### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### FORM 10-QSB

# ☑ QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2007.

OR

### **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT**

For the transition period from \_\_\_\_\_ to \_

**Commission File Number: 000-50614** 



(Exact name of small business issuer as specified in its charter)

FLORIDA

(State or other jurisdiction of incorporation or organization)

59-3410522 (IRS Employer Identification No.)

13700 Progress Boulevard Alachua, Florida 32615 (Address of principal executive offices)

> (386) 418-4018 (Issuer's telephone number)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  $\boxtimes$  No  $\square$ 

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

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 11, 2007, there were 23,192,443 shares of Common Stock, \$.001 par value, outstanding.

Transitional Small Business Disclosure Format (check one): Yes 🗆 No 🗵

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### PART I-FINANCIAL INFORMATION

### ITEM 1. FINANCIAL STATEMENTS

### Oragenics, Inc.

**Balance Sheets** 

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

See accompanying notes.

### Oragenics, Inc.

### Statements of Operations (Unaudited)

		Three months ended March 31	
	2007	2006	
Revenue	\$ 33,088	\$ —	
Operating expenses:			
Research and development	366,258	500,285	
General and administration	217,812	364,846	
Total operating expenses	584,070	865,131	
Loss from operations	(550,982)	(865,131)	
Other income (expense):			
Interest income	9,826	7,359	
Interest expense	—	(641)	
Gain on sale of property and equipment		2,024	
Total other income, net	9,826	8,742	
Net loss	\$ (541,156)	\$ (856,389)	
Basic and diluted net loss per share	<u>\$</u> (0.03)	\$ (0.05)	
Shares used to compute basic and diluted net loss per share	23,127,721	18,562,784	

See accompanying notes.

### Oragenics, Inc.

### Statements of Cash Flows (Unaudited)

		Three months ended March 31	
	2007	2006	
Operating activities			
Net loss	\$(541,156)	\$(856,389)	
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	69,206	70,765	
Gain on sale of property and equipment	—	(2,024)	
Stock-based compensation expense resulting from fair value based method	34,083	98,199	
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(7,523)	(44,098)	
Accounts payable and accrued expenses	57,357	(28,975)	
Deferred compensation	(22,500)	22,500	
Net cash used in operating activities	(410,533)	(740,022)	
Investing activities			
Purchases of property and equipment	(6,079)	(1,540)	
Proceeds from sale of property and equipment		5,000	
Net cash provided by (used in) investing activities	(6,079)	3,460	
Financing activities			
Net proceeds from issuance of common stock	459,067	524,304	
Net cash provided by financing activities	459,067	524,304	
Net increase (decrease) in cash and cash equivalents	42,455	(212,258)	
Cash and cash equivalents at beginning of period	707,278	937,789	
Cash and cash equivalents at end of period	\$ 749,733	\$ 725,531	

See accompanying notes.

### 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, 2007 and December 31, 2006 and for the three months ended March 31, 2007 and 2006 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-QSB 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, 2007 are not necessarily indicative of the results that may be expected for the year ended December 31, 2007 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, 2006 which is included in our Annual Report on Form 10-KSB filed with the Securities and Exchange Commission on March 23, 2006. In that report the Company disclosed that it expects to incur substantial expenditures to further develop each of its technologies. It further stated that it 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.

#### 3. Income Taxes

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

### ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATIONS

The following information should be read in conjunction with the Financial Statements, including the notes thereto, included elsewhere in this Form 10-QSB. 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-QSB.

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

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

On April 25, 2007 we received notification from the American Stock Exchange (the Amex) that the Company is 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. The Company expects to submit a plan by May 25, 2007 that would return us to compliance with all of the continued listing standards. On May 1, 2007, one of our independent directors, Mr. Hawes, resigned from the Company's Board of Directors. The Company expects to appoint a replacement within sixty days.

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

SMaRT Replacement Therapy<sup>™</sup> is a single, painless one time topical treatment that has the potential to offer lifelong protection against dental caries (tooth decay). The therapy is based on genetically altering the bacterium, Streptococcus mutans (S. mutans), which is the primary etiologic agent in tooth decay. Present in the normal flora of the mouth, Streptococcus mutans converts dietary sugar to lactic acid; the lactic acid, in turn, causes the erosion of tooth enamel that results in the destruction of the tooth surface and eventually the entire tooth. SMaRT Replacement Therapy™ permanently replaces resident acid producing Streptococcus mutans with a patented genetically engineered strain of Streptococcus mutans that does not produce lactic acid. Applied topically to tooth surfaces with a swab, the therapy requires only one application. We have begun Phase I clinical trials and expect to partner with a major healthcare products or pharmaceutical company prior to initiating Phase III clinical trials. To facilitate further patient recruitment in our Phase I clinical trial, we opened an additional clinical site in June 2005, however, we had very limited patient enrollment through December 31, 2005 due to the rigorous requirements for enrollment imposed upon us by the FDA. In January 2006, we concluded this study, closed the clinical sites, and discussed with the FDA our problems with patient enrollment and how we could modify our protocol to allow us to move forward in our clinical trials. A formal re-submission of an amended protocol was filed with the FDA on March 9, 2006. We addressed additional protocol changes suggested by the FDA and filed a second re-submission July 20, 2006. Based on further suggestions by the FDA for protocol changes made on September 29, 2006, we filed a third re-submission in early February 2007. We do not anticipate instituting a second Phase I clinical study until such time as the FDA approves our protocol changes for the study. We remain committed to complete the human safety study of SMaRT Replacement Therapy<sup>™</sup> in a manner that is satisfactory to the FDA. Should the FDA approve our resubmitted protocol, we estimate the cost in the third quarter of 2007 will be approximately \$500,000 subject to available funding.

**MU 1140<sup>TM</sup> (Mutacin 1140)** is a highly potent bactericidal peptide that is produced by our strain of *Streptococcus mutans*. We developed a proprietary manufacturing process for MU 1140<sup>TM</sup> and are now refining the process so that sufficient quantities can be produced to allow us to conduct preclinical studies needed to enable the filing of an Investigational New Drug (IND) application. During the second quarter of 2006, we completed a significant preclinical study and demonstrated that MU 1140<sup>TM</sup> is effective in an animal infection model against *Staphylococcus aureus*. If we are able to secure adequate funding, we plan to continue to perform preclinical testing including more detailed animal safety and efficacy studies using MU 1140<sup>TM</sup>.

**Probiora3<sup>TM</sup>** (**Probiotics**) are live microorganisms that confer health benefits to the host when administered in adequate amounts; the use of yogurt containing live *Lactobacillus* cultures is an example of a probiotic application. We have identified three natural strains of oral bacteria that provide significant protection against the causative organisms of periodontal disease and dental caries. Probiotic treatments may be marketed as a cosmetic or as "health supplements" in certain geographic areas without the need for extensive regulatory oversight. We believe that with an appropriate partner. we may achieve commercialization of our probiotic product (Probiora3<sup>TM</sup>) in these markets in first half of 2008. Two sets of subjects completed our Probiora3<sup>TM</sup> human study, and we believe the results confirmed that the product is safe for human use and demonstrated a substantial effect of Probiora3<sup>TM</sup> in reducing the levels of specific disease-causing bacteria in the mouths of young, healthy adult subjects. We are continuing our efforts to seek regional and international partners for market opportunities in the oral care and/or food and nutritional supplement industries to determine interest and deal structure preferences for the rights to the Probiora3<sup>TM</sup> technology.

**IVIAT<sup>TM</sup>** and **CMAT<sup>TM</sup>** are technologies that enable the simple, fast identification of novel and potentially important gene targets associated with the natural onset and progression of infections, cancers and other diseases in humans and other living organisms, including plants. These technologies offer the potential to generate and develop a number of product candidates for future out-licensing to corporate partners, particularly in the area of cancer and infectious diseases, as well as agricultural and other non-human uses. We filed for funding under SBIR grants with the National Institutes of Health and, if such funding becomes available, we will pursue additional research. On April 3, 2007 we were notified that the National Institute of Science and the National Cancer Institute has awarded a SBIR grant to support our research efforts to identify unique proteins that are expressed when normal, health bowel cells become cancerous. This six month Phase I grant for approximately \$100,000 has a start date of May 1, 2007.

**LPT3-04<sup>TM</sup>** is a small molecule weight loss/management agent for which we filed a U.S. patent application on April 5, 2006 to protect our intellectual property rights to the agent and its analogs. As a natural substance, LPT3-04<sup>TM</sup> is orally available and we believe it has an excellent safety and tolerability profile. While

we are optimistic about the future prospects for this small molecule, we are in mid to late discovery stage of this research and development project. There can be no assurance that a patent will be issued or that new technology will be successfully developed by us. Although we intend to continue our development efforts regarding this technology including undertaking a human study for safety and weight loss, we currently do not have sufficient capital resources to fully develop this technology. We are seeking a commercial partner that is actively involved in the weight loss/management market.

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

### **Business Objectives and Milestones**

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

### SMaRT Replacement Therapy<sup>TM</sup>

Initiate second Phase I clinical safety trial.

### **МU 1140<sup>тм</sup>**

• Complete preclinical studies, including animal toxicity and efficacy, required for an investigational new drug application (IND) submission.

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• Submit an investigational new drug application to the FDA.

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

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

### LPT3-04<sup>тм</sup>

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

### **DPOLTTM**

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

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

• Validate gene markers for Mycobacteriam tuberculosis.

### СМАТтм

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

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

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

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

### **Results of Operations**

#### Three Months Ended March 31, 2007 and 2006

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

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

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

#### Liquidity and Capital Resources

Our operating activities used cash of \$410,533 for the three months ended March 31, 2007 and \$740,022 for the three months ended March 31, 2006. Our working capital was \$468,697 as of March 31, 2007. Cash used by operations in the three months ended March 31, 2007 resulted primarily from our net loss from operations of \$541,156.

No cash was provided by our investing activities for the three months ended March 31, 2007. We do not anticipate any significant spending on additional property and equipment during the remainder of 2007.

Our financing activities for the three months ended March 31, 2007 provided net cash of \$459,067, which consists of \$472,500 in gross proceeds from the exercise of 787,500 warrants at \$0.60 per share. We intend to use the net proceeds for working capital and general corporate purposes.

During the remainder of 2007, provided additional financing is obtained, we expect to spend approximately \$1,400,000 to maintain normal research and development operations, approximately \$150,000 to perform additional studies on Probiora<sup>3TM</sup> and MU 1140<sup>TM</sup> and approximately \$500,000 to continue our Phase I SMaRT Replacement Therapy clinical trial.

On May 23, 2005, we entered into a stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"). Pursuant to the terms of the stock purchase agreement, Fusion Capital has agreed to purchase from us up to \$9,000,000 of our common stock over a 30 month period commencing from the date of the stock purchase agreement. Pursuant to the terms of a registration rights agreement, dated May 23, 2005, we filed a registration statement with the Securities and Exchange Commission covering shares which may be purchased by Fusion Capital under the stock purchase agreement and we agreed to file any required post-effective amendment to maintain the effectiveness of such registration statement. We currently need to file a post-effective amendment to the registration statement we previously filed covering the shares Fusion Capital may acquire from us. Until such time as the post-effective amendment to the registration statement has been filed and is declared effective, Fusion Capital is not obligated to purchase shares from us and while they have give us oral assurances that they will not terminate the stock purchase agreement, they may do so at any time.

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 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. The purchase price for the common stock to be sold to Fusion Capital pursuant to the stock purchase agreement with Fusion Capital will fluctuate based on the price of our common stock. 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. Given the requirements to file a post-effective amendment and the fluctuation in our stock price, there can be no assurance that we will be able to sell any shares of our common stock to Fusion Capital pursuant to the stock purchase that we will be able to sell any shares of our common stock to Fusion Capital pursuant to the stock purchase that we will be able to sell any shares of our common stock to Fusion Capital pursuant to the stock purchase that we will be able to sell any shares of our common stock to Fusion Capital pursuant to the stock purchase that we will be able to sell any shares of our common stock to Fusion Capital pursuant to the stock purchase agreement.

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 \$12,200,237 as of March 31, 2007. Cash used in operations for 2006 was \$2,224,538. The first three months of 2007 was \$410,533. By March 31, 2007, our principal source of liquidity was \$749,733 of cash and cash equivalents. These operating results occurred while developing and attempting to commercialize and manufacture products from entirely new and unique technologies. Our business plan requires significant spending related primarily to clinical testing expenditures, as well as conducting basic research. These factors place a significant strain on our limited financial resources and adversely affect our ability to continue as a going concern. Our ultimate success depends on our ability to continue to raise capital for our operations.

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

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

Our future success depends on our ability to continue to raise capital and ultimately generate revenue and attain profitability. We cannot be certain that additional capital, whether through selling additional debt or equity securities or

obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current stockholders may experience substantial dilution.

To date, we have not obtained financing sufficient to fully support our plans going forward. Until such time as additional financing for our operations is obtained, we expect to continue to need to curtail our spending. While we continue to focus on completing the Phase I clinical trial for our SMaRT Replacement Therapy<sup>TM</sup> technology, conducting additional preclinical studies for our MU 1140<sup>TM</sup> antibiotic technology and LPT3-04<sup>TM</sup> weight loss agent, and developing strategic partners for Probiora3<sup>TM</sup> and LPT3-04<sup>TM</sup>, we do not have sufficient capital resources to complete these projects. As we move into more advanced stages concerning our products and their testing our monthly budget and of cash usage rate is likely to increase accordingly. Our available working capital at March 31, 2007 is \$468,697 which included \$472,500 from proceeds from warrants being exercised is insufficient to enable us to continue to operate through the third quarter of 2007. While we believe additional capital may become available based upon the SBIR grant or through possible future exercises of outstanding warrants, there can be no assurance of the same. In the event adequate capital is not raised we would likely need to cease all operations until we are able to raise additional capital. Thereafter, without sufficient capital to fund our operations, we will be unable to continue as a going concern and will have to cease operations.

### **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-QSB 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-QSB 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 third quarter of 2007 and we will require additional financing as soon as possible. If we are not able to raise additional capital, among other things:

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

At March 31, 2007 and December 31, 2006, we had working capital of approximately \$468,697 and \$453,576, respectively. The independent registered public accounting firm's report as of and for the year ended December 31, 2006, includes an explanatory paragraph to their audit opinion stating that our recurring losses from operations and limited working capital raise substantial doubt about our ability to continue as a going concern. We have an operating cash flow deficit of \$410,533 for the three months ended March 31, 2007 and have sustained operating cash flow deficit of \$2,224,538 in 2006. Our ability to obtain additional funding will determine our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

We have yet to establish any history of profitable operations. Our limited revenues to date have not been related to the commercialization or licensing of our products and have not been sufficient to sustain our operations. We expect that our revenues will not be sufficient to sustain our operations for the foreseeable future. Our profitability will require the successful commercialization of our SMaRT Replacement Therapy<sup>TM</sup>, Probiora<sup>3TM</sup>, MU 1140<sup>TM</sup>, LPT3-04<sup>TM</sup> and other technologies we either license or own. No assurances can be given when this will occur or that we will ever be profitable.

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

The extent we are able to rely on our stock purchase agreement with Fusion Capital as a source of funding will depend on a number of factors, conditions and limitations beyond our control including, the prevailing market price of our common stock. Specifically, Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than \$0.75. If obtaining sufficient financing from Fusion Capital were to prove unavailable or prohibitively dilutive and if we are unable to commercialize and sell products resulting from the development of our technologies, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we are able to access the full \$9.0 million under the common 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 are required to maintain an effective registration statement in connection with the shares acquired by Fusion Capital pursuant to the stock purchase agreement. We currently need to file a post-effective amendment to the registration statement we previously filed covering the shares Fusion Capital may acquire from us. Until such time as the post-effective amendment to the registration statement is filed and declared effective, Fusion Capital is not obligated to purchase shares from us and while they have given us oral assurances that they will not terminate the stock purchase agreement, they may do so any time.

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

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

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

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

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

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

All of our product candidates are in the early development stage. Although we have current data which indicates the promise of the concept of our SMaRT Replacement Therapy<sup>TM</sup>, Probiora3<sup>TM</sup>, MU 1140<sup>TM</sup> and LPT3-04<sup>TM</sup> technologies, we can offer you no assurance that the technologies will be effective at a level sufficient to support a profitable business venture. If they are not, we will be unable to create marketable products, we will not generate revenues from our operations, and we may have to cease operations. The science on which our SMaRT Replacement Therapy<sup>TM</sup>, Probiora3<sup>TM</sup>, MU 1140<sup>TM</sup> and LPT3-04<sup>TM</sup> technologies are based may also fail due to flaws or inaccuracies on which the data are based, or because the data are totally or partially incorrect, or not predictive of future results. If our science proves to be flawed, incorrect or otherwise fails, we will not be able to create a marketable product or generate revenues and we may have to cease operations.

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

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

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

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

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

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

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



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

To date the testing of our SMaRT Replacement Therapy<sup>TM</sup> technology has been undertaken solely in animals and a limited number of humans. Studies have proven our genetically altered strain of *S. mutans* to be effective in preventing tooth decay in animals. It is possible that our strain of *S. mutans* will be shown to be less effective in preventing tooth decay in humans in clinical trials. If our SMaRT Replacement Therapy<sup>TM</sup> technology is shown to be ineffective in preventing tooth decay in humans, we will be unable to commercialize and generate revenues from this technology. To date the testing of the antibiotic substance, Mutacin 1140 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 unable to commercialize it and generate revenues from sales of Mutacin 1140. If we are unable to generate revenues from our technologies, we may have to cease operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In the event of an infringement or violation, we may face litigation and may be prevented from pursuing product development or commercialization. We may receive in the future, notice of claims of infringement of other parties' proprietary rights. Infringement or other claims could be asserted or prosecuted against us in the future and it is possible that past or future assertions or prosecutions could harm our business. We received notification from Celunol (formerly B.C. International Corporation) on July 29, 2002 that a gene utilized in our licensed, patented strain of *S. mutans* infringes a patent which it holds under a license. On September 17, 2006, Celunol notified Oragenics regarding the possibility of sublicenses to date. As of this date, no further communication has been received from Celunol. Their notification did not state that they intended to pursue legal remedies. Our management does not believe the gene in question infringes that

patent. We have sent them correspondence setting out our position. If necessary, we would need to be prepared to assert our rights vigorously with respect to such matter, which we may not be able to do without sufficient funding. If litigation should ensue and we are unsuccessful in that litigation, we could be enjoined for a period of time from marketing products which infringe any valid patent rights held or licensed by Celunol and/or we could owe substantial damages.

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

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

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

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

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

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

The commercial success of our SMaRT Replacement Therapy<sup>TM</sup>, Probiora<sup>3TM</sup>, MU 1140<sup>TM</sup>, LPT3-04<sup>TM</sup> and other technologies will depend in part on government and public acceptance of their production, distribution and use. Biotechnology has enjoyed and continues to enjoy substantial support from the scientific community, regulatory agencies and many governmental officials in the United States and around the world. Future scientific developments, media coverage and political events may diminish such support. Public attitudes may be influenced by claims that health products based on biotechnology are unsafe for consumption or pose unknown risks to the environment or to traditional social or economic practices. Securing governmental approvals for, and consumer confidence in, such products poses numerous challenges, particularly outside the United States. The market success of technologies developed through biotechnology

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

Historically, the daily trading volume of our common stock has been relatively low. We cannot guarantee that an active public market for our common stock will be sustained or that the average trading volume will remain at present levels or increase. In addition, the stock market in general, has experienced significant price and volume fluctuations. Volatility in the market price for particular companies has often been unrelated or disproportionate to the operating performance of those companies. Broad market factors may seriously harm the market price of our common stock, regardless of our operating

performance. In addition, securities class action litigation has often been initiated following periods of volatility in the market price of a company's securities. A securities class action suit against us could result in substantial costs, potential liabilities, and the diversion of management's attention and resources. Since our initial public offering in June 2003 and through March 2007 our stock price has fluctuated from \$5.00 to \$0.34 per share. To the extent our stock price fluctuates and/or remains low, it could impair our ability to raise capital through the offering of additional equity securities.

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

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur. In addition, these factors could make it more difficult for us to raise funds through future offerings of common stock. As of March 31, 2007, there were 23,192,443 shares of our common stock outstanding, with another 1,587,500 shares of common stock issuable upon exercise of warrants to investors, 1,255,000 shares issuable upon exercise of options issued and an additional 1,745,000 shares available for issuance under our stock option plans. The issuance of 1,000,000 shares of our stock underlying these options is covered by an S-8 registration statement we filed with the SEC and may be resold into the market. The shares of common stock held in escrow pursuant to Canadian law and underwriter requirements in connection with our initial public offering pursuant to escrow agreements were released as of June 30, 2006 and the escrow arrangement was concluded in accordance with its terms. Released shares may be resold into the market under Rule 144. This could cause the market price of our common stock to drop significantly.

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

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

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

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

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

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

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

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

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

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

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

#### **Forward-Looking Statements**

This 10-QSB contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements include statements regarding, among other things, (a) our projected sales and profitability, (b) our strategies, (c) anticipated trends in our industry, (d) our future financing plans, and (e) our anticipated needs for working capital. Forward-looking statements, which involve assumptions and describe our future plans, strategies, and expectations, are generally identifiable by use of the words "may," "will," "should," "expect," "anticipate," "estimate," "believe," "intend," or "project" or the negative of these words or other variations on these words or comparable terminology. This information may involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from the future results, performance, or achievements expressed or implied by any forward-looking statements. These statements may be found under "Management's Discussion and Analysis or Plan of Operation" and "Business," as well as in this 10-QSB 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-QSB 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 3. CONTROLS AND PROCEDURES

### **Disclosure Controls and Procedures**

We have established and are currently maintaining disclosure controls and procedures for our Company designed to ensure that information required to be disclosed in our filings under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the required time periods specified in the SEC's rules and forms. Our Chief Executive Officer and Chief Financial Officer conducted an evaluation of the effectiveness of the Company's disclosure controls and procedures and have concluded that our disclosure controls and procedures are effective as of the end of the period covered by this report.

### **Changes in Internal Controls**

We have also evaluated our internal controls over financial reporting, and there have been no changes in our internal controls over financial reporting during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

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### **PART II – OTHER INFORMATION**

### 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):

In January 2007, we issued 762,500 shares of common stock to warrant holders in connection with our December 2005 private financing. As of January 16, 2007 all the outstanding warrants associated with this early termination of warrants were exercised. Proceeds of \$457,500 are included in the reported working capital as of March 31, 2007.

On March 8, 2007, we issued 25,000 shares of common stock to Canaccord Capital Corporation ITF Richard Lee Hendricks and/or Colleen Ostlund in connection with the exercise of their warrants at \$0.60 per share.

### ITEM 6. EXHIBITS

Exhibit <u>Number</u>	Exhibit Description	Form	File No	Exhibit	Filing Date	Filed Herewith
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.					Х
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.					Х
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).					Х
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).					Х

### 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 11<sup>th</sup> day of May, 2007.

### **ORAGENICS, INC.**

BY: /s/ Robert T. Zahradnik

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

### CERTIFICATION

I, Robert T. Zahradnik, certify that:

- 1. I have reviewed this quarterly report on Form 10-QSB of Oragenics, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying 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 11, 2007

/s/ Robert T. Zahradnik

Robert T. Zahradnik President (Chief Executive Officer)

### CERTIFICATION

I, Robert T. Zahradnik, certify that:

- 1. I have reviewed this quarterly report on Form 10-QSB of Oragenics, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying 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 11, 2007

/s/ Robert T. Zahradnik

Robert T. Zahradnik Interim 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-QSB for the period ended March 31, 2007 as filed with the Securities and Exchange Commission on the date here of (the "Report"), I, Robert T. Zahradnik, 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 11th day of May, 2007.

/s/ Robert T. Zahradnik

Robert T. Zahradnik 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-QSB for the period ended March 31, 2007 as filed with the Securities and Exchange Commission on the date here of (the "Report"), I, Robert T. Zahradnik, Interim 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 11th day of May, 2007.

/s/ Robert T. Zahradnik

Robert T. Zahradnik Interim Chief Financial Officer