exercisable by the accredited investors at any time over a two-year period at an exercise price of \$0.60 per share. On January 16, 2007, we called all outstanding warrants associated with our December, 2005 private placement pursuant to the terms of the warrant. A total of 1,387,500 warrants were exercised that provided \$832,500 in additional working capital and following the call of the warrants no further warrants associated with the private placement remain outstanding.

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. The stock purchase agreement has expired per the 30-month contract terms. 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. 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. In addition, we currently are required to file a post-effective registration statement for the sale of the shares acquired by Fusion Capital, which we have not done and until we do so we will not be able to utilize the Fusion Capital stock purchase agreement as a source of funding. 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 in 2006.

On February 15, 2008, we were awarded a two year NSF SBIR Phase II grant to advance development of its small peptide antibiotic synthesis program using the Company's proprietary DPOLT. This federal grant will support studies focused on the synthesis and testing of our lead antibiotic, MU 1140. While the grant will total \$500,000, to date we have receive \$125,000 of these restricted funds with the remaining balance to be issued during the remaining two-year grant period.

Our business is based on commercializing entirely new and unique technologies, and our current business plan contains a variety of assumptions and expectations that are subject to uncertainty, including assumptions and expectations about manufacturing capabilities, clinical testing cost and pricing, continuing technological improvements, strategic licensing relationships and other relevant matters. These assumptions take into account recent financings, as well as expected but currently unidentified additional financings. We have experienced losses from operations during the last three fiscal years and have an accumulated deficit of \$14,762,429 as of March 31, 2008. The net loss for the first three months of 2008 was \$791,636. Cash used in operations for the year ended December 31, 2007 was \$1,913,760 and for the three months ending March 31, 2008 was \$531,881. As of March 31, 2008, our principal source of liquidity was \$1,966,877 of cash and cash equivalents. Our current and historical 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, as well as conducting basic research. These factors place a significant strain on our limited financial resources and adversely affect our ability to continue as a going concern. Our ultimate success depends on our ability to continue to raise capital for our operations.

Our capital requirements for 2008 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 through joint ventures and/or partnerships, 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. We will require substantial funds to conduct research and development and preclinical and Phase I clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase II and III clinical testing and manufacture and marketing of any products that are approved for commercial sale. We must generate additional capital resources to enable us to continue as a going concern. Our plans include seeking financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to assure continuation of our operations and research and development programs as well as seeking equity financing.

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

We will continue to seek additional funds for all of these activities including but not limited to conducting preclinical studies for our MU 1140 antibiotic technology and LPT3-04 weight loss agent, developing strategic partners for Probiora3 and LPT3-04, and to seek federal funding to develop our biomarker technology. As we move into more advanced stages concerning our product development and testing, our monthly budget is likely to increase. Our available working capital at March 31, 2008 is \$1,695,932 which included the proceeds from warrants being exercised in February 2008 and NSF SBIR grant each discussed above. While we believe our available working capital is sufficient for us to continue to operate through the fourth quarter of 2008, it is inadequate capital for conducting future studies and for developing business partnerships for our technologies. If additional capital is not raised prior to the end of the fourth quarter of 2008, we would likely need to cease all operations until we are able to acquire the necessary funds.

#### ITEM 4T. CONTROLS AND PROCEDURES

#### **Evaluation of Disclosure Controls and Procedures**

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

#### **Changes in Internal Controls**

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

#### PART II—OTHER INFORMATION

#### ITEM 1A. RISK FACTORS

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

#### Risks Associated with Our Company

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

We do not have sufficient capital to sustain our operations beyond the fourth quarter of 2008 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, 2008 and December 31, 2007, we had working capital of approximately \$1,695,932 and \$260,534, respectively. Independent registered public accounting firm's report as of and for the year ended December 31, 2007, includes an explanatory paragraph 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 \$531,881 for the three months ended March 31, 2008 and have sustained operating cash flow deficit of \$1,913,760 in 2007. 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 MU 1140, Probiora3, LPT3-04, SMaRT Replacement Therapy 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 cause us to be unable to obtain such additional financing.

On ability to utilize the stock purchase agreement with Fusion Capital as a source of funding depends on a number of factors, conditions and limitations some of which are beyond our control including the prevailing market price of our common stock. Specifically, Fusion Capital shall 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. In addition, we must maintain an effective registration statement relating to the shares we sell to Fusion Capital and we currently would need to file a post-effective amendment to our existing registration statement in order to meet this requirement. Even though this stock purchase agreement has expired per the 30-month contract terms, 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 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. 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.

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

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

All of our product candidates are in the early development stage. Although we have current data which indicates the promise of the concept of our MU 1140, SMaRT Replacement Therapy, Probiora3, 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 MU 1140, SMaRT Replacement Therapy, Probiora3, 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, subject to available funding, that we will remain engaged in research and development for a considerable period of time, and there can be no assurance that we will be able to generate adequate funding or revenue from operations to do so.

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

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

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

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

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

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

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

It is possible we will be unable to find a method to produce MU 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, MU 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 MU 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 MU 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 drug products, we must demonstrate through preclinical testing and clinical trials that our products are safe and effective for use in humans. The conduct of clinical trials is a lengthy, time-consuming and expensive process.

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

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

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

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

We intend to consider sublicensing our technologies to strategic partners prior to commercialization. If we do so, our sub-licensees will pay the costs of any remaining clinical trials, and manufacturing and marketing of our technologies. If we

are unable to sublicense our technologies, we will have to pay for the costs of Phase II and III trials and new drug applications to the FDA ourselves. We would also have to set up our own manufacturing facilities and find our own distribution channels. This would greatly increase our future capital requirements and we cannot be assured we would be able to obtain the necessary financing. If we cannot obtain financing, we may have to cease operations.

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

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

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

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

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

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

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

ensue and we are unsuccessful in that litigation, we could be enjoined for a period of time from marketing products which infringe any valid patent rights held or licensed by Celunol and/or we could owe substantial damages. On February 12, 2007 Celunol and the Diversa Corporation announced that they had signed a definitive merger agreement.

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

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

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

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

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

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

The commercial success of our MU 1140, SMaRT Replacement Therapy, Probiora3, LPT3-04 and other technologies will depend in part on government and public acceptance of their production, distribution and use. Biotechnology has enjoyed and continues to enjoy substantial support from the scientific community, regulatory agencies and many governmental officials in the United States and around the world. Future scientific developments, media coverage and political events may diminish such support. Public attitudes may be influenced by claims that health products based on biotechnology are unsafe for consumption or pose unknown risks to the environment or to traditional social or economic practices. Securing governmental approvals for, and consumer confidence in, such products poses numerous challenges, particularly outside the United States. The market success of technologies developed through biotechnology such as ours could be delayed or impaired in certain geographical areas because of such factors. Products based on our technologies may

compete with a number of traditional dental therapies and drugs manufactured and marketed by major pharmaceutical companies and other biotechnology companies. Market acceptance of products based on our technologies will depend on a number of factors including potential advantage over alternative treatment methods. We can offer you no assurance that dentists, physicians, patients or the medical and dental communities in general will accept and utilize products developed from our technologies. If they do not, we may be unable to generate sufficient revenues from our technologies, which may cause us to have to cease operations.

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

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

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

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

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

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

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

#### Risk Factors Relating to our Common Stock

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

Our common stock is listed on the American Stock Exchange ("AMEX"). 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 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. We submitted a plan on May 24, 2007 to AMEX for regaining compliance with all of the continued listing standards. On July 2, 2007, AMEX notified the Company that it had completed its review and has determined that the Company's compliance plan makes a reasonable demonstration of the Company's ability to regain compliance with the continued listing standards by the end of the plan period, October 27, 2008 and is therefore continuing the Company's listing pursuant to an extension. Due to AMEX requirements we are required to now have stockholder equity in excess of \$2,000,000 to maintain our listing. The proceeds from our recent financings and warrant exercises are insufficient, alone, to regain compliance with AMEX listing requirements by the end of the extension period. We have until October 27, 2008 to regain AMEX compliance but there can be no assurance that we will be able to do so.

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

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

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

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

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

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

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

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

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

#### 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, 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 directors, officers and key personnel;
- release of escrow or other transfer restrictions on our outstanding shares of common stock or sales of additional shares of common stock;
- potential litigation initiated against us;
- · adverse announcements by our competitors; and
- the additional sale of common stock by us in capital raising transactions.

Historically, the daily trading volume of our common stock has been relatively low. 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 March 31, 2008 our stock price has fluctuated from \$5.00 to \$0.28 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 or result in substantially greater dilution to existing shareholders from any equity based capital raise.

## 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 1, 2008, there were 32,538,807 shares of our common stock outstanding, with another 1,641,136 shares of common stock issuable upon exercise of warrants to investors, 1,650,000 shares issuable upon exercise of options outstanding and an additional 3,350,000 shares available for option grants 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. We have issued a significant number of shares in connection with private placements that are available for resale pursuant to registration statements we have filed covering the resale of such shares as well as shares issuable upon exercise of warrants also issued with respect to such private placements. The selling shareholders named in these registration statements may resell the shares they own and the shares they acquire upon exercise of the warrants. In August 2007, we issued 4,600,000 shares of our common stock with warrants to acquire an additional 4,600,000 shares of our common stock in a private placement and since that time 4,536,364 shares have been issued base upon the exercise of warrants. We were obligated to file a registration covering the resale of such shares. We filed such registration statement and it was declared effective by the SEC on September 26, 2007. The sale of shares by selling shareholders pursuant to such registration statement and other registration statements we have filed for selling shareholders to resell the shares of our common stock they acquired from us in private transactions, as well as pursuant to the recently amended Rule 144 of the Securities Act, could cause our stock price to decline significantly.

#### Forward-Looking Statements

This 10-Q 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 anticipated needs for and availability of working capital, (b) our future financing plans, (c) our strategies, (d) our projected sales and profitability,(e) anticipated trends in our industry. Forward-looking statements, which involve assumptions and describe our future plans, strategies, and expectations, are generally identifiable by use of the words "may," "will," "should," "expect," "anticipate," "estimate," "believe," "intend," or "project" or the negative of these words or other variations on these words or comparable terminology. This information may involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from the future results, performance, or achievements expressed or implied by any forward-looking statements. These statements may be found under "Management's Discussion and Analysis or Plan of Operation" and "Business," as well as in this 10-Q 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 10-Q 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.

#### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) We issued the following restricted securities during the period covered by this report to the named individual pursuant to exemptions under the Securities Act of 1933 including Section 4(2):

On February 8, 2008, we issued an aggregate of 1,150,000 shares of common stock to warrant holders in connection with their exercise of the warrants at a reduced price of \$0.44. The warrants were originally issued to accredited investors in connection with our March 6, 2006 private placement. The remaining unexercised warrants, 350,000, expired as of February 8, 2008 in accordance with the terms of the warrants. Proceeds of \$506,000 were received by us from the exercise of the warrants and are included in the reported working capital as of March 31, 2008. As part of this offering, our Chief Scientific Officer, Jeffrey D. Hillman, acquired 62,500 shares upon exercising of his warrants, our former President & CEO, Robert T. Zahradnik, acquired 62,500 shares upon exercising of his warrants, and George T. Hawes acquired 737,500 shares upon the exercise of his warrants.

On February 29, 2008, we issued an aggregate of 3,386,364 shares of common stock to warrant holders in connection with their exercise of the warrants at a reduced exercise price of \$0.44. The warrants were originally issued to accredited investors and certain officers and directors in connection with our August 7, 2007 private placement. As of February 29, 2008, 1,213,636 outstanding warrants associated with this original private placement will expire August 8, 2008 at an exercise price of \$0.58. Proceeds of \$1,490,000 were received by us from the exercise of warrants and are included in the reported working capital as of March 31, 2008. Our shareholder, George T. Hawes, acquired 500,000 shares upon the exercise of his warrants.

# ITEM 6. EXHIBITS

| Exhibit<br>Number<br>10.1 | Exhibit Description  Executive Employment Agreement for Stanley B. Stein as President and CEO.  | <u>Form</u> | <u>File No</u> | <u>Exhibit</u> | Filing Date | Filed<br><u>Herewith</u><br>X |
|---------------------------|---|-------------|----------------|----------------|-------------|-------------------------------|
| 31.1                      | Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended. |             |                |                |             | X                             |
| 31.2                      | Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended. |             |                |                |             | X                             |
| 32.1                      | Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).               |             |                |                |             | X                             |
| 32.2                      | Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).               |             |                |                |             | X                             |

## **SIGNATURES**

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this  $6^{th}$  day of May, 2008.

# ORAGENICS, INC.

BY: /s/ Stanley B. Stein

Stanley B. Stein, President and Chief Executive Officer

#### EXECUTIVE EMPLOYMENT AGREEMENT

THIS EXECUTIVE EMPLOYMENT AGREEMENT, dated as of April 8, 2008 (the "Agreement"), by and between ORAGENICS, INC., a Florida corporation, (the "Company"), and STANLEY B. STEIN (the "Executive").

WHEREAS, the Company is a biotechnology company currently engaged in the business of research and development of proprietary technologies;

WHEREAS, Executive has served as the Company's Interim President and Chief Executive Officer since on or about February 12, 2008; and

**WHEREAS**, the Company wishes to assure itself of the continued services of the Executive on an non-interim basis for the period provided in this Agreement and the Executive is willing to serve in the employ of the Company for such period upon the terms and conditions hereinafter set forth.

**NOW THEREFORE**, in consideration of the mutual covenants herein contained, the parties, intending to be legally bound, hereby agree as follows:

#### 1. EMPLOYMENT

The Company hereby agrees to employ the Executive upon the terms and conditions herein contained, and the Executive hereby agrees to accept such employment for the term described below. The Executive agrees to serve as the Company's Chief Executive Officer during the term of this Agreement and shall report only to the Company's Board of Directors. In such capacity, the Executive shall have such powers and responsibilities consistent with his position as the Chief Executive Officer and Board of Directors may assign to him.

Throughout the term of this Agreement, the Executive shall devote his best efforts and substantially all of his business time and services to the business and affairs of the Company.

#### 2. TERM OF AGREEMENT

The one (1) year initial term of the employment of Executive under this Agreement shall commence as of the date set forth above (the "Effective Date"). After the expiration of such initial one year employment period, the term of the Executive's employment hereunder shall automatically be extended without further action by the parties for successive one (1) year renewal terms, provided that if either party gives the other party at least thirty (30) days advance written notice of his or its intention to not renew this Agreement for an additional term, the Agreement shall terminate upon the expiration of the current term.

Notwithstanding the foregoing, the Company shall be entitled to terminate this Agreement immediately, subject to a continuing obligation to make any payments required under Section 5 below, if the Executive (i) becomes disabled as described in Section 5(b), (ii) is terminated for Cause, as defined in Section 5(c), or (iii) voluntarily terminates his employment before the current term of this Agreement expires, as described in Section 5(d).

#### 3. SALARY AND BONUS

The Executive shall receive an annual base salary during the term of this Agreement at a rate of not less than \$175,000, payable in installments consistent with the Company's normal payroll schedule. The Board shall review this base salary at annual intervals, and may adjust the Executive's annual base salary from time to time as the Board deems to be appropriate.

The Executive shall also be eligible to receive bonuses from the Company during the term of this Agreement in the discretion of the Compensation Committee of the Board of Directors.

#### 4. ADDITIONAL COMPENSATION AND BENEFITS

The Executive shall receive the following additional compensation and welfare and fringe benefits:

- (a) Stock Options. Pursuant to a Stock Option Agreement of even date the Executive is being granted no statutory stock options with respect to 750,000 shares of common stock under the Company's Amended and Restated 2002 Stock Option and Incentive Plan (the "Stock Option Plan").
- (b) Vacation. The Executive shall be entitled to up to four (4) weeks of vacation during each year during the term of this Agreement and any extensions thereof, prorated for partial years. Unused vacation at the end of each year of employment hereunder, if any, time shall not be carried over.

(c) Business Expenses. The Company shall reimburse the Executive for all reasonable expenses he incurs in promoting the Company's business, including expenses for travel, entertainment of business associates, service and usage charges for business use of cellular phones and similar items, upon presentation by the Executive from time to time of an itemized account of such expenditures.

In addition to the benefits provided pursuant to the preceding paragraphs of this Section 4, the Executive shall be eligible to participate in such other executive compensation and retirement plans of the Company as are applicable generally to other officers, and in such welfare benefit plans, programs, practices and policies of the Company as are generally applicable to other executives of the Company.

#### 5. PAYMENTS UPON TERMINATION

(a) Involuntary Termination. If the Executive's employment is terminated by the Company during the term of this Agreement, the Executive shall be entitled to receive his base salary accrued through the date of termination. The Executive shall also receive any nonforfeitable benefits already earned and payable to him under the terms of any deferred compensation, incentive or other benefit plan maintained by the Company, payable in accordance with the terms of the applicable plan.

If the termination is not for death as described in Section 7, disability as described in paragraph (b), for Cause as described in paragraph (c) or a voluntary termination by the Executive as described in paragraph (d), or the Company notifies Executive of its intent not to renew this Agreement the Company shall also be obligated to make a series of nine (9) equal monthly payments to the Executive equal to one-twelfth (1/12th) of the Executive's annual base salary, as in effect on the date of termination. In addition, any unvested stock options held by the Executive shall become vested and exercisable for a period set forth in the Stock Option Plan for such events following the date of termination.

- (b) Disability. The Company shall be entitled to terminate this Agreement, if the Board determines that the Executive has been unable to attend to his duties for at least ninety (90) days in any 12 month period because of a medically diagnosable physical or mental condition, and has received a written opinion from a physician acceptable to the Board that such condition prevents the Executive from resuming full performance of his duties and is likely to continue for an indefinite period. Upon such termination, the Company shall pay to Executive a monthly disability benefit equal to one-twelfth (1/12th) of his current annual base salary at the time he became permanently disabled. Payment of such disability benefit shall commence on the last day of the month following the date of the termination by reason of permanent disability and cease with the earliest of (i) the month in which the Executive returns to active employment, either with the Company or otherwise, (ii) the end of the initial term of this Agreement, or the current renewal term, as the case may be, or (iii) the fourth month after the date of the termination. Any amounts payable under this Section 5(b) shall be reduced by any amounts paid to the Executive under any long-term disability plan or other disability program or insurance policies maintained or provided by the Company.
- (c) Termination for Cause. If the Executive's employment is terminated by the Company for Cause, the amount the Executive shall be entitled to receive from the Company shall be limited to his base salary accrued through the date of termination, and any nonforfeitable benefits already earned and payable to the Executive under the terms of deferred compensation or incentive plans maintained by the Company.

For purposes of this Agreement, the term "Cause" shall be limited to (i) any action or omission by the Executive involving willful disloyalty to the Company, such as embezzlement, fraud, misappropriation of corporate assets or a breach of the covenants set forth in Sections 9, 10 or 11 below; or (ii) the Executive being convicted of a felony; or (iii) the Executive being convicted of any lesser crime or offense committed in connection with the performance of his duties hereunder or involving moral turpitude, fraud or that causes the Company a substantial and material financial detriment; (iv) the material failure or refusal by the Executive to substantially perform his duties hereunder as directed by the Board (other than any such failure or refusal resulting from the Executive's incapacity due to physical or mental disability); or (v) an act or omission of the Executive which constitutes a material breach of this Agreement which is not cured as specified below. Notwithstanding the foregoing, no termination pursuant to subsection (iv) or (v) shall be treated as termination for cause unless the Board has provided Executive with at least thirty (30) days prior written notice specifying in reasonable detail the alleged breach and giving the Executive a reasonable opportunity to correct such breach.

(d) Voluntary Termination by the Executive. If the Executive resigns or otherwise voluntarily terminates his employment before the end of the current term of this Agreement, the amount the Executive shall be entitled to receive from the Company shall be limited to his base salary accrued through the date of termination, and any nonforfeitable benefits already earned and payable to the Executive under the terms of any deferred compensation or incentive plans of the Company.

#### 6. EFFECT OF CHANGE IN CORPORATE CONTROL

(a) In the event of a Change in Corporate Control, the vesting of any stock options or other awards granted to the Executive under the terms of the Company's Stock Option Plan shall become immediately vested in full and, in the case of stock options, exercisable in full

In addition, if, at any time during the period of six (6) consecutive months following the occurrence of a Change in Corporate Control, the Executive is involuntarily terminated (other than for Cause) by the Company, the Executive shall be entitled to receive as severance pay in lieu of the monthly payments described in Section 5(a) above, a series of twenty-four (24) equal monthly payments to the Executive equal to one-twelfth  $(1/12^{th})$  of the Executive's annual base salary in effect at the time of the Change in Corporate Control.

- (b) For purposes of this Agreement, a "Change in Corporate Control" shall include any of the following events:
- (1) The acquisition in one or more transactions of more than thirty percent (30%) of the Company's outstanding Common Stock by any corporation, or other person or group (within the meaning of Section 14(d)(3) of the Securities Exchange Act of 1934, as amended);
- (2) Any merger or consolidation of the Company into or with another corporation in which the Company is not the surviving entity, or any transfer or sale of substantially all of the assets of the Company or any merger or consolidation of the Company into or with another corporation in which the Company is the surviving entity and in connection with such merger or consolidation, more than fifty percent of the outstanding shares of Common Stock shall be changed into or exchanged for other stock or securities of any other person, or cash, or any other property.
- (3) Any election of persons to the Board of Directors which causes a majority of the Board of Directors to consist of persons other than (i) persons who were members of the Board of Directors on the Effective Date, and (ii) persons who were nominated for election as members of the Board by the Board of Directors (or a Committee of the Board) at a time when the majority of the Board (or of such Committee) consisted of persons who were members of the Board of Directors on the Effective Date; provided, that any person nominated for election by the Board of Directors composed entirely of persons described in (i) or (ii), or of persons who were themselves nominated by such Board, shall for this purpose be deemed to have been nominated by a Board composed of persons described in (i).
- (4) Any person, or group of persons, announces a tender offer for at least thirty percent (30%) of the Company's Common Stock.

<u>provided that</u>, no acquisition of stock by any person in a public offering or private placement of the Company's common stock or other transaction approved by the Company's Board of Directors shall be considered a Change in Corporate Control.

#### 7. DEATH

If the Executive dies during the term of this Agreement, the Company shall pay to the Executive's estate a lump sum payment equal to the sum of the Executive's base salary accrued through the date of death plus the total unpaid amount of any bonuses earned with respect to the fiscal year of the Company most recently ended. In addition, the death benefits payable by reason of the Executive's death under any retirement, deferred compensation or other employee benefit plan maintained by the Company shall be paid to the beneficiary designated by the Executive in accordance with the terms of the applicable plan or plans.

#### 8. WITHHOLDING

The Company shall, to the extent permitted by law, have the right to withhold and deduct from any payment hereunder any federal, state or local taxes of any kind required by law to be withheld with respect to any such payment.

#### 9. PROTECTION OF CONFIDENTIAL INFORMATION

The Executive agrees that he will keep all confidential and proprietary information of the Company or relating to its business (including, but not limited to, information regarding the Company's methods of operation, product development and trade secrets) confidential, and that he will not (except with the Company's prior written consent), while in the employ of the Company or thereafter, disclose any such confidential information to any person, firm, corporation, association or other entity, other than in furtherance of his duties hereunder, and then only to those with a "need to know." The Executive shall not make use of any such confidential information for his own purposes or for the benefit of any person, firm, corporation, association or other entity (except the Company) under any circumstances during or after the term of his employment. The foregoing shall not apply to any information which is already in the public domain, or is generally disclosed by the Company or is otherwise in the public domain at the time of disclosure.

The Executive recognizes that because his work for the Company will bring him into contact with confidential and proprietary information of the Company, the restrictions of this Section 9 are required for the reasonable protection of the Company and its investments and for the Company's reliance on and confidence in the Executive.

#### 10. COVENANT NOT TO COMPETE

The Executive hereby agrees that he will not, either during the employment term or during the period of twelve (12) months from the time the Executive's employment under this Agreement is terminated, engage in any business activities on behalf of any enterprise which competes with the Company in the specific business or businesses then conducted by the Company in the United States or an other geographic area the Company conducts business. The Executive will be deemed to be engaged in such competitive business activities if he participates in such a business enterprise as an employee, officer, director, consultant, agent, partner, proprietor, or other participant; provided that the ownership of no more than 2 percent of the stock of a publicly traded corporation engaged in a competitive business shall not be deemed to be engaging in competitive business activities.

The Executive agrees that he shall not for himself or for any other person, firm, corporation, partnership or other entity, for a period of twelve (12) months from the time his employment under this Agreement ceases (for whatever reason), directly or indirectly,

- (i) solicit or employee, former employee who was employed by the Company in the preceding 90 days or full-time consultant of the Company for the purposes of hiring or retaining such employee or consultant,
- (ii) contact any present or prospective client, customer or vendor of the Company to solicit such a person to enter into a contract or arrangement with any competitor of the Company, or
- (iii) make known the names and/or addresses of such clients, customers or vendors or any information relating in any manner to the Company's trade or business relationships with such clients, customers or vendors.

#### 11. OWNERSHIP OF DEVELOPMENTS

All copyrights, patents, trade secrets, or other intellectual property rights associated with any ideas, concepts, techniques, inventions, processes, or works of authorship develop or created by Executive during the course of performing work for the Company or its clients (collectively, the "Work Product") shall belong exclusively to the Company and shall, to the extent possible, be considered a work made by the Executive for hire for the Company within the meaning of Title 17 of the United States Code. To the extent the Work Product may not be considered work made by the Executive for hire for the Company, the Executive agrees to assign and automatically assigns at the time of creation of the Work Product, without any requirement of further consideration, any right, title, or interest the Executive may have in such Work Product. Upon the request of the Company, the Executive shall take such further actions, including execution and delivery of instruments of conveyance, as may be appropriate to give full and proper effect to such assignment.

Solely for purposes of Sections 9, 10, 11 and 12 hereof only, the term "Company" also shall include any existing or future subsidiaries of the Company that are operating during the time periods described herein and any other entities that directly or indirectly, through one or more intermediaries, control, are controlled by or are under common control with the Company during the periods described herein.

#### 12. INJUNCTIVE RELIEF

The Executive acknowledges and agrees that it would be difficult to fully compensate the Company for damages resulting from the breach or threatened breach of the covenants set forth in Sections 9, 10 and 11 of this Agreement and accordingly agrees that the Company shall be entitled to temporary and injunctive relief, including temporary restraining orders, preliminary injunctions and permanent injunctions, to enforce such provisions in any action or proceeding instituted in the United States District Court for the Middle District of Florida or in any court in the State of Florida having subject matter jurisdiction. This provision with respect to injunctive relief shall not, however, diminish the Company's right to claim and recover damages.

It is expressly understood and agreed that although the parties consider the restrictions contained in this Agreement to be reasonable, if a court determines that the time or territory or any other restriction contained in this Agreement is an unenforceable restriction on the activities of the Executive, no such provision of this Agreement shall be rendered void but shall be deemed amended to apply as to such maximum time and territory and to such extent as such court may judicially determine or indicate to be reasonable.

The Executive acknowledges and confirms that (a) the restrictive covenants contained in Sections 9 and 10 hereof are reasonably necessary to protect the legitimate business interests of the Company, and (b) the restrictions contained in Sections 9 and 10 hereof (including without limitation the length of the term of the provisions of

Sections 9 and 10 hereof) are not overbroad, overlong, or unfair and are not the result of overreaching, duress or coercion of any kind. The Executive further acknowledges and confirms that his full, uninhabited and faithful observance of each of the covenants contained in Sections 9 and 10 hereof will not cause him any undue hardship, financial or otherwise, and that enforcement of each of the covenants contained herein will not impair his ability to obtain employment commensurate with his abilities and on terms fully acceptable to him or otherwise to obtain income required for the comfortable support of him and his family and the satisfaction of the needs of his creditors. The Executive acknowledges and confirms that his special knowledge of the business of the Company is such as would cause the Company serious injury or loss if he were to use such ability and knowledge to the benefit of a competitor or were to compete with the Company in violation of the terms of Sections 9 and 10 hereof. The Executive further acknowledges that the restrictions contained in Sections 9 and 10 hereof are intended to be, and shall be, for the benefit of and shall be enforceable by, the Company's successors and assigns.

If the Executive shall be in violation of any provision of Sections 9 and 10, then each time limitation set forth in the applicable section shall be extended for a period of time equal to the period of time during which such violation or violations occur. If the Company seeks injunctive relief from such violation in any court, then the covenants set forth in Sections 9 and 10 shall be extended for a period of time equal to the pendency of such proceeding including all appeals by the Executive.

#### 13. SEPARABILITY

If any provision of this Agreement shall be declared to be invalid or unenforceable, in whole or in part, such invalidity or unenforceability shall not affect the remaining provisions hereof which shall remain in full force and effect.

#### 14. ASSIGNMENT

This Agreement shall be binding upon and inure to the benefit of the heirs and representatives of the Executive and the assigns and successors of the Company, but neither this Agreement nor any rights hereunder shall be assignable or otherwise subject to hypothecation by the Executive.

#### 15. ENTIRE AGREEMENT

This Agreement represents the entire agreement of the parties and shall supersede any and all previous contracts, arrangements or understandings between the Company and the Executive. The Agreement may be amended at any time by mutual written agreement of the parties hereto.

#### 16. GOVERNING LAW

This Agreement shall be construed, interpreted, and governed in accordance with the laws of the State of Florida, other than the conflict of laws provisions of such laws.

17. COUNTERPARTS AND FACSIMILE. This Agreement may be executed in two (2) counterparts and by facsimile of electronic transmission, each of which shall be considered an original.

IN WITNESS WHEREOF, the Company has caused this Agreement to be duly executed, and the Executive has hereunto set his hand, as of the day and year first above written.

| ORAGENICS, INC.           |  |
|---------------------------|--|
| By:/s/ Jeffrey D. Hillman |  |
| EXECUTIVE:                |  |
| By:/s/ Stanley B. Stein   |  |

#### CERTIFICATION

#### I, Stanley B. Stein, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Oragenics, Inc.;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact
  necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading
  with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 6, 2008 /s/ Stanley B. Stein

Stanley B. Stein President (Chief Executive Officer)

#### CERTIFICATION

#### I, Dorothy J. Delfino, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Oragenics, Inc.;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact
  necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading
  with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 6, 2008 /s/ Dorothy J. Delfino

Dorothy J. Delfino Chief Financial Officer

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

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

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in this Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

Dated this 6th day of May, 2008

/s/ Stanley B. Stein

Stanley B. Stein Chief Executive Officer

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

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

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in this Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

Dated this 6th day of May, 2008

/s/ Dorothy J. Delfino

Dorothy J. Delfino Chief Financial Officer