

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ORAGENICS, INC.

BALANCE SHEETS
(IN US DOLLARS)

	March 31, 2004	December 31, 2003	

	(Unaudited)		
ASSETS			
Current assets:			
Cash and cash equivalents	\$ 6,012,319	\$ 3,583,757	
Prepaid expenses	26,959	24,637	

Total current assets	6,039,278	3,608,394	
Equipment	61,420	42,371	

Total assets	\$ 6,100,698	\$ 3,650,765	
	=====		
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable and accrued expenses	\$ 209,780	\$ 140,614	
Accrued interest	-	25,582	
Deferred compensation	-	44,672	

Total current liabilities	209,780	210,868	
Stockholders' equity:			
Preferred stock, no par value; 20,000,000 shares authorized; none issued and outstanding at March 31, 2004 and December 31, 2003	-	-	
Common stock, \$0.001 par value; 100,000,000 shares authorized; 14,314,630 and 13,296,204 shares issued and outstanding at March 31, 2004 and December 31, 2003, respectively	14,315	13,296	
Additional paid in capital	8,808,139	5,820,697	
Accumulated deficit	(2,931,536)	(2,394,096)	

Total stockholders' equity	5,890,918	3,439,897	

Total liabilities and stockholders' equity	\$ 6,100,698	\$ 3,650,765	
	=====		

See accompanying notes.

ORAGENICS, INC.

STATEMENTS OF OPERATIONS
(UNAUDITED)
(IN US DOLLARS)

Three months ended
March 31
2004 2003

Revenue	\$	--	\$	--
Operating expenses:				
Research and development		262,295		106,826
General and administration		282,166		101,073
Total operating expenses		544,461		207,899
Loss from operations		(544,461)		(207,899)
Other income (expense):				
Interest income		7,021		19
Interest expense		--		(3,562)
Total other income (expense), net		7,021		(3,543)
Net loss	\$	(537,440)	\$	(211,442)
Basic and diluted net loss per share	\$	(0.04)	\$	(0.02)
Shares used to compute basic and diluted net loss per share		13,413,558		9,425,704

See accompanying notes.

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ORAGENICS, INC.

STATEMENTS OF CASH FLOWS
(UNAUDITED)
(IN US DOLLARS)

THREE MONTHS ENDED MARCH 31
2004 2003

OPERATING ACTIVITIES

Net loss	\$	(537,440)	\$	(211,442)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation		5,163		2,469
Stock-based compensation expense			(9,445)	--
Changes in operating assets and liabilities:				
Costs associated with initial public offering		--		(48,400)
Prepaid expenses		(2,322)		4,086
Accounts payable and accrued expenses		69,166		93,004
Accrued interest		(25,582)		3,562
Deferred compensation		(44,672)		56,501
Net cash used in operating activities		(545,132)		(100,220)

INVESTING ACTIVITY

Purchases of equipment		(24,212)		(23,642)
Net cash used in investing activity		(24,212)		(23,642)

FINANCING ACTIVITIES

Net proceeds from issuance of common stock		2,997,906		--
Proceeds from notes payable to stockholder		--		100,000

Net cash provided by financing activities	2,997,906	100,000
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Net increase (decrease) in cash and cash equivalents	2,428,562	(23,862)
Cash and cash equivalents at beginning of period	3,583,757	25,580
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Cash and cash equivalents at end of period	<u>\$ 6,012,319</u>	<u>\$ 1,718</u>

See accompanying notes.

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ORAGENICS, INC.

NOTES TO FINANCIAL STATEMENTS
(UNAUDITED)

1. Basis of Presentation

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

The accompanying unaudited condensed financial statements as of and for the three month periods ended March 31, 2004 and 2003 have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the financial condition, results of operations and cash flows for the periods presented. The results of operations for the interim period March 31, 2004 are not necessarily indicative of the results that may be expected for the year ended December 31, 2004 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, 2003 included in our Annual Report on Form 10-KSB filed with the Securities and Exchange Commission.

In December 2002, the FASB issued Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation - Transition and Disclosure (FAS 148). FAS 148 amends an earlier standard on accounting for stock-based compensation, Accounting for Stock-Based Compensation (FAS 123), to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, FAS 148 amends the disclosure requirements of FAS 123 to require more prominent disclosure about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The Company continues to follow the intrinsic value method of accounting as prescribed by Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, to account for employee stock options issued.

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ORAGENICS, INC.

NOTES TO FINANCIAL STATEMENTS
(UNAUDITED)

1. Basis of Presentation (continued)

The following table illustrates the effects on net loss and net loss per

share if the Company had applied the fair value recognition provisions of FAS 123 to stock-based employee compensation.

	Three months ended March 31	
	2004	2003
	----	----
Net loss, as reported	\$ (537,440)	\$ (211,442)
Less: Effect of stock-based employee compensation expense included in reported net income	(9,445)	-
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(30,747)	-
Pro forma net loss	<u>\$ (577,632)</u>	<u>\$ (211,442)</u>
Net loss per share:		
Basic and diluted --as reported	<u>\$ (.04)</u>	<u>\$ (.02)</u>
Basic and diluted --pro forma	<u>\$ (.04)</u>	<u>\$ (.02)</u>

2. Initial Public Offering

On June 24, 2003, we completed an initial public offering of our common stock. The managing underwriter for our initial public offering was Haywood Securities, Inc. The shares of common stock sold in the offering were registered under the Securities Act of 1933 on a registration statement (File No. 333-100568) that was declared effective by the Securities and Exchange Commission on June 11, 2003. Under the registration statement, we registered 2,400,000 units at a price of \$1.25 per unit. All 2,400,000 units were sold in the offering that provided gross proceeds of \$3,000,000 and net proceeds to us of \$2,282,612 after deducting \$717,388 in commissions paid to the underwriter and other expenses incurred in connection with the offering.

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ORAGENICS, INC.

NOTES TO FINANCIAL STATEMENTS (UNAUDITED)

2. Initial Public Offering (continued)

Each unit consisted of one share of common stock, one half of one non-transferable Series A Common Stock Purchase Warrant and one half of one non-transferable Series B Common Stock Purchase Warrant. One whole Series A warrant was exercisable on or before December 24, 2003 to acquire one share of common stock at a price of \$2.00 per share. All Series A warrants were exercised on or prior to December 24, 2003 providing proceeds of \$2,400,000. One whole Series B warrant was exercisable on or before March 24, 2004 to acquire one share of common stock at a price of \$3.00 per share. A total of 995,400 Series B warrants were exercised on or before March 24, 2004 providing proceeds of \$2,986,200 and the remaining 204,600 Series B warrants expired unexercised on March 24, 2004. In addition to receiving a cash commission for each share sold, the underwriting agent for the IPO received 100,000 shares of common stock of the Company and warrants to purchase 500,000 shares of common stock of the Company at \$1.25 per share until June 24, 2005. As of March 31, 2004, 193,526 underwriter warrants were exercised providing proceeds to the Company of \$241,908.

Through March 31, 2004 we have applied a total of \$1,912,800 in net proceeds from our initial public offering as follows:

Reduction of notes payable and accrued interest thereon to directors and

officers:		
Brian McAlister (Cornet Capital Corp.)	\$	179,757
Robert Zahradnik		88,477
Jeffrey Hillman		15,429
Deferred compensation payable to officers		189,302
Patent expenses paid to University of Florida		100,000
Regulatory consulting fees		127,828
Mutacin 1140 production research		206,730
Pre-clinical research		439,380
General and administration costs		517,185
Purchase of computer and laboratory equipment		48,712

	\$	1,912,800

Other than normal and recurring compensation and payment on notes payable, there were no other payments, directly or indirectly, to any of our officers or directors or any of their associates, or to any persons owning ten percent or more of our outstanding common stock from the proceeds of this offering. Unexpended proceeds are held in one financial institution and invested overnight in obligations of the U. S. Government or its agencies.

3. 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 antidilutive.

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, and the Management's Discussion and Analysis of Financial Condition and Results of Operations included in our 2003 Annual Report on Form 10-KSB filed with the Securities and Exchange Commission.

OVERVIEW

We are a biotechnology company aimed at adding value to novel technologies and products sourced from innovative research at the University of Florida and other academic centers. Our aim is to in-license and develop products through human proof-of-concept (Phase I or II) prior to partnering with major pharmaceutical, biotechnology or healthcare product firms for advanced clinical development and commercialization. We have generated no revenues from operations during the last two years. All of our revenues have been from a sponsored research agreement which has expired; none have been from sales.

We are currently developing the following products, each of which addresses potential market opportunities:

- o REPLACEMENT THERAPY is a single, painless topical treatment that has the potential to offer life-long protection from most tooth decay. We expect to initiate Phase I safety studies with this product during 2004.
- o MUTACIN 1140 is a novel antibiotic with activity against essentially all Gram-positive bacteria including vancomycin-resistant Staphylococcus aureus. We are currently in early preclinical stages of development for Mutacin 1140.
- o "PROBIOTIC" TECHNOLOGY employs naturally occurring beneficial bacteria to promote oral and periodontal health. Such products may be marketed as "health supplements" with limited regulatory filings, offering the opportunity for near-term commercialization.
- o "OTHER" TECHNOLOGIES include technologies that we may develop from our research and development activities or that we may license, including our recently licensed technology called in vivo induced antigen technology that enables 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.

A more detailed discussion of each technology follows:

REPLACEMENT THERAPY

Streptococcus mutans (*S. mutans*) is a strain of bacteria residing on everyone's teeth. The activity of this bacterium in converting sugar to lactic acid is the principal cause of tooth decay. Our Replacement Therapy employs a patented, genetically modified strain of *S. mutans* that does not produce this decay-producing acid. When applied to a person's teeth via a painless mouthwash, this organism will displace the resident acid-producing *S. mutans* providing potentially life-long protection against most dental decay. Replacement therapy is the result of 25 years of research by our founder, chairman and chief scientific officer, Jeffrey Hillman, DMD, PhD, a world-renowned molecular

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geneticist and expert on oral microbiology. Our plans are to initiate Phase I trials of this treatment during 2004.

MUTACIN 1140

Research has shown that the effective oral colonization by our Replacement Therapy bacterial strain is due to its production of a highly potent bactericidal substance with a broad antimicrobial spectrum of activity. Research has characterized this substance, called mutacin 1140, as a novel lantibiotic - a peptide containing the unusual amino acid lanthionine. Scientists have identified approximately 20 lantibiotics to date, including nisin, a substance used as a food preservative that has been given status as "GRAS" or "generally recognized as safe" by regulatory authorities.

In vitro studies show mutacin 1140 to have highly effective antibiotic activity against all Gram-positive bacteria tested to date including vancomycin-resistant *Staphylococcus Aureus* and *Enterococcus faecalis*, both of which are rapidly growing healthcare problems. Moreover, to date, bacteria exposed to mutacin 1140 have not acquired resistance to mutacin 1140's bactericidal effects. We are currently conducting preclinical development and developing a method for the commercial production of mutacin 1140. The company expects to complete this effort and file an Investigational New Drug application to begin clinical testing of mutacin 1140 in 2005.

"PROBIOTIC" TECHNOLOGY

Probiotics are live microorganisms that confer a health benefit to their host when administered in adequate amounts; the use of yogurt containing live *Lactobacillus* cultures to improve vaginal and urinary tract health is an example of a common probiotic application. Our research suggests that probiotics can reduce the levels of "bad" bacteria that contribute to poor oral health. We have identified three natural strains of bacteria and have demonstrated in laboratory tests and animal studies the ability of these organisms to provide significant protection against the causative organisms of periodontal disease and tooth decay. We plan to initiate human studies of our probiotic treatment in 2004. Because probiotic treatments are not generally subject to regulatory oversight, we believe we may achieve commercialization of this product in certain markets within two years. Probiotics have been targeted at improving the digestive system for many years, and they have broad market acceptance for this use in Japan and growing market appeal in Europe and the United States. If successfully developed, our probiotic treatment will be one of the first probiotic products marketed for the maintenance of oral health.

OTHER TECHNOLOGY

From time to time we may develop or license additional technologies that we believe would have significant market potential. For example, we recently licensed technology that will offer us the potential to generate and develop a number of product candidates for future out-licensing to corporate partners, particularly in the area of cancer. This technology platform was developed by our founder, chairman and chief scientific officer, Jeffrey D. Hillman, and University of Florida scientists. It is called in vivo induced antigen technology (IVIAT). IVIAT can quickly and easily identify in vivo induced genes in human infections without the use of animal models, facilitating the discovery of new targets for the development of vaccines, antimicrobials and diagnostics. Dr. Hillman and his collaborators have further developed methods based on this

approach to create Change Mediated Antigen Technology (CMAT). CMAT can be used to identify gene targets associated with the onset and progression of cancerous processes and autoimmune diseases. It can also be used to identify novel genes in plant diseases, including genes expressed by the pathogen when it causes the disease and genes expressed by the plant in response to the disease.

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BUSINESS OBJECTIVES AND MILESTONES

The specific goal of our business is to successfully develop, clinically test and obtain US Food and Drug Administration (FDA) approval for sales of products based on our licensed, patented technologies. Our present strategy involves undertaking the animal studies necessary for approval of an investigational new drug application for each technology. If successful, we will then undertake and complete Phase I human clinical trials. We intend at that point to consider a sublicense of each of our technologies to one or more pharmaceutical companies, who will be responsible for funding the completion of the Phase II and III clinical trials for the technologies, the cost of the new drug application, and for the manufacture and distribution of products based on our technologies. In order to accomplish these objectives, we must take the following actions:

REPLACEMENT THERAPY

1. Obtain FDA approval to begin human clinical studies.
2. Complete Phase I clinical trials.

MUTACIN 1140

1. Develop a suitable production method for mutacin 1140.
2. Complete preclinical studies, including animal toxicity and efficacy, required for an investigational new drug application submission.
3. Submit an investigational new drug application to the FDA.

PROBIOTIC TECHNOLOGY

1. Conduct pre-market safety studies in animals.
2. Develop appropriate manufacturing and packaging systems.
3. Complete one human study.

OTHER TECHNOLOGY

1. Complete research on tuberculosis targets as described in the National Institutes of Allergy and Infectious Diseases (NIAID) Grant.
2. Begin program with CMAT on cancer targets.

These actions, both individually and in the aggregate, are expected to be costly and will require additional capital to complete.

CRITICAL ACCOUNTING POLICIES

Our significant accounting policies are more fully described in the Notes to Financial Statements that are contained in our 2003 Annual Report on Form 10-KSB filed with the Securities and Exchange Commission. Application of these policies is particularly important to the portrayal of our financial condition

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and results of operations. These accounting policies require us to make subjective judgments in determining estimates about the effect of matters that are inherently uncertain. Actual results could differ materially from these estimates.

RESULTS OF OPERATIONS

THREE MONTHS ENDED MARCH 31, 2004 AND 2003

We had no revenues in the three months ended March 31, 2004 and 2003. Our operating expenses increased 162% to \$544,461 in the three months ended March 31, 2004 from \$207,899 in the same period in 2003. Research and development expenses increased 146% to \$262,295 in the three months ended March 31, 2004 from \$106,826 in the same period in 2003, reflecting the increase in research staff from four to nine persons amounting to approximately \$110,000, costs associated with regulatory and other research consultants amounting to approximately \$31,000 and the increased consumption of laboratory supplies of approximately \$12,500. General and administration expenses increased 179% to \$282,166 in the three months ended March 31, 2004 from \$101,073 in the same period in 2003, reflecting the full time hiring of our Chief Financial Officer which increased costs by approximately \$25,000, incurrence of consulting fees of approximately \$41,000 for investor and public relations and incurrence of professional fees and related costs predominantly associated with public entity filings of approximately \$92,000.

Interest income increased to \$7,021 in the three months ended March 31, 2004 from \$19 during the same period in 2003, reflecting the higher average cash balances maintained during the quarterly period in 2004 as a result of the funds available from our initial public offering ("IPO") and the subsequent exercise of common stock warrants associated with the IPO. We incurred no interest expense for the three months ended March 31, 2004 as compared to \$3,562 during the same period in 2003 as a result of repaying all notes to shareholders in 2003.

We incurred net losses of \$537,440 and \$211,442 during the three months ended March 31, 2004 and 2003, respectively. The increase in our net loss was principally caused by our hiring of personnel and increase in costs associated with supporting those employees, as well as the increase in fees to consultants to support our research efforts and our public company filings.

LIQUIDITY AND CAPITAL RESOURCES

From inception through early June 2003, we financed our operations primarily through the issuance of common stock for \$508,616, the issuance of notes payable to shareholders totaling \$260,454 and a sponsored research agreement totaling \$357,787. On June 24, 2003, we completed an initial public offering of our common stock that provided net proceeds to us of \$2,282,612 after deducting \$717,388 in commissions paid to the underwriter and other expenses incurred in connection with the offering. In addition, common stock warrants issued in connection with our initial public offering have provided additional proceeds of approximately \$5,600,000 through March 31, 2004, of which \$2,997,906 was received during the first quarter of 2004. We anticipate that total net proceeds of approximately \$7,900,000 from our initial public offering and subsequent warrant exercises will be adequate to satisfy our operating expenses and capital requirements as planned through 2005.

We had cash and cash equivalents of \$6,012,319 at March 31, 2004 that are held in one financial institution and invested overnight in obligations of the U. S. Government or its agencies.

We lease our laboratory and office facilities, as well as certain equipment, under a 12-month cancelable operating lease with annual renewal options. We have also entered into an agreement to lease a newly constructed facility in Alachua, Florida for five years with occupancy expected to begin in August 2004. To date we have paid \$13,193 as a security deposit and initial rent payment, as well as \$17,380 for specialized building design costs. We estimate that our additional capital outlay for leasehold improvements and equipment will be approximately \$275,000 that will be paid during the second and third quarters of 2004. The lease agreement requires monthly payments of \$6,400, exclusive of utilities, insurance and real estate taxes.

We expect to continue to incur substantial research and development expenses including continued increases in personnel and costs related to research, preclinical testing and clinical studies, as well as significant

administrative costs associated with public filings. We will require substantial funds to conduct research and development and preclinical and Phase I clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase II and III clinical testing and manufacture and marketing of any products that are approved for commercial sale. Our future capital requirements will depend on many factors, including continued scientific progress in our research and development programs, the magnitude of these programs, the scope and results of preclinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims, competing technological and market developments and our ability to establish development, manufacturing and marketing arrangements. We intend to seek additional funding through sublicensing arrangements and through public or private financings, but there can be no assurance that additional financing will be available on acceptable terms or at all.

RISK FACTORS AFFECTING OUR BUSINESS

Investors should carefully consider the following risk factors, in addition to the other information concerning the factors affecting forward-looking statements. Each of the risk factors could adversely affect our business, operating results and financial condition as well as adversely affect the value of an investment in us.

Certain oral statements made by management from time to time and certain statements contained herein and in documents incorporated herein by reference that are not historical facts are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and, because such statements involve risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. The terms "Oragenics," "Company," "we," "our," and "us" refer to Oragenics, Inc. The words "expect," "believe," "goal," "plan," "intend," "anticipate," "estimate," "will" and similar expressions and variations thereof if used, are intended to specifically identify forward-looking statements. Forward-looking statements are statements regarding the intent, belief or current expectations, estimates or projections of Oragenics, our directors or our officers about Oragenics and the industry in which we operate, and assumptions made by management, and include among other items, (i) our strategies regarding growth, including our intention to develop and market our products; (ii) our financing plans; (iii) trends affecting our financial condition or results of operations; (iv) our ability to continue to control costs and to meet our liquidity and other financing needs; (v) our ability to respond to and meet regulatory demands. These statements are not

guarantees of future performance and are subject to a number of known and unknown risks, uncertainties, and other factors, including those discussed below and elsewhere in this report and those set forth under "Risk Factors Affecting Our Business" in our 2003 Annual Report on Form 10-KSB filed with the Securities and Exchange Commission, that could cause actual results to differ materially from future results, performances, or achievements expressed or implied by such forward-looking statements. Consequently, undue reliance should not be placed on these forward-looking statements. Although we believe our expectations are based on reasonable assumptions, we can give no assurance that the anticipated results will occur. We undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Investors and prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and that actual results may differ materially from those in the forward-looking statements as a result of various factors which include, among others, (i) general economic conditions, particularly those affecting our ability to raise additional capital; (ii) conditions in the capital markets, including the interest rate environment and the availability of capital, which could affect our internal growth and possibilities for licensing and/or strategic alliances; (iii) changes in the competitive marketplace that could affect our expected revenue and/or costs of product development; (iv) our rights to the use of intellectual property and the potential for others to challenge and otherwise adversely affect or impair such rights; and (v) other factors including those identified in our filings from time to time with the SEC.

WE HAVE EXPERIENCED A HISTORY OF LOSSES AND EXPECT TO INCUR FUTURE LOSSES. WE HAVE GENERATED EXTREMELY LIMITED REVENUE FROM OUR OPERATIONS, AND NO REVENUE FROM SALES. THEREFORE, WE MUST CONTINUE TO RAISE MONEY FROM INVESTORS AND SEEK PARTNERS WITH WHOM TO COLLABORATE OUR RESEARCH AND DEVELOPMENT EFFORTS SO AS TO FUND OUR OPERATIONS. IF WE ARE UNABLE TO FUND OUR OPERATIONS, WE MAY CEASE DOING BUSINESS.

We have recorded minimal revenue to date and we have incurred a cumulative operating loss of approximately \$2,925,000 through March 31, 2004. Our losses have resulted principally from costs incurred in research and development activities related to our efforts to develop our technologies and from the associated administrative costs. We expect to incur significant operating losses and negative cash flows over the next several years due to the costs of expanded research and development efforts and preclinical and clinical trials and hiring additional personnel. We will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Even if we do achieve profitability, we may not be able to sustain or increase profitability. We have limited capital resources and it is likely that we will require additional capital to meet our future capital requirements. There is no assurance that such capital will be available to us or, if available, be on terms acceptable to us. To the extent we are unable to raise additional capital and our operating losses continue, we will need to take actions to reduce our costs of operations, which may adversely impact future operations, employee morale, business relations and other aspects of our business. An increase in capital resulting from a capital raising transaction under adverse business circumstances could result in substantial dilution to existing holders of our common stock and adversely impact our stock price.

THE FDA HAS PUT OUR INVESTIGATIONAL NEW DRUG APPLICATION FOR OUR REPLACEMENT THERAPY TECHNOLOGY ON CLINICAL HOLD. IF WE ARE UNABLE TO OBTAIN OR MAINTAIN REGULATORY CLEARANCE OR APPROVAL FOR OUR TECHNOLOGIES, WE WILL BE UNABLE TO GENERATE REVENUES AND MAY HAVE TO CEASE OPERATIONS.

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Our technologies have not been cleared for marketing by the FDA or foreign regulatory authorities and cannot be commercially distributed in the United States or any international markets until such clearance is obtained. Before regulatory approvals can be obtained, our technologies will be subject to extensive preclinical and clinical testing. These processes are lengthy and expensive. We cannot assure that such trials will demonstrate the safety or effectiveness of our technologies. There is a possibility that our replacement therapy and mutacin 1140 technologies may be found to be unsafe or ineffective or otherwise fail to satisfy regulatory requirements. The FDA has put our investigational new drug application for our replacement therapy technology on clinical hold. This means that we may not begin human clinical trials under our application until the FDA gives us permission to do so. We have amended our first investigational new drug application three times to respond to the FDA's concerns. We filed a new investigational new drug application in March of 2003. This investigational new drug application has also been placed on hold until we satisfy the FDA's safety concerns. 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 obtain or maintain FDA clearance for one or all of our technologies we may have to cease operations.

OUR PRODUCT CANDIDATES ARE IN THE PRELIMINARY 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.

Our three product candidates are in the preliminary development state. Although we have current data which indicates the promise of the concept of our replacement therapy and mutacin 1140 technologies, we can offer you no assurance that the technologies will be effective at a level sufficient to support a profitable business venture. If they are not, we will be unable to create marketable products, we will not generate revenues from our operations, and we will have to cease operations. The science on which our replacement therapy and mutacin 1140 technologies are based may also fail due to flaws or inaccuracies on which the data are based, or because the data is 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 will 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 obtaining regulatory approval to produce 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 shareholders. We anticipate we will remain engaged in research and development for a considerable period of time.

IT IS POSSIBLE THAT OUR REPLACEMENT THERAPY TECHNOLOGY WILL BE LESS EFFECTIVE IN HUMANS THAN IT HAS BEEN SHOWN TO BE IN ANIMALS. IT IS POSSIBLE OUR MUTACIN 1140 TECHNOLOGY WILL BE SHOWN TO BE INEFFECTIVE OR HARMFUL IN HUMANS. IF EITHER OF

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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 replacement therapy technology has been undertaken solely in animals. Those studies have proven our genetically altered strain of *S. mutans* to be effective in preventing tooth decay. 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 replacement therapy technology is shown to be ineffective in preventing tooth decay in humans, we will be unable to commercialize and generate revenues from this technology. To date the testing of our antibiotic substance, mutacin 1140, has been undertaken solely in the laboratory. We have not yet conducted animal or human studies of mutacin 1140. It is possible that when we conduct these studies, they will show that mutacin 1140 is ineffective or harmful. If mutacin 1140 is shown to be ineffective or harmful, we will be unable to commercialize it and generate revenues from sales of mutacin 1140. If we are unable to generate revenues from either technology, 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 UNDERTAKE THE PRECLINICAL AND CLINICAL TRIALS THAT ARE REQUIRED IN ORDER TO OBTAIN FDA PERMISSION TO SELL IT, AND WE WILL BE UNABLE TO GENERATE REVENUES FROM IT, 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 order for us to conduct the preclinical and Phase I clinical studies that we must complete in order to find a partner who will sub-license this technology from us and finance the Phase II and III clinical studies we must complete in order to obtain FDA approvals necessary to sell products based on this technology, we must demonstrate a method of producing commercial quantities of this substance economically. To date we have not found such a method and it is possible we will be unable to find one. If we are not able to find such a method, we will be unable to generate revenues from this technology and we may have to cease operations.

BEGINNING IN 2004, WE MUST SPEND AT LEAST \$1 MILLION ANNUALLY ON DEVELOPMENT OF THE TECHNOLOGIES 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 OUR TECHNOLOGIES MAY BE TERMINATED, AND WE MAY HAVE TO CEASE OPERATIONS.

We hold our replacement therapy and mutacin 1140 technologies under licenses from the University of Florida Research Foundation, Inc. Under the licenses, we must spend at least \$1 million per year beginning in 2004 and thereafter on development of those technologies before the first commercial sale

of products derived from those technologies. If we do not, our licenses could be terminated. Until commercial sales of such 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 our technologies and have to cease operations.

The University of Florida Research Foundation, Inc. may terminate our licenses in respect of our replacement therapy technology and our mutacin 1140 technology if we breach our obligations to timely pay monies to it, submit development reports to it or commit any other breach of the covenants contained in the license agreement. There is no assurance that we will be able to comply

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with these conditions. If we cannot, and if our license is terminated, our investment in development of our replacement therapy technology will become valueless and we may have to cease operations.

IF CLINICAL TRIALS FOR OUR PRODUCTS ARE UNSUCCESSFUL OR DELAYED, WE WILL BE UNABLE TO MEET OUR ANTICIPATED DEVELOPMENT AND COMMERCIALIZATION TIMELINES, WHICH COULD CAUSE OUR STOCK PRICE TO DECLINE.

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

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

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

The 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.

WE INTEND TO CONSIDER RELYING ON THIRD PARTIES TO PAY THE MAJORITY OF THE COSTS OF 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 THEM 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 licensed, patented technologies to pharmaceutical companies after completion of Phase I clinical studies. If we do so, our sublicensees will pay the costs of Phase II and III clinical trials, and manufacturing and marketing 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 are not, 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. 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

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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, OTHERS COULD COMPETE AGAINST US MORE DIRECTLY, WHICH WOULD 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.

IF THIRD PARTIES CLAIM WE ARE INFRINGING THEIR INTELLECTUAL PROPERTY RIGHTS, WE COULD SUFFER SIGNIFICANT LITIGATION OR LICENSING EXPENSES OR BE PREVENTED FROM MARKETING OUR PRODUCTS.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of others. However, regardless of our intent, our technologies may infringe the patents or violate other proprietary rights of third parties. In the event of such 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 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. Their notification did not state that they intended to pursue legal remedies. Management of our Company does not believe the gene in question infringes that patent. We have sent them correspondence setting out our position and we have not heard anything further from them. If necessary, we are prepared to assert our rights vigorously with respect to such matter. 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 B.C. International Corporation and/or we could owe substantial damages. If we become involved in any claims, litigation, interference or other administrative proceedings, we may incur substantial expense and the efforts of our technical and management personnel may be significantly diverted. Any future claims or adverse determinations with respect to our intellectual property rights may subject us to loss of our proprietary position or to significant liabilities, may require us to seek licenses from third parties, cause delays in the development and release of new products or services and/or may restrict or prevent us from manufacturing and selling certain of our products. If we are required to seek licenses from third parties, costs associated with these arrangements may be substantial and may include ongoing royalties. Furthermore, we may not be able to obtain the necessary licenses on satisfactory terms, if at all.

WE ARE SUBJECT TO SUBSTANTIAL GOVERNMENT REGULATION, WHICH COULD MATERIALLY ADVERSELY AFFECT OUR BUSINESS.

The production and marketing of our products 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 devices 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 our products to market, and we cannot guarantee that any of our products will be approved. The pre-marketing approval process can be particularly expensive, uncertain and lengthy, and a number of products for which FDA approval has been sought by other companies have never been approved for marketing. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling, and record-keeping procedures. If we do not comply with applicable regulatory requirements, such violations could result in warning letters, non-approval, suspensions of regulatory approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

Delays in or rejection of FDA or other government entity approval of our new products 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 U.S. In the U.S. 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 our current products for broader or different applications or to market updated products that represent extensions of our basic technology. In addition, we may not receive FDA export approval to export our products in the future, and countries to which products are to be exported may not approve them for import.

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 products. 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 products could make it more difficult and costly to obtain approval for new products, 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 replacement therapy and mutacin 1140 licensed technologies that have been developed through biotechnology 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 produced with 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

\$1,000,000 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 CAN'T OBTAIN THIRD PARTY REIMBURSEMENT FOR PRODUCTS BASED ON OUR TECHNOLOGIES, WE MAY HAVE TO CEASE OPERATIONS.

In the United States, success in obtaining payment for a new product from third parties such as insurers depends greatly on the ability to present data which demonstrates positive outcomes and reduced utilization of other products or services as well as cost data which shows that treatment costs using the new product are equal to or less than what is currently covered for other products. If we fail to present such clinical data that will adversely affect our ability to obtain favorable third party reimbursement, we will earn less revenue and we may have to cease operations.

OUR STOCK PRICE HAS BEEN VOLATILE AND OUR TRADING VOLUME HAS BEEN LOW.

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:

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

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 and through April 30, 2004, our stock price has fluctuated from a high of \$4.50 to a low of \$1.69 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 April 30, 2004, there were 14,318,380 shares of our common stock outstanding, with another 302,724 shares of common stock issuable upon exercise of our underwriter warrants and 740,000 shares issuable upon exercise of options issued or available for issuance under our stock option plans. The stock underlying these options has been registered for resale with the SEC. We currently have approximately 6,808,861 shares of our common stock held in escrow pursuant to Canadian law and underwriter requirements in connection with our initial public offering pursuant to escrow agreements. These shares are released from escrow periodically in three and six month increments and are subject to the

limitations of the respective escrow agreements. Of these shares, 6,150,573 are held by principals of the Company, 449,955 are held by the University of Florida Research Foundation, Inc. and 208,333 are held by other non-principal shareholders.

WE MAY BE UNABLE TO MAINTAIN THE LISTING OF OUR COMMON STOCK ON THE TSX VENTURE EXCHANGE TIER 2 AND PENNY STOCK RULES MAY APPLY TO THE SALE OF OUR COMMON STOCK THAT, IN EACH CASE, WOULD MAKE IT MORE DIFFICULT FOR SHAREHOLDERS TO DISPOSE OF THEIR COMMON STOCK.

Our common stock is listed on the TSX Venture Exchange Tier 2 in Canada. We cannot guarantee that it will always be listed. The TSX Venture Exchange Tier 2 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.

If our common stock is delisted from the TSX Venture Exchange Tier 2, trading in our common stock would be conducted, if at all, on the NEX Board of the TSX Venture Exchange in Canada and on the NASD'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.

There are separate rules regulating United States broker-dealers who trade on behalf of customers in unlisted stocks. These rules require broker-dealers to:

- o sell common stock only to purchasers for which transactions in penny stocks are suitable unless such purchasers are established customers as defined in Rule 15g-9 of the Securities Exchange Act of 1934;
- o sell common stock only to purchasers that have sufficient knowledge and experience in financial matters that the person reasonably may be expected to be capable of evaluating the risks of transactions in penny stock; and
- o receive the purchaser's written consent to the transaction prior to sale.

The United States Securities and Exchange Commission has adopted regulations that define "penny stock" to include common stock that has a market price of less than \$5.00 per share, subject to certain exceptions. Our shares of common stock are covered by the penny stock rules under Section 15(g) of the Securities Exchange Act of 1934, as amended, and the related rules of the SEC. They impose additional sales practice requirements on United States broker/dealers who sell our securities. Broker-dealers engaging in the sale of penny stocks must comply with, among other things, the following requirements:

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- o delivery to purchasers, prior to the transaction, of a risk disclosure statement prepared by the Securities and Exchange Commission relating to the penny stock market;
- o disclosure to purchasers of the commissions payable to the broker-dealer and its registered representative;
- o disclosure to purchasers of current quotations for the securities; and
- o delivery to customers with monthly statements disclosing recent price information for all penny stock held in the customer's account and information on the limited market in penny stocks.

The broker must provide the bid and offer quotations and compensation information before effecting the transaction. This information must be contained in the customer's confirmation. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for a stock that is subject to the penny stock rules because of the lack of ability or incentive of broker-dealers to sell our common stock.

Our shares are subject to the foregoing rules in the United States. The foregoing rules apply to broker/dealers. The application of the penny stock rules may affect your ability to resell your shares in the United States because some broker/dealers may not be willing to make a market in our securities because of the burdens imposed upon them by the penny stock rules. Also, the broker prepares the information provided to the broker's customers. Because we do not prepare the information, we cannot assure you such information is current or complete.

Our common stock is defined as a penny stock under the Securities and Exchange Act of 1934, and its rules. Because our common stock is a penny stock, you may not be able to resell your shares in the United States. This is because the Exchange Act and the penny stock rules impose additional sales practice and disclosure requirements on broker/dealers who sell our securities to persons other than accredited investors. As a result, fewer broker/dealers are willing to make a market in our stock.

WE MUST MAINTAIN A CURRENT PROSPECTUS AND REGISTRATION STATEMENT IN ORDER FOR OUR OUTSTANDING WARRANTS TO BE EXERCISED BY THEIR HOLDERS.

We must maintain an effective registration statement on file with the Securities and Exchange Commission before the holder of any of our warrants may be redeemed or exercised. It is possible that we may be unable to cause a registration statement covering the common stock underlying the warrants to be effective. We anticipate that we may need to meet state registration requirements for sales of securities in states where an exemption from registration is not otherwise available. The warrants may expire unexercised, which would result in the holders losing all the value of their investment in the warrants. There can be no assurance that we will be able to maintain an effective registration statement covering the issuance of common stock upon redemption or exercise of the warrants. If we are unable to maintain an effective registration for the issuance of common stock upon exercise of the warrants, we may be subject to claims by the warrant holders.

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ITEM 3. CONTROLS AND PROCEDURES

DISCLOSURE CONTROLS AND PROCEDURES

Our Chief Executive Officer and Chief Financial Officer have established and are currently maintaining disclosure controls and procedures for our company. The disclosure controls and procedures have been designed to ensure that material information relating to our Company is made known to them as soon as it is known by others within our Company. 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. USE OF PROCEEDS

Note 2 of the Financial Statements included in Part I of this filing of Form 10-QSB as to use of proceeds during the quarterly period ended March 31, 2004 is hereby incorporated by reference.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(A) EXHIBITS ITEM DESCRIPTION

- 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.
- 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.

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).

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).

(B) REPORTS ON FORM 8-K FILED DURING THE QUARTER ENDED MARCH 31, 2004

On January 5, 2004, the Company filed a Form 8-K announcing that all Series A common stock warrants had been exercised at \$2.00 per share providing total funds of \$2,400,000. The Company also announced the hiring of MontRidge LLC as its investor relations consultant.

On January 22, 2004, the Company filed a Form 8-K announcing that its common shares had been accepted for quotation on the OTC Bulletin Board under the symbol "OGEN."

On February 2, 2004, the Company filed a Form 8-K announcing the hiring of Dr. Eric Chojnicki as Vice President of Product Development.

On February 18, 2004, the Company filed a Form 8-K announcing that ground-breaking ceremonies were held for the construction of facilities in Alachua, Florida for the Company's new headquarters.

On March 4, 2004, the Company filed a Form 8-K announcing that it had licensed novel technology for which a Phase I SBIR award had been granted by the National Institute of Allergy and Infectious Diseases.

March 15, 2004, the Company filed a Form 8-K announcing that the Recombinant DNA Advisory Committee had unanimously recommended approval of the first human clinical study of the Company's Replacement Therapy technology.

On March 29, 2004, the Company filed a Form 8-K announcing that 995,400 Series B common stock warrants had been exercised at \$3.00 per share providing total funds of \$2,986,200 and the remaining 204,600 warrants had expired unexercised.

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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 7th day of May, 2004.

ORAGENICS, INC.

BY: /s/ Mento A. Soponis

Mento A. Soponis, President and
Principal Executive Officer

BY: /s/ Paul A. Hassie

Paul A. Hassie, Secretary,
Treasurer, Principal Accounting Officer
and Principal Financial Officer

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CERTIFICATION

I, Mento A. Soponis, 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 7, 2004

/s/ Mento A. Soponis

Mento A. Soponis
President
(principal executive officer)

EXHIBIT 31.2

CERTIFICATION

I, Paul A. Hassie, 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 7, 2004

/s/ Paul A. Hassie

Paul A. Hassie
Chief Financial Officer
(principal financial officer)

EXHIBIT 32.1

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, 2004 as filed with the Securities and Exchange Commission on the date here of (the "Report"), I, Mento A. Soponis, 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 7th day of May, 2004.

/s/ Mento A. Soponis
Mento A. Soponis
Chief Executive Officer

EXHIBIT 32.2

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, 2004 as filed with the Securities and Exchange Commission on the date here of (the "Report"), I, Paul A. Hassie, 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 7th day of May, 2004.

/s/ Paul A. Hassie
Paul A. Hassie
Chief Financial Officer