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FORM 10-QSB

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES

|X| EXCHANGE ACT OF 1934 For the quarterly period ended September 30, 2004.

OR

|_| TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT

For the transition period from _____ to _____

Commission File Number: 000-50614

ORAGENICS, INC.
(Exact name of small business issuer as specified in its charter)

FLORIDA	59-3410522
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

12085 Research Drive
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 |X| 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 November 3, 2004, there were 14,323,380 shares of Common Stock, $.001 par value, outstanding.

Transitional Small Business Disclosure Format (check one): Yes |_| No |X|

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PART II - OTHER INFORMATION

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Oragenics, Inc.

Balance Sheets
(In US Dollars)

	September 30, 2004 (Unaudited)	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 4,314,355	$ 3,583,757
Prepaid expenses and other current assets	187,293	24,637
Total current assets	4,501,648	3,608,394
Property and equipment, net	306,623	42,371
Total assets	$ 4,808,271	$ 3,650,765
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 326,817	$ 140,614
Accrued interest	--	25,582
Deferred compensation	--	44,672
Total current liabilities	326,817	210,868
Stockholders' equity:		
Preferred stock, no par value; 20,000,000 shares authorized; none issued and outstanding at September 30, 2004 and December 31, 2003	--	--
Common stock, $0.001 par value; 100,000,000 shares authorized; 14,323,380 and 13,296,204 shares issued and outstanding at September 30, 2004 and December 31, 2003, respectively	14,323	13,296
Additional paid in capital	8,680,099	5,820,697
Accumulated deficit	(4,212,968)	(2,394,096)
Total stockholders' equity	4,481,454	3,439,897
Total liabilities and stockholders' equity	$ 4,808,271	$ 3,650,765

See accompanying notes.

Oragenics, Inc.

Statements of Operations
(Unaudited)
(In US Dollars)

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	Three months ended September 30		Nine months ended September 30	
	2004	2003	2004	2003
<S>	<C>	<C>	<C>	<C>
Revenue	$ 118,642	$ --	$ 162,877	$ --
Operating expenses:				
Research and development	567,743	205,615	1,248,423	596,205
General and administration	177,818	192,811	764,801	442,560
Total operating expenses	745,561	398,426	2,013,224	1,038,765
Loss from operations	(626,919)	(398,426)	(1,850,347)	(1,038,765)
Other income (expense):				
Interest income	13,149	3,799	31,475	4,275
Interest expense	--	(2,095)	--	(10,993)
Total other income (expense), net	13,149	1,704	31,475	(6,718)
Net loss	$ (613,770)	$ (396,722)	$ (1,818,872)	$ (1,045,483)
Basic and diluted net loss per share	$ (0.04)	$ (0.03)	$ (0.13)	$ (0.10)
Shares used to compute basic and diluted net loss per share	14,323,380	11,958,701	14,019,561	10,334,260

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See accompanying notes.

Oragenics, Inc.

Statements of Cash Flows
(Unaudited)
(In US Dollars)

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	Nine months ended September 30	
	2004	2003
<S>	<C>	<C>
Operating activities		
Net loss	$(1,818,872)	$(1,045,483)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	16,728	8,601
Noncash issuance of common stock and common stock options	--	54,000
Stock-based compensation expense (credit)	(90,977)	170,291
Changes in operating assets and liabilities:		
Costs associated with initial public offering	--	271,937
Prepaid expenses	(162,656)	(81,800)
Accounts payable and accrued expenses	186,203	(150,201)
Accrued interest	(25,582)	6,236
Deferred compensation	(44,672)	(13,999)
Net cash used in operating activities	(1,939,828)	(780,418)
Investing activity		
Purchases of property and equipment	(280,980)	(40,877)
Net cash used in investing activity	(280,980)	(40,877)

Financing activities		
Net proceeds from issuance of common stock	2,951,406	2,488,862
Proceeds from notes payable to stockholder	--	175,000
Payments of notes payable to stockholder	--	(175,000)
Net cash provided by financing activities	2,951,406	2,488,862
Net increase in cash and cash equivalents	730,598	1,667,567
Cash and cash equivalents at beginning of period	3,583,757	25,580
Cash and cash equivalents at end of period	$ 4,314,355	$ 1,693,147

</TABLE>

See accompanying notes.

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 and nine month periods ended September 30, 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-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 September 30, 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 which are included in our Annual Report on Form 10-KSB filed with the Securities and Exchange Commission on March 17, 2004.

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.

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

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	Three months ended September 30		Nine months ended September 30	
	2004	2003	2004	2003
<S>	<C>	<C>	<C>	<C>
Net loss, as reported	$ (613,770)	$ (396,722)	$(1,818,872)	$(1,045,483)
Effect of stock-based employee compensation expense (credit) included in reported net income	(63,700)	114,228	(90,977)	170,291
Total stock-based employee compensation expense determined under fair value based method for all awards	(34,255)	(1,950)	(98,026)	(5,850)
Pro forma net loss	$ (711,725)	$ (284,444)	$(2,007,875)	$ (881,042)
Net loss per share:				
Basic and diluted --as reported	$ (0.04)	$ (0.03)	$ (0.13)	$ (0.10)
Basic and diluted --pro forma	$ (0.05)	$ (0.02)	$ (0.14)	$ (0.09)

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2. Initial Public Offering

On June 24, 2003, we completed an initial public offering (IPO) 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.

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 September 30, 2004, 202,276 underwriter warrants were exercised providing proceeds to the Company of

$252,845. With respect to the remaining 297,724 unexercised underwriter warrants, the Company is required to maintain an effective registration statement for the shares of common stock underlying the warrants and filed a post effective amendment on Form S-3 with the Securities and Exchange Commission on October 15, 2004. A portion of the estimated costs incurred to date of $57,437 associated with this filing through September 30, 2004 are netted against proceeds and recorded as a component of stockholders' equity.

Through September 30, 2004 we have applied a total of $3,671,151 of the $7,864,220 in net proceeds from our initial public offering as follows:

Reduction of notes payable and accrued interest thereon to directors and officers:

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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	164,073
Mutacin 1140 production research	357,325
Pre-clinical research	1,158,304
General and administration costs	1,113,004
Purchase of computer and laboratory equipment	305,480
	$ 3,671,151

</TABLE>

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. Management believes that the Company has used, and continues to use, the net proceeds from the offering consistent with its business strategy described in the Form SB-2 registration statement.

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 anti-dilutive.

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 on March 17, 2004.

Overview

We are an emerging biotechnology company focused on the development and licensure of innovative products and technologies for improving human health. We aim to add value to novel technologies and products sourced from innovative research at the University of Florida and other academic centers. Our lead product is a novel oral rinse for the prevention of tooth decay. On October 22, 2004 we received a letter from the U. S. Food and Drug Administration (FDA) stating the Investigational New Drug (IND) application for our replacement therapy technology remains on clinical hold pending specific changes to the clinical protocol submitted by us. The requested changes are predominantly clarifications in the conduct of the proposed clinical trial and do not require any further testing. We resubmitted our protocol to the FDA on October 30, 2004. We expect clinical trials are now likely to commence in the first quarter of 2005. Our goals are to in-license and develop products through human

proof-of-concept (Phase I or II), after which we will consider partnering with major pharmaceutical, biotechnology or healthcare product firms for advanced clinical development and commercialization. We have generated limited, non-recurring revenues from operations during the last two years. Revenues totaling $162,877 during the nine months ended September 30, 2004 have been from two Small Business Innovation Research (SBIR) grants. We currently generate no revenue from any of the products we are seeking to develop.

Our principal executive offices are located at 12085 Research Drive, Alachua, Florida 32615 and our internet address is www.oragenics.com. Our annual report on Form 10-KSB, quarterly reports on Form 10-QSB, current reports on Form 8-K, amendments to such reports and our other Securities and Exchange Commission filings are available through our website free of charge as soon as reasonably practicable after such reports are electronically filed with the Securities and Exchange Commission. The information contained on our website is not intended to be part of this report. Our common stock is listed exclusively on the American Stock Exchange ("AMEX") and traded under the symbol "ONI". Prior to October 13, 2004 our common stock was also listed on the TSX Venture Exchange in Canada and we have since voluntarily ceased trading on such Canadian Exchange because we believe that being listed solely on AMEX is in the best interests of our Company and our shareholders.

Our strategy continues to be to develop and sublicense our current technologies and license new technologies in our fields of expertise. We are continuing with our efforts to begin clinical trials on our replacement therapy product and are working to develop a methodology for large scale production of Mutacin 1140. Consistent with our strategy, in August 2003 our researchers developed an oral probiotic technology stemming from our research on our replacement therapy technology. We believe our oral probiotic technology appears to present a significant opportunity for near-term revenues and we have decided to patent this technology and move forward with a strategy for product development. Our current development plans for our oral probiotic technology during the next year include incurring costs of approximately $1.75 million for contract manufacturing and clinical research. We expect this will position us to be able to sublicense our oral probiotic technology for commercial development in Asia and Europe that will generate sublicense fees and product royalties.

To help achieve the goals we have set forth, we hired two executive level R&D specialists during the nine months ended September 30, 2004. In February 2004, we hired Eric Chojnicki as Vice President of Product Development. In September 2004, we hired Edmund Mickunas as Vice President of Regulatory and Clinical Affairs. Eric and Ed have brought expertise to Oragenics that will help us develop the technologies we currently own, work to streamline our regulatory submissions and clinical study programs and identify new technologies for potential acquisition. We also retain various entities to assist with FDA and other regulatory submissions and clinical trial design and administration for our replacement therapy technology, and dossier documentation for our oral probiotic technology.

In March 2004, we licensed novel technologies for the rapid identification of potential therapeutic, vaccine or diagnostic targets implicated in the onset and progression of disease from iviGene Corporation. iviGene is a company that maintains common ownership with us in that three officers and directors of Oragenics are shareholders of iviGene. Under this license, we will receive exclusive worldwide rights to these technologies, referred to as IVIAT and CMAT, in the areas of cancer and tuberculosis, as well as agricultural and other non-human applications. We made no initial up frontpayment for this license, but we are obligated to pay iviGene royalties on revenues generated from sub-license fees, milestone payments and royalties from others for products created from the IVIAT or CMAT technologies. In connection with this license, we received a Phase I SBIR award totaling up to $100,000 that was granted by the National Institute of Allergy and Infectious Diseases (NIAID). As of September 30, 2004, the Company incurred costs of $96,210 subject to the grant, of which $60,000 was reimbursed to us and $36,210 is expected to be paid in the fourth quarter of 2004. No royalties will be due iviGene on the receipt of funds from this grant, however, under the terms of the agreement with iviGene we are committed to expend a minimum of $100,000 in 2004 and $200,000 per year thereafter in order to maintain our license.

We currently have the following technologies in various stages of development:

- Replacement Therapy is a single, painless topical treatment that has the potential to offer life-long protection from most tooth decay. Subject to FDA approval of our amended IND application, we expect to initiate Phase I clinical safety trials with this product in the first quarter of 2005.

- Mutacin 1140 is a novel antibiotic with activity against essentially all Gram-positive bacteria including multidrug resistant Staphylococcus aureus and Enterococcus faecalis. Mutacin 1140 has a number of other characteristics that suggest its potential use in the treatment of a variety of infectious diseases. In particular, researchers have not succeeded to date in demonstrating bacterial resistance to this antibiotic. We are currently in the preclinical stage of development and have not filed an investigational new drug application for Mutacin 1140.

- Oral Probiotic Technology employs naturally occurring beneficial bacteria to promote dental and periodontal health. Probiotics are widely employed in Asia and Europe, and acceptance in the United States is growing. Such products may be marketed as "health supplements" without the need for extensive regulatory filings, offering the opportunity for near-term commercialization. We plan to conduct an extensive safety study and, depending on the results of such safety study, negotiate arrangements with manufacturing and marketing partners for our oral probiotic technology within the next year.

- IVIAT and CMAT are related platform technologies that we have recently licensed from iviGene Corp. IVIAT, which stands for In Vivo Induced Antigen Technology, and which we believe provides a simple, fast and sensitive method for identification of novel and potentially important new targets for use in the diagnosis and prevention of infectious diseases. CMAT, which stands for Change Mediated Antigen Technology, we believe identifies novel and potentially important targets for diagnosis and treatment of cancers and other diseases in humans and other living organisms, including plants. These technologies are in the early stages of research and development and as such there is no anticipation for making any regulatory filings with regards to IVIAT or CMAT in the near future.

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 studies necessary for IND regulatory approval for each technology. If successful, we will then be in a position to undertake, when necessary, human clinical trials relating to safety. 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 additional clinical studies relating to efficacy 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 with respect to each of our product development efforts, we must take the following actions:

Replacement Therapy

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

2. Complete Phase I clinical trials.

Mutacin 1140

1. Develop a suitable method for clinical quantity production of Mutacin 1140.

2. Complete preclinical studies, including animal toxicity and efficacy, required for an investigational new drug application submission.

3. Engage marketing partners in Europe and Asia.

Oral Probiotic Technology

1. Conduct pre-market safety studies in animals.

2. Develop appropriate manufacturing and packaging systems.

3. Complete one human study.

IVIAT and CMAT

1. Establish research program with CMAT on cancer targets.

These actions, both individually and in the aggregate, are expected to be costly and will require additional capital, beyond what is currently available to us in order to accomplish them. In addition, current funds available may need to be allocated among the technologies we are developing toward those that management believes could provide an opportunity for near term revenue growth.

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 and Canada. The preparation of financial statements in accordance with accounting principles generally accepted in the United States and Canada 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 significant estimates that have a material impact on our results of operations or financial condition.

Results of Operations

Three Months Ended September 30, 2004 and 2003

We had revenues of $118,642 associated with two SBIR grants in the three months ended September 30, 2004 and no revenues during the same period in 2003. Our operating expenses increased 87% to $745,561 in the three months ended September 30, 2004 from $398,426 in the same period in 2003. Research and development expenses increased 176% to $567,743 in the three months ended September 30, 2004 from $205,615 in the same period in 2003, reflecting the doubling of our research staff amounting to approximately $46,000, the hiring of two senior executives amounting to approximately $100,000, regulatory and pre-clinical manufacturing costs associated with our replacement therapy technology amounting to approximately $100,000, costs associated with developing the oral probiotic technology of approximately $95,000, increased patent costs of approximately $9,000 associated with new technologies, the increased consumption of laboratory supplies of approximately $50,000 and the increase in facility and general R&D operating costs amounting to approximately $25,000 associated with the general increase in R&D activity, less a reduction in expenses in connection with compensation expense for options approximating $63,000 caused by a significantly lower stock price in 2004. General and administration expenses decreased 8% to $177,818 in the three months ended September 30, 2004 from $192,811 in the same period in 2003, reflecting the reduction in expenses in connection with compensation expense for options approximating $109,000 caused by a significantly lower stock price in 2004, offset by increases caused by the full time hiring of our Chief Financial Officer amounting to approximately $24,000, the hiring of an accounting manager resulting in increased costs of approximately $18,000, the incurrence of consulting fees of approximately $37,000 for investor and public relations consulting and additional premium costs of approximately $15,000 relating to the increase in coverage for directors' and officers' liability insurance.

Interest income increased 246% to $13,149 in the three months ended

September 30, 2004 from $3,799 during the same period in 2003, reflecting the higher average cash balances maintained during the quarterly period in 2004 as a result of the exercise of common stock warrants associated with the IPO. We incurred no interest expense for the three months ended September 30, 2004 as compared to $2,095 during the same period in 2003 as a result of the repayment of all notes to shareholders in December 2003.

We incurred net losses of $613,770 and $396,722 during the three months ended September 30, 2004 and 2003, respectively. The increase in our net loss amounting to $217,048 was principally caused by our hiring of additional personnel and increase in costs associated with supporting those employees, as well as the regulatory and pre-clinical manufacturing undertaken for our replacement therapy and oral probiotic technologies and the increase in consulting fees to support our research efforts and our public company status.

Nine Months Ended September 30, 2004 and 2003

We had revenues of $162,877 associated with two SBIR grants in the nine months ended September 30, 2004 and no revenues during the same period in 2003. Our operating expenses increased 94% to $2,013,224 in the nine months ended September 30, 2004 from $1,038,765 in the same period in 2003. Research and development expenses increased 109% to $1,248,423 in the nine months ended September 30, 2004 from $596,205 in the same period in 2003, reflecting the

doubling of our research staff amounting to approximately $165,000, the hiring of two senior executives amounting to approximately $250,000, regulatory and pre-clinical manufacturing costs associated with our replacement therapy technology amounting to approximately $128,000, costs associated with developing the oral probiotic technology of approximately $125,000, the increased consumption of laboratory supplies of approximately $77,000 and the increase in facility and general R&D operating costs amounting to approximately $41,000 associated with the general increase in R&D activity, less a reduction in patent costs of $34,000 whereby a one-time charge of $100,000 was required in 2003 and a reduction in compensation expense for options approximating $100,000 caused by a significantly lower stock price in 2004. General and administration expenses increased 73% to $764,801 in the nine months ended September 30, 2004 from $442,560 in the same period in 2003, reflecting the full time hiring of our Chief Financial Officer and the hiring of our accounting manager which increased costs by approximately $108,000, a one-time charge of $65,000 for listing on the American Stock Exchange, incurrence of consulting fees of approximately $120,000 for investor, public relations and financial consulting, increased costs for travel of approximately $34,000 associated with business trips to Europe and Asia, additional premium costs of approximately $21,000 relating to the increase in coverage for directors' and officers' liability insurance, the incurrence of professional fees and related costs predominantly associated with public entity filings of approximately $122,000 and the increase in facility and general administrative costs amounting to approximately $13,000, less a reduction in expenses in connection with the compensation expense for options approximating $161,000 caused by a significantly lower stock price in 2004.

Interest income increased by $27,200 to $31,475 in the nine months ended September 30, 2004 from $4,275 during the same period in 2003, reflecting the higher average cash balances maintained during the nine month period ended September 30, 2004 as a result of the funds available from the exercise of common stock warrants associated with the IPO. We incurred no interest expense for the nine months ended September 30, 2004 as compared to $10,993 during the same period in 2003 as a result of repaying all notes to shareholders in December 2003.

We incurred net losses of $1,818,872 and $1,045,483 during the nine months ended September 30, 2004 and 2003, respectively. The increase in our net loss was principally caused by our hiring of additional personnel and increase in costs associated with supporting those employees, as well as the regulatory and pre-clinical manufacturing undertaken for our replacement therapy and oral probiotic technologies and the increase in consulting fees to support our research efforts and our public company status.

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 September 30, 2004, of which approximately $3,009,000 was received in 2004. Through September 30, 2004 we have used $3,671,151 of the $7,864,220 in net proceeds from our initial public offering to repay certain indebtedness and pay expenses for research, development and general corporate purposes.

We have invested the remainder of the proceeds in overnight obligations of the U. S. Government or its agencies that are held in one financial institution and at September 30, 2004 we had cash and cash equivalents of $4,314,355. We anticipate that this cash will be adequate to satisfy our anticipated operating expenses and capital requirements as currently planned through 2005.

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 the fourth quarter of 2004. To date we have paid $13,193 as a security deposit and initial rent payment, as well as $150,469 for specialized building design costs. We estimate that our additional capital outlay for leasehold improvements and equipment will be approximately $160,000 that will be paid during the fourth quarter 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 are currently interviewing candidates for the executive level position of business development and expect this hiring to be complete before the end of 2004. 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, our ability to establish development, manufacturing and marketing arrangements and our ability to generate revenue. We intend to seek additional funding through sublicensing arrangements, government grants and through public or private financings. In October 2004, we entered into an agreement with an investment advisory firm to assist us in raising capital by acting as a financial advisor and placement agent for a proposed private placement of our common stock. There can be no assurance that additional financing will be available to us on acceptable terms, or at all. Any such financings may be dilutive in ownership, preferences, rights, or privileges to our shareholders. If we are unable to obtain funds when needed or on acceptable terms, we may be required to curtail our current development programs and forego future development opportunities.

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.

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 in 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 $4,206,000 through September 30, 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.

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 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.

All of our product candidates are in the preliminary development state. Although we have current data which indicates the promise of the concept of our 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 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 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 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 shareholders. We anticipate we will remain engaged in research and development for a considerable period of time, and there can be no assurance that we will be able to generate adequate revenue from operations.

It is possible that our replacement therapy and oral probiotic technology will be less effective in humans than they have been shown to be in animals. It is possible our Mutacin 1140 technology will be shown to be ineffective or harmful in humans. If any of these technologies are shown to be ineffective or harmful in humans, we will be unable to generate revenues from them, and we may have to cease operations.

To date the testing of our replacement therapy technology has been undertaken solely in animals. Those studies have proven our genetically altered strain of Streptococcus mutans ("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 oral probiotic technology has been undertaken solely in animals. Those studies have shown our technology to be effective at helping to reduce certain bacteria that are believed to cause periodontal disease. It is possible that our oral probiotic technology will not be effective in reducing those bacteria and will not improve periodontal health. If our oral probiotic technology is shown to be ineffective or harmful to humans, we will be unable to commercialize it and generate revenues from sales. To date the testing of the 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 these studies are conducted, they will show that Mutacin 1140 is ineffective or harmful. If Mutacin 1140 is shown to be ineffective or harmful, we will be unable to commercialize it and generate revenues from sales of Mutacin 1140. If we are unable to generate revenues from our technologies, we may have to cease operations.

It is possible we will be unable to find a method to produce Mutacin 1140 in large-scale commercial quantities. If we cannot, we will be unable to undertake the preclinical and clinical trials that are required in order to obtain FDA permission to sell it, 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 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 develop a suitable method for clinical quantity production of Mutacin 1140, 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 our replacement therapy and Mutacin 1140 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 these technologies may be terminated, and we may have to cease operations.

We hold our replacement therapy and Mutacin 1140 technologies under licenses from the University of Florida Research Foundation, Inc. Under the

terms of the licenses, we must spend at least $1 million per year 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 these technologies and have to cease operations.

The University of Florida Research Foundation, Inc. may terminate our licenses in respect of our replacement therapy technology and our Mutacin 1140 technology if we breach our obligations to timely pay monies to it, submit development reports to it or commit any other breach of the covenants contained in the license agreement. There is no assurance that we will be able to comply with these conditions. If we cannot, and if our license is terminated, our investment in development of our replacement therapy and Mutacin 1140 technologies will become valueless and we may have to cease operations.

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. 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.

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 sublicensees 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. 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, 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 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 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 products based on our licensed, patented technologies for broader or different applications or to market updated products that represent extensions of our basic technologies. In addition, we may not receive FDA approval to export our products based on our licensed, patented technologies in the future, and countries to which products are to be exported may not approve them for import.

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

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

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

The commercial success of our replacement therapy, oral probiotics and Mutacin 1140 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 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 historically has been volatile and our stock's trading volume has been low.

Although our common stock began trading on the American Stock Exchange under the symbol "ONI" in May, 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 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 September 30, 2004 our stock price has fluctuated from $4.50 to $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 September 30, 2004, there were 14,323,380 shares of our common stock outstanding, with another 297,724 shares of common stock issuable upon exercise of our underwriter warrants, 960,000 shares issuable upon exercise of options issued and an additional 540,000 shares available for issuance under our stock option plans. The issuance of our stock underlying these options is covered by an S-8 registration statement we filed with the SEC. The Company currently has

approximately 5,280,422 shares of common stock held in escrow pursuant to Canadian law and underwriter requirements in connection with its 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 4,920,458 are held by principals of the Company and 359,964 are held by the University of Florida Research Foundation, Inc. On December 24, 2004, approximately 1,230,115 shares held by principals (including a former director) will be released from

escrow as well as 89,991 shares held by the University of Florida Research Foundation, Inc. The shares held by the principals (excluding the former director) will be subject to Rule 144 for resales. The shares held by the University of Florida Research Foundation, Inc. will be eligible for resale without restriction.

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 shareholders 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.

If our common stock is delisted from the American Stock Exchange, trading in our common stock would be conducted, if at all, 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.

Forward-Looking Statements

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; and (vi) our expectation with respect to generating near-term revenue from our oral probiotic technology. 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 above 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; (v) our

inability to successfully partner with manufacturers and distributors with respect to our oral probiotic technology; and (vi) other factors including those identified in our filings from time to time with the SEC.

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.

PART II - OTHER INFORMATION

ITEM 2. CHANGES IN SECURITIES AND SMALL BUSINESS ISSUER PURCHASES OF EQUITY SECURITIES.

a. None
b. None
c. None
d. Note 2 of the Financial Statements included in Part I of this filing of Form 10-QSB as to use of proceeds through September 30, 2004 is hereby incorporated by reference.
e. None

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 September 30, 2004

On September 22, 2004, the Company filed a Form 8-K announcing that it had been invited to present at the BIO Emerging Company Investor Forum in San Francisco in October 2004.

On September 29, 2004, the Company filed a Form 8-K announcing the hiring of Edmund Mickunas for the position of Vice President, Regulatory and Clinical Affairs.

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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 3rd day of November, 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

Exhibit 31.1

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: November 3, 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: November 3, 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 September 30, 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 3rd day of November, 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 September 30, 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 3rd day of November, 2004.

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