

THE SECURITIES EVIDENCED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE U.S. SECURITIES ACT, AS AMENDED, OR ANY OTHER APPLICABLE SECURITIES LAWS AND HAVE BEEN ISSUED IN RELIANCE UPON AN EXEMPTION FROM THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND SUCH OTHER SECURITIES LAWS. NEITHER THIS SECURITY NOR ANY INTEREST OR PARTICIPATION HEREIN MAY BE SOLD, ASSIGNED, TRANSFERRED, PLEDGED, ENCLUMBERED, OR OTHERWISE DISPOSED OF, EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED PURSUANT TO A VALID EXEMPTION THEREFROM UNDER THE SECURITIES ACT.

Warrant No. \_\_\_\_\_

**WARRANT TO PURCHASE SHARES OF COMMON STOCK OF  
ORAGENICS, INC.**

THIS CERTIFIES that, for value received, [ ] is entitled to purchase from Orogenics, Inc., a Florida corporation (the "Corporation"), subject to the terms and conditions hereof, [ ] shares (the "Warrant Shares") of common stock, \$0.001 par value (the "Common Stock"). This warrant, together with all warrants hereafter issued in exchange or substitution for this warrant, is referred to as the "Warrant" and the holder of this Warrant is referred to as the "Holder." The number of Warrant Shares is subject to adjustment as hereinafter provided. Notwithstanding anything to the contrary contained herein, this Warrant shall expire and no longer be exercisable at 5:00 p.m. Eastern Standard Time (EST) on [Four years from the closing at which issued] (the "Termination Date") provided however, that in the event the Corporation's Common Stock trades on the American Stock Exchange at or above \$4.75 per share for a period of fifteen (15) consecutive days during the term of this Warrant the corporation may accelerate the expiration date of this Warrant upon written notice to the Holder, giving the Holder thirty (30) days to exercise this warrant after which thirty-day period this Warrant shall expire and no longer be exercisable.

**1. Exercise of Warrants.**

(a) The Holder may, at any time prior to the Termination Date, exercise this Warrant in whole or in part at an exercise price per share equal to \$3.50 per share, subject to adjustment as provided herein (the "Warrant Price"), by the surrender of this Warrant (properly endorsed) at the principal office of the Corporation, or at such other agency or office of the Corporation in the United States of America as the Corporation may designate by notice in writing to the Holder at the address of such Holder appearing on the books of the Corporation, and by payment to the Corporation of the Warrant Price in lawful money of the United States by check or wire transfer for each share of Common Stock being purchased. Upon any partial exercise of this Warrant, there shall be executed and issued to the Holder a new Warrant in respect of the shares of Common Stock as to which this Warrant shall not have been exercised. In the event of the exercise of the rights represented by this Warrant, a certificate or certificates for the Warrant Shares so purchased, as applicable, registered in the name of the Holder, shall be delivered to the Holder hereof as soon as practicable after the rights represented by this Warrant shall have been so exercised.

(b) If, but only if, at any time after one year from the date of issuance of this Warrant there is no effective registration statement registering the resale of the Common Stock underlying this Warrant by the Holder, this Warrant may also be exercised at such time by means of a "cashless exercise" in which, at any time prior to the Termination Date, the Holder of this Warrant may, at its option, exchange this Warrant, in whole or in part (a "Warrant Exchange"), into Warrant Shares by surrendering this Warrant at the principal office of the Corporation, accompanied by a notice stating such Holder's intent to effect such exchange, the number of Warrant Shares to be exchanged and the date on which the Holder requests that such Warrant Exchange occur (the "Notice of Exchange"). The Warrant Exchange shall take place on the date specified in the Notice of Exchange or, if later, within five (5) days of the date the Notice of

Exchange is received by the Corporation (the "Exchange Date"). Certificates for the Warrant Shares issuable upon such Warrant Exchange and, if applicable, a new Warrant of like tenor evidencing the balance of the Warrant Shares remaining subject to this Warrant, shall be issued as of the Exchange Date and delivered to the Holder within three (3) business days following the Exchange Date. In connection with any Warrant Exchange, this Warrant shall represent the right to subscribe for and acquire the number of Warrant Shares (rounded to the next highest integer) equal to the quotient obtained by dividing  $[(A-B) (X)]$  by (A), where:

- (A) – the Closing Bid Price (as hereinafter defined) on the trading day preceding the date on which the Company receives the Exercise Documentation;
- (B) – the exercise price of this Warrant, as adjusted; and
- (X) – the number of shares of Common Stock issuable upon exercise of this Warrant in accordance with the terms of this Warrant.

2. Reservation of Warrant Shares. The Corporation agrees that, prior to the expiration of this Warrant, it will at all times have authorized and in reserve, and will keep available, solely for issuance or delivery upon the exercise of this Warrant, the number of Warrant Shares as from time to time shall be issuable by the Corporation upon the exercise of this Warrant.

3. No Shareholder Rights. This Warrant shall not entitle the holder hereof to any voting rights or other rights as a shareholder of the Corporation.

4. Transferability of Warrant. Prior to the Termination Date and subject to compliance with applicable laws, this Warrant and all rights hereunder are transferable, in whole or in part, at the office or agency of the Company by the Holder in person or by duly authorized attorney, upon surrender of this Warrant together with the Assignment Form annexed hereto properly endorsed for transfer.

5. Certain Adjustments. With respect to any rights that Holder has to exercise this Warrant and convert into shares of Common Stock, Holder shall be entitled to the following adjustments:

(a) Merger or Consolidation. If at any time there shall be a merger or a consolidation of the Corporation with or into another corporation when the Corporation is not the surviving corporation, then, as part of such merger or consolidation, lawful provision shall be made so that the holder hereof shall thereafter be entitled to receive upon exercise of this Warrant, during the period specified herein and upon payment of the aggregate Warrant Price then in effect, the number of shares of stock or other securities or property (including cash) of the successor corporation resulting from such merger or consolidation, to which the holder hereof as the holder of the stock deliverable upon exercise of this Warrant would have been entitled in such merger or consolidation if this Warrant had been exercised immediately before such merger or consolidation. In any such case, appropriate adjustment shall be made in the application of the provisions of this Warrant with respect to the rights and interests of the holder hereof as the holder of this Warrant after the merger or consolidation.

(b) Reclassification, Recapitalization, etc. If the Corporation at any time shall, by subdivision, combination or reclassification of securities, recapitalization, automatic conversion, or other similar event affecting the number or character of outstanding shares of Common Stock, or otherwise, change any of the securities as in which purchase rights under this Warrant exist into the same or a different number of securities of any other class or classes, this Warrant shall thereafter represent the right to acquire such number and kind of securities as would have been issuable as the result of such change with respect to the securities that were subject to the purchase rights under this Warrant immediately prior to such subdivision, combination, reclassification or other change.

(c) Split or Combination of Common Stock and Stock Dividend. In case the Corporation shall at any time subdivide, redivide, recapitalize, split (forward or reverse) or change its outstanding shares of Common Stock into a greater number of shares or declare a dividend upon its Common Stock payable solely in shares of Common Stock, the Warrant Price shall be proportionately reduced and the number of Warrant Shares proportionately increased. Conversely, in case the outstanding shares of Common Stock of the Corporation shall be combined into a smaller number of shares, the Warrant Price shall be proportionately increased and the number of Warrant Shares proportionately reduced. Notwithstanding the foregoing, in no event will the Warrant Price be reduced below the par value of the Common Stock.

(d) Issuances of Additional Shares of Stock. If at any time prior to the exercise of this Warrant, the Corporation shall issue, or be deemed to have issued, Additional Shares of Common Stock (as hereinafter defined) without consideration or for a consideration per share less than \$2.75 per share (subject to adjustment) (the "Dilutive Price") in effect immediately prior to such issuance or sale, then forthwith upon the occurrence of any such event (the "Dilutive Event") the Exercise Price shall be adjusted on a weighted average basis pursuant to the formula set forth in the attached Exhibit "A."

As used herein, "Additional Shares of Common Stock" shall mean all shares of Common Stock issued or deemed to be issued (pursuant to the following sentence) by the Corporation after the date hereof, but shall not include (i) options granted or shares issued pursuant to the Corporation's stock option plan, (ii) any shares issued pursuant to options and warrants outstanding as of October 29, 2004 provided that the exercise price of such options or warrants shall not have been amended after the date of the Memorandum and (iii) options, warrants or shares of either Common Stock or Preferred Stock (or combination thereof) to be issued by the Company's Board of Directors in good faith in connection with any non-financial strategic alliance or acquisition. If the Corporation issues any Options or Convertible Securities (as hereinafter defined), the maximum number of shares of Common Stock issuable thereunder, shall be deemed to be Additional Shares of Common Stock issued as of the time of such issue, if the consideration per share of such Additional Shares of Common Stock (as hereinafter determined) is less than \$2.75, until such time as such Options or Convertible Securities shall terminate or be exercised or converted into Common Stock, upon which time the number of shares of Common Stock actually thereupon issued shall be deemed to be Additional Shares of Common Stock. As used herein, (i) "Options" shall mean rights, options or warrants to subscribe for, purchase or otherwise acquire either Common Stock or Convertible Securities and (ii) "Convertible Securities" shall mean any evidences of indebtedness, shares (other than Common Stock) or other securities directly or indirectly convertible into or exchangeable for Common Stock.

6. Legend and Stop Transfer Orders. Unless the Warrant Shares have been registered under the Securities Act, upon exercise of any part of the Warrant, the Corporation shall instruct its transfer agent to enter stop transfer orders with respect to such Warrant Shares, and all certificates or instruments representing the Warrant Shares shall bear on the face thereof substantially the following legend:

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7. Redemption. The Corporation shall have the right, upon 30 days' written notice to the Holder ("Redemption Notice"), to redeem all or any portion of this Warrant at a price equal to \$ 0.1 per Warrant Share, provided that (i) the Warrant Shares have been registered for resale pursuant to the Securities Act, and have been freely tradable without restriction or legend for at least the 30-day period preceding such notice and will continue to be freely tradable for at least 30 days following such redemption date and (ii) the Closing Bid Price (as hereinafter defined) for the Common Stock has been at least \$4.75 (subject to adjustment to reflect forward or reverse stock splits, stock dividends, recapitalizations and the like) for the 15-trading day period immediately preceding the date of the Redemption Notice from the Corporation to the Holder. As used herein, "Closing Bid Price", shall mean the closing bid price of the Common Stock as reported by the American Stock Exchange on the date in question (based on a trading day from 9:30 a.m. EST to 4:02 p.m. EST (and, if no closing bid price is reported, the closing price as so reported, and if neither the closing bid price nor the closing price is so reported, the last reported price of the Common Stock as determined by an independent evaluator mutually agreed to by the Holder and the Corporation).

8. **Miscellaneous.** This Warrant shall be governed by and construed in accordance with the laws of the State of Florida. All the covenants and provisions of this Warrant by or for the benefit of the Corporation shall bind and inure to the benefit of its successors and assigns hereunder. Nothing in this Warrant shall be construed to give to any person or corporation other than the Corporation and the holder of this Warrant any legal or equitable right, remedy or claim under this Warrant. This Warrant shall be for the sole and exclusive benefit of the Corporation and the holder of this Warrant. The section headings herein are for convenience only and are not part of this Warrant and shall not affect the interpretation hereof. Upon receipt of evidence satisfactory to the Corporation of the loss, theft, destruction or mutilation of this Warrant, and of indemnity reasonably satisfactory to the Corporation, if lost, stolen or destroyed, and upon surrender and cancellation of this Warrant, if mutilated, the Corporation shall execute and deliver to the Holder a new Warrant of like date, tenor and denomination.

IN WITNESS WHEREOF, the Corporation has caused this Warrant to be executed by its duly authorized officers under its seal, this \_\_\_\_\_ day of \_\_\_\_\_, 2004.

ORAGENICS, INC.

By: \_\_\_\_\_  
Name:  
Title:

**WARRANT EXERCISE FORM**

**To Be Executed by the Holder in Order to Exercise Warrant**

To: Oragenics, Inc.  
12085 Research Drive  
Alachua, Florida 32615  
Attn: Paul Hassie, Principal Financial Officer

Dated: \_\_\_\_\_

The undersigned, pursuant to the provisions set forth in the attached Warrant No. \_\_\_\_\_, hereby irrevocably elects to purchase *(check applicable box)*:

- ☐ \_\_\_\_\_ shares of the Common Stock of Oragenics, Inc. covered by such Warrant; or
- ☐ the maximum number of shares of Common Stock covered by such Warrant pursuant to the cashless exercise procedure set forth in subsection 1(b) (if applicable).

The undersigned herewith makes payment of the full purchase price for such shares at the price per share provided for in such Warrant. Such payment takes the form of *(check applicable box or boxes)*:

- ☐ \$\_\_\_\_\_ in lawful money of the United States; and/or
- ☐ if the provisions of subsection 1(b) of this Warrant are in effect, the cancellation of such portion of the attached Warrant as is exercisable for a total of \_\_\_\_\_ Warrant Shares (using a Fair Market Value of \$\_\_\_\_\_ per share for purposes of this calculation); and/or
- ☐ if the provisions of subsection 1(b) of this Warrant are in effect, the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 1(b), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 1(b).

The undersigned hereby requests that certificates for the Warrant Shares purchased hereby be issued in the name of:

\_\_\_\_\_

\_\_\_\_\_  
(please print or type name and address)

\_\_\_\_\_  
(please insert social security or other identifying number)

and be delivered as follows:

\_\_\_\_\_

\_\_\_\_\_  
(please print or type name and address)

\_\_\_\_\_  
(please insert social security or other identifying number)

and if such number of shares of Common Stock shall not be all the shares evidenced by this Warrant Certificate, that a new Warrant for the balance of such shares be registered in the name of, and delivered to, Holder.

\_\_\_\_\_  
Signature of Holder

SIGNATURE GUARANTEE:

\_\_\_\_\_

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**ASSIGNMENT FORM**

(To assign the foregoing warrant, execute  
this form. Do not use this form to exercise the warrant.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

\_\_\_\_\_ whose address is

\_\_\_\_\_

\_\_\_\_\_

Dated: \_\_\_\_\_,

Holder's Signature: \_\_\_\_\_

Holder's Address: \_\_\_\_\_

\_\_\_\_\_

Signature Guaranteed: \_\_\_\_\_

NOTE: The signature to this Assignment Form must correspond with the name as it appears on the face of the Warrant, without alteration or enlargement or any change whatsoever, and must be guaranteed by a bank or trust Corporation. Officers of corporations and those acting in a fiduciary or other representative capacity should file proper evidence of authority to assign the foregoing Warrant.

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**EXHIBIT "A"**

**WEIGHTED AVERAGE ADJUSTMENT FORMULA**

$$NEP = OEP \times \frac{OB + X}{OA}$$

where

NEP = the New Exercise Price

OEP = the existing Exercise Price immediately before the new Issue  
("Old Exercise Price")

OB = the total outstanding shares of Common Stock immediately before  
The new issue

X = number of shares issuable at the Old Exercise Price (applicable to the  
Warrant Shares as to which the calculation is being made) for the total  
Consideration to be received for the new issue

OA = the total outstanding shares of Common Stock immediately after the  
new issue

For purposes of example to illustrate the operation of this anti-dilution formula on Warrant Shares with a hypothetical Exercise Price of \$2.00, the following example assumes a subsequent issuance by the Company of an additional 1,000,000 shares of Preferred Stock at a price of \$1.00 per share assuming that there are 2,000,000 shares of common stock outstanding.

$$NEP = \$2.00 \times \frac{(2,000,000 + 500,000)}{3,000,000} = \$2.00 \times \frac{2,500,000}{3,000,000} = \$1.66$$

New Exercise Price of Warrants = \$1.66

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## SUBSCRIPTION AGREEMENT

Oragenics, Inc.  
12085 Research Drive  
Alachua, Florida 32615

Ladies and Gentlemen,

The undersigned (the "Investor") is writing to advise you of the following terms and conditions under which the undersigned hereby offers to subscribe (the "Offer") for the securities of this private placement (the "Offering") offered by Oragenics, Inc., a Florida corporation (the "Company"). The exclusive placement agent for the Offering is Westminster Securities Corporation (the "Placement Agent"). The Company is issuing units consisting of (a) 10,000 shares of common stock of the Company, \$0.001 par value ("Common Stock") at a purchase price of \$2.75 per share (the "Shares") and (b) 5,000 detachable warrants (the "Warrants") to purchase one share each of common stock at an exercise price of \$3.50 per share (the "Warrant Shares"). The Shares and the Warrants shall be collectively referred to as the "Units".

The Company may issue a minimum of twenty-five (25) units (the Minimum Offering") and a maximum of eighty (80) Units (the "Maximum Offering") in this offering (the "Offering"). The Company and the Placement Agent, upon mutual agreement, may also sell additional Units representing an over-allotment allowance in the event the Offering is oversubscribed. The undersigned understands that the Units are being issued pursuant to the exemption from registration requirements of the Securities Act of 1933, as amended (the "Securities Act" or the "Act"), provided by Section 4(2) of the Act. As such, the Units and the underlying Warrant Shares are "restricted securities".

The Units are being offered on a "best efforts, all or none" basis by the Company through the Placement Agent with respect to the Minimum Offering, during an offering period commencing on the date of the Company's Private Placement Memorandum (the "Memorandum") dated October 29, 2004 (the "Commencement Date") and continuing until December 15, 2004 (the "Offering Period"). If the Minimum Offering is completed within the Offering Period, the remaining Units up to the amount of the Maximum Offering will be offered on a "best efforts" basis until the first to occur of (i) the completion of the Maximum Offering, (ii) December 31, 2004 or (iii) the termination of the Offering by mutual agreement of the Placement Agent and the Company (the "Final Closing").

All proceeds received from subscribers for the Units offered hereby will be deposited by the Placement Agent in a special non-interest bearing escrow account (the "Escrow Account") with Merchant & Southern Bank (also known as M&S Bank) and will be released to the Company against delivery by the Company to the Placement Agent of certificates representing the Shares and the Warrants comprising the Units (each such date, "Closing Date").

Capitalized terms not otherwise defined herein shall have the meanings set forth in the Memorandum.

I. Subscription.

(A) Subject to the terms and conditions hereinafter set forth in this Subscription Agreement, the undersigned hereby offers to purchase Units as set forth in the Investor Signature Page attached hereto.

(B) If the Offer is accepted, the Units shall be paid for by the delivery of such amount by wire transfer or check payable to the order of "M&S Bank as Escrow Agent for Oragenics, Inc.", which is being delivered contemporaneously herewith.

(C) Once a minimum of \$687,500 in Units have been sold and proceeds of a minimum of \$687,500 in cleared funds are on deposit in the Escrow Account (the "Minimum Escrow Date") and such subscriptions are accepted by the Company, an initial closing will be held as soon as practicable thereafter.

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(D) Additional closings will be held, at the discretion of the Company and the Placement Agent, at reasonable intervals during the Offering Period, but in no event later than the Final Closing.

2. Conditions to Offer.

(A) The Offering is made subject to the following conditions: (i) that the Company shall have the right to accept or reject this Offer, in whole or in part, for any reason whatsoever; and (ii) that the undersigned agrees to comply with the terms of this Subscription Agreement.

(B) Acceptance of this Offer shall be deemed given by the countersigning of this Subscription Agreement on behalf of the Company.

3. Representations and Warranties of the Undersigned

The undersigned, in order to induce the Company to accept this Offer, hereby warrants and represents as follows:

(A) The undersigned has sufficient liquid assets to sustain a loss of the undersigned's entire investment.

(B) The undersigned represents that he (she or it) is an Accredited Investor as that term is defined in Regulation D promulgated under the Securities Act of 1933, as amended. In general, an "Accredited Investor" is deemed to be an institution with assets in excess of \$5,000,000 or individuals with net worth in excess of \$1,000,000 or annual income exceeding \$200,000 or \$300,000 jointly with their spouse.

(C) The Company has not made any other representations or warranties to the undersigned with respect to the Company except as contained herein. The Company has not rendered any investment advice to the undersigned with respect to the Company.

(D) The undersigned has not authorized any person or institution to act as his Purchaser Representative (as that term is defined in Regulation D of the General Rules and Regulations under the Act) in connection with this transaction. The undersigned has such knowledge and experience in financial, investment and business matters that he is capable of evaluating the merits and risks of the prospective investment in the Units. The undersigned has consulted with such independent legal counsel or other advisers as he has deemed appropriate to assist the undersigned in evaluating his proposed investment in the Units.

(E) The undersigned represents that he (i) has adequate means of providing for his current financial needs and possible personal contingencies, and has no need for liquidity of investment in the Units; (ii) can afford to (a) hold unregistered securities for an indefinite period of time as required and (b) sustain a complete loss of the entire amount of the subscription; and (iii) has not made an overall commitment to investments which are not readily marketable which is disproportionate so as to cause such overall commitment to become excessive.

(F) The undersigned has reviewed, or been given the opportunity to review, the Memorandum. The undersigned has also been afforded the opportunity to ask questions of, and receive answers from, the officers and/or directors of the Company concerning the terms and conditions of the Offering and to obtain any additional information, to the extent that the Company possesses such information or can acquire it without unreasonable effort or expense, necessary to verify the accuracy of the information furnished; and has availed himself of such opportunity to the extent he considers appropriate in order to permit him to evaluate the merits and risks of an investment in the Units. It is understood that all documents, records and books pertaining to this investment have been made available for inspection, and that the books and records of the Company will be available upon reasonable notice for inspection by investors during reasonable business hours at its principal place of business.

(G) The undersigned acknowledges that none of the Units or the Warrant Shares have been registered under the Act in reliance on an exemption for transactions by an issuer not involving a public offering based on the undersigned's representations set forth herein, and further understands that the undersigned is purchasing the Units without being furnished any prospectus setting forth all of the information that would be required to be furnished under the Act.

(H) The undersigned further acknowledges that this Offering has not been passed upon or the merits thereof endorsed or approved by any state or federal authorities.

(I) The Units being subscribed for are being acquired solely for the account of the undersigned for personal investment and not with a view to, or for resale in connection with, any distribution in any jurisdiction where such sale or distribution would be precluded. By such representation, the undersigned means that no other person has a beneficial interest in the Units (or underlying Warrant Shares) subscribed for hereunder, and that no other person has furnished or will furnish directly or indirectly, any part of or guarantee the payment of any part of the consideration to be paid to the Company in connection therewith. The undersigned does not intend to dispose of all or any part of the Units (or underlying Shares or Warrant Shares) except in compliance with the provisions of the Act and applicable state securities laws and understands that the Units are being offered pursuant to a specific exemption under the provisions of the Act, which exemption(s) depends, among other things, upon compliance with the provisions of the Act. By making the foregoing representation, the undersigned is not agreeing to hold the securities for any particular period of time.

(J) Unless the Shares or the Warrant Shares are subject to an effective registration statement, the undersigned further represents and agrees that the undersigned will not sell, transfer, pledge or otherwise dispose of or encumber the Units (or underlying Warrant Shares) unless prior to any such sale, transfer, pledge, disposition or encumbrance, the undersigned will, if requested, furnish the Company and its transfer agent with an opinion of counsel satisfactory to the Company in form and substance that registration under the Act or applicable state securities laws is not required.

(K) The undersigned hereby agrees that the following or similar legend shall be on the face of the certificates evidencing the Units, the Shares and the Warrant Shares:

"These securities have not been registered under the Securities Act of 1933, as amended (the "Act") or under the securities laws of any state. They may not be sold, offered for sale, pledged or hypothecated in the absence of a registration statement in effect with respect to the securities under such act or an opinion of counsel reasonably satisfactory to the company that such registration is not required pursuant to a valid exemption therefrom under the Act.

In addition, the undersigned agrees that the Company may place "stop transfer" orders with its transfer agents with respect to each certification evidencing the Units, the Shares and the Warrant Shares in order to implement the restrictions set forth in this Agreement.

Certificates evidencing the Shares and Warrant Shares shall not contain any legend (including the legend set forth above), (i) while a registration statement (including the Registration Statement) covering the resale of such security is effective under the Securities Act, or (ii) following any sale of such Shares or Warrant Shares pursuant to Rule 144, or (iii) if such Shares or Warrant Shares are eligible for sale under Rule 144(k), or (iv) if such legend is not required under applicable requirements of the Securities Act (including judicial interpretations and pronouncements issued by the Staff of the Commission). The Company shall cause its counsel to issue a legal opinion to the Company's transfer agent promptly after the Effective Date if required by the Company's transfer agent to effect the removal of the legend hereunder. If all or any portion of a Warrant is exercised at a time when there is an effective registration statement to cover the resale of the Warrant Shares, such Warrant Shares shall be issued free of all legends. The Company agrees that following the Effective Date or at such time as such legend is no longer required under this Section (4)(K), it will, no later than three Trading Days following the delivery by a Purchaser to the Company or the Company's transfer agent of a certificate representing Shares or Warrant Shares, as the case may be, issued with a restrictive legend (such date, the "Legend Removal

(Date"). deliver or cause to be delivered to such Purchaser a certificate representing such Securities that is free from all restrictive and other legends. The Company may not make any notation on its records or give instructions to any transfer agent of the Company that enlarge the restrictions on transfer set forth in this Section.

(L) The undersigned hereby acknowledges that the Placement Agent, its affiliates and/or its beneficial owners may subscribe for Units.

(M) The undersigned has completed or caused to be completed the Stock Certificate Questionnaire and the Registration Statement Questionnaire, attached to this Agreement as Appendix I (collectively, the "Questionnaires"), for use in preparation of the Registration Statement (as defined in Section 5(B)(1) below), and the answers to such Questionnaires are true and correct as of the date of this Agreement and will be true and correct as of the effective date of the Registration Statement; provided that the undersigned shall be entitled to update such information by providing written notice thereof to the Company before the effective date of such Registration Statement.

The undersigned certifies that each of the foregoing representations and warranties set forth in subsection (A) through (M) inclusive of this Section 3 are true as of the date hereof and shall survive such date.

#### 4. Representations and Warranties of the Company.

The Company hereby makes the following representations and warranties to the Investors:

(A) Subsidiaries. The Company has no direct or indirect subsidiaries.

(B) Organization and Qualification. The Company is an entity duly incorporated or otherwise organized, validly existing and in good standing under the laws of the jurisdiction of the State of Florida, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. The Company is not in violation of any of the provisions of its articles of incorporation, bylaws or other organizational or charter documents.

(C) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the Offering. The execution and delivery of this Subscription Agreement by the Company and the consummation by it of the transactions contemplated hereby have been duly authorized by all necessary action on the part of the Company and no further consent or action is required by the Company, other than the Required Approvals. This Subscription Agreement, when executed and delivered in accordance with the terms hereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, subject to applicable bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and similar laws affecting creditors' rights and remedies generally and general principles of equity. The Company is not in violation of any of the provisions of its articles of incorporation, bylaws or other organizational or charter documents.

(D) No Conflicts. The execution, delivery and performance of this Subscription Agreement by the Company and the consummation by the Company of the Offering do not and will not: (i) conflict with or violate any provision of the Company's articles of incorporation, bylaws or other organizational or charter documents, or (ii) subject to obtaining the Required Approvals (as defined below), conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company debt or otherwise) or other understanding to which the Company is a party or by which any property or asset of the Company is bound or affected, or (iii) result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority as currently in effect to which the Company is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company is bound or affected; except in the case of each of clauses (ii) and (iii), such as could not, individually or in the aggregate (a) adversely affect the legality, validity or enforceability of the Offering, (b) have or result in or be reasonably likely to have or result in a material adverse effect on the results of operations, assets, prospects, business or condition (financial or otherwise)

of the Company, taken as a whole, or (c) adversely impair the Company's ability to perform fully on a timely basis its obligations under this Subscription Agreement (any of (a), (b) or (c), a "Material Adverse Effect").

(E) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other person in connection with the execution, delivery and performance by the Company of this Subscription Agreement, other than (i) the filing with the Commission of the Registration Statement, (ii) the filing with the Commission of a Form D pursuant to Commission Regulation D, and (iii) applicable Blue Sky filings (collectively, the "Required Approvals").

(F) Issuance of the Securities. The Units, and each component or underlying security, are duly authorized and, when issued and paid for in accordance with this Subscription Agreement, will be duly and validly issued, fully paid and nonassessable, free and clear of all liens, and not subject to any preemptive rights. The Company has reserved from its duly authorized capital stock a number of shares of Common Stock required for issuance of the Shares and the Warrant Shares.

(G) Capitalization. The number of shares and type of all authorized, issued and outstanding capital stock of the Company is as set forth in the Memorandum. No person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the Offering. Except as set forth in the Memorandum or SEC Reports (defined below), and for options and shares of capital stock issued or issuable under the Company's option plans, there are no outstanding options, warrants, script rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exchangeable for, or giving any person any right to subscribe for or acquire, any shares of Common Stock, or contracts, commitments, understandings or arrangements by which the Company is or may become bound to issue additional shares of Common Stock, or securities or rights convertible or exchangeable into shares of Common Stock. The issuance and sale of the Units will not obligate the Company to issue shares of Common Stock or other securities to any person (other than the Investors and the Placement Agent) and will not result in a right of any holder of Company securities to adjust the exercise, conversion, exchange or reset price under such securities.

(H) SEC Reports; Financial Statements. The Company has filed all reports required to be filed by it under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the two years preceding the date hereof (or such shorter period as the Company was required by law to file such material) (the foregoing materials being collectively referred to herein as the "SEC Reports") in accordance with the time requirements of the Securities Act and the Exchange Act. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act and the rules and regulations of the Commission promulgated thereunder, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. The Company has advised Investor(s) that a correct and complete copy of each SEC Report (together with all exhibits and schedules thereto and as amended to date) is available at <http://www.sec.gov>, a website maintained by the Commission where Investor(s) may view the SEC Reports. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with generally accepted accounting principles applied on a consistent basis during the periods involved ("GAAP"), except as may be otherwise specified in such financial statements or the notes thereto, and fairly present in all material respects the financial position of the Company and its consolidated subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(I) Material Changes. Since the date of the latest audited financial statements included within the SEC Reports, except as specifically disclosed in the SEC Reports: (i) there has been no event, occurrence or development that has had a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary

course of business consistent with past practice and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or required to be disclosed in filings made with the Commission. (iii) the Company has not altered its method of accounting or the identity of its auditors (iv) the Company has not declared or made any dividend or distribution of cash or other property to its stockholders except in the ordinary course of business consistent with prior practice, or purchased, redeemed or made any agreements to purchase or redeem any shares of its capital stock except consistent with prior practice or pursuant to existing Company stock option or similar plans, and (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company stock option or similar plans.

(J) Litigation. Except as set forth in the SEC Reports, there is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company or any of its properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "Action") which: (i) adversely affects or challenges the legality, validity or enforceability of this Subscription Agreement or the Units or (ii) would, if there were an unfavorable decision, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect. The Company is not and has not been the subject of any Action involving a claim of violation of or liability under federal or state securities laws. The Company does not have pending before the Commission any request for confidential treatment of information. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Commission involving the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

(K) Compliance. Except as described in the Memorandum or the SEC Reports, the Company: (i) is not in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company received notice of a claim that it is in default under or that it is in violation of, any material indenture, loan or credit agreement or any other material agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), which default or violation would have or result in a Material Adverse Effect, (ii) is not in violation of any order of any court, arbitrator or governmental body, or (iii) is not and has not been in violation of any statute, rule or regulation of any governmental authority, except in each case as would not, individually or in the aggregate, have or result in a Material Adverse Effect.

(L) Regulatory Permits. The Company possesses all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct its business as described in the SEC Reports, except where the failure to possess such permits would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect ("Material Permits"), and the Company has not received any notice of proceedings relating to the revocation or modification of any Material Permit.

(M) Listing and Maintenance Requirements. The Company's Common Stock currently trades on the American Stock Exchange (AMEX). The Company is, and has no reason to believe that it will not in the foreseeable future continue to be, in compliance with the periodic SEC reporting requirements necessary to maintain trading on the AMEX.

(N) Internal Accounting Controls. The Company maintains a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. As disclosed in the SEC Reports, the Company has established disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the Company and designed such disclosures controls and procedures to ensure that material information relating to the Company is made known to the certifying

officers by others within those entities. The Company's certifying officers have evaluated the effectiveness of the Company's controls and procedures as of May 31, 2004 (such date, the "Evaluation Date"). The Company presented in the Form 10-QSB for the quarter ended June 30, 2004 the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no significant changes in the Company's internal controls (as such term is defined in Item 307(b) of Regulation S-B under the Exchange Act).

(C) Disclosure. The disclosure provided to the Investor regarding the Company, its business and the transactions contemplated hereby, furnished by or on behalf of the Company, including all of the SEC Reports, does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading. The Company acknowledges and agrees that the Investor makes or has made no representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in this Subscription Agreement.

5 Covenants of the Company.

(A) Board Approval. The Company has held a meeting of its board of directors ("Board") which authorized the issuance of the Units in this Offering.

(B) Registration Rights. The Company grants registration rights to the Investor(s) under the following terms and conditions:

(1) The Company will prepare and file, at its own expense, within thirty (30) days of the Final Closing, a registration statement under the Securities Act (the "Registration Statement") with the Commission sufficient to permit the non-underwritten public offering and resale of the Shares (subject to adjustment as set forth in Section 5(C) below) and Warrant Shares (subject to adjustment as set forth in the Warrant form) (the "Registrable Securities") through the facilities of all appropriate securities exchanges, if any, on which the Company's Common Stock is being sold or on the over-the-counter market if the Company's Common Stock is traded thereon.

(2) The Company will use commercially reasonable efforts to cause such Registration Statement to become effective within one hundred and twenty (120) days from the Final Closing or, if earlier, within five (5) days of Commission clearance to request acceleration of effectiveness. The number of shares designated in the Registration Statement to be registered shall include all of the Registrable Securities and shall include appropriate language regarding reliance upon Rule 416 to the extent permitted by the Commission. The Company will notify the Investors of the effectiveness of the Registration Statement within three business days of such event. In the event that the number of shares so registered shall prove to be insufficient to register the resale of all of the Registrable Securities, then the Company shall be obligated to file, within thirty (30) days of notice from any Investor, a further Registration Statement registering such remaining shares and shall use commercially reasonable efforts to prosecute such additional Registration Statement to effectiveness within one hundred and twenty (120) days of the date of such notice.

(3) The Company will maintain the Registration Statement or post-effective amendment filed under the terms of the subscription agreement effective under the Securities Act until the earlier of (i) the date that all of the Registrable Securities have been sold pursuant to such Registration Statement, (ii) all Registrable Securities have been otherwise transferred to persons who may trade such shares without restriction under the Securities Act, and the Company has delivered a new certificate or other evidence of ownership for such securities not bearing a restrictive legend, or (iii) all Registrable Securities may be sold at any time, without volume or manner of sale limitations pursuant to Rule 144(k) or any similar provision then in effect under the Securities Act in the opinion of counsel to the Company (the "Effectiveness Period").

(4) If, at any time during which the Registration Statement required by Section 5(B)(1) and 5(B)(2) above is not effective, the Company shall determine to proceed with the preparation

and filing of a separate registration statement pursuant to the Securities Act in connection with the proposed offer and sale of any of its securities by it or any of its security holders (other than a registration statement on Form S-4, S-8, or other limited purpose form), the Company will give written notice of its determination to all the Investors. Upon receipt of a written request from any Investor, within thirty (30) days after receipt of any such notice from the Company, the Company will cause all such Registrable Securities requested by the Investor to be included in such Registration Statement, all to the extent required to permit the sale or other disposition by such Investors, of such shares. The obligation of the Company under this Section 5(B)(4) shall be unlimited as to the number of Registration Statements to which it applies, unless the Effectiveness Period has ended.

(5) All fees, disbursements and out-of-pocket expenses and costs incurred by the Company in connection with the preparation and filing of the Registration Statement and in complying with applicable federal securities and Blue Sky laws (including, without limitation, all attorneys' fees of the Company) shall be borne by the Company. The Investors shall bear the cost of underwriting and/or brokerage discounts, fees and commissions, if any, applicable to the Registrable Securities being registered and the fees and expenses of their counsel. The Company shall use its reasonable best efforts to qualify any of the Securities for sale in such states as any Investor reasonably designates and shall furnish indemnification. However, the Company shall not be required to qualify in any state which will require an escrow or other restriction relating to the Company and/or the sellers, or which will require the Company to qualify to do business in such state or require the Company to file therein any general consent to service of process. The Company at its expense will supply the Investors with copies of the applicable Registration Statement and any prospectus included therein and other related documents in such quantities as may be reasonably requested by the Investors.

(6) In the event that (i) the Registration Statement is not filed with the Commission within thirty (30) days of the Final Closing, (ii) such Registration Statement is not declared effective by the Commission within the earlier of one hundred and twenty (120) days from the Final Closing Date or five (5) days of clearance by the Commission to request effectiveness, (iii) such Registration Statement is not maintained as effective by the Company for the Effectiveness Period or as allowed by 5(B)(9) below or (iv) the additional Registration Statement referred to in Section 5(B)(2) is not filed within thirty (30) days or declared effective within ninety (90) days as set forth therein (each a "Registration Default") then the Company will pay Investor (prorated on a daily basis), as partial compensation for such failure and not as a penalty one percent (1.0%) of the purchase price of the Registrable Securities purchased from the Company and held by the Investor for each month (or portion thereof) until such Registration Statement has been filed (in the case of clause (i) and clause (iv)), and in the event of late effectiveness (in case of clause (ii) above) or lapsed effectiveness (in the case of clause (iii) above), one percent (1%) of the purchase price of the Registrable Securities purchased from the Company and held by the Investor each month (or portion thereof) (regardless of whether one or more such Registration Defaults are then in existence, but without duplication of such partial compensatory payments) until such Registration Statement has been declared effective. Such compensatory payments shall be made to the Investors in cash or in stock, at the Company's option, no later than the fifth business day following the month in which such Registration Default(s) occurred, provided, however, that the payment of such amounts shall not relieve the Company from its obligations to register the Securities pursuant to this Section. If the compensatory payments are made in stock, such stock shall be included in an amendment to the Registration Statement, when effective, and shall have unlimited piggyback rights pursuant to Section 5(B)(4) above.

(7) If the Company does not remit the payment to the Investors as set forth in Section 5(B)(6) above, the Company will pay the Investors interest at the rate of 12% per annum, or the highest rate permitted by law, if less, until such sums have been paid in full, and reasonable costs of collection, including attorneys' fees, in addition to the liquidated damages. The registration of the Securities pursuant to this provision or payment of such compensatory amounts shall not affect or limit the Investors' other rights or remedies as set forth in this Agreement or at law.

(8) In the event a registration statement is not effective at any time after one year following the Final Closing date (other than an Allowed Delay, as defined in Section 5(B)(9)(ii) below), compensatory payments as defined in Section 5(B)(6) above shall cease, and the Warrants shall become exercisable pursuant to a cashless exercise feature. At such time, the Company shall cause its counsel to issue such legal opinions as may be reasonably requested by the Investors in connection with any sales of the Shares or the Warrant Shares in accordance with Rule 144 under the Securities Act. In addition, the Investors shall be entitled to unlimited piggyback registration rights under Section 5(B)(4) above.

(9) In the case of each registration effected by the Company pursuant to any section herein, the Company will keep each Investor advised in writing as to the initiation of each registration and as to the completion thereof. At its expense, the Company will:

(i) Prepare and file with the Commission such amendments and supplements to such registration statement and the prospectus used in connection with such registration statement as may be necessary to comply with the provisions of the Securities Act with respect to a disposition of all securities covered by such registration statement;

(ii) Notify the Investors at any time when a prospectus relating thereto is required to be delivered under the Securities Act, of the happening of any event as a result of which the prospectus included in such registration statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading or incomplete in light of the circumstances then existing, and at the request of the shareholders, prepare and furnish to them a reasonable number of copies of a supplement to or an amendment of such prospectus as may be necessary so that, as thereafter delivered to the Investors, such prospectus shall not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading or incomplete in light of the circumstances then existing; provided that, for not more than thirty (30) consecutive calendar days (or a total of not more than seventy-five (75) calendar days in any twelve (12) month period), the Company may delay the disclosure of material non-public information concerning the Company the public disclosure of which at the time is not, in the good faith opinion of the Company in the best interests of the Company and which may, based on the written advice of outside counsel, be delayed under applicable law or regulation (an "Allowed Delay"); provided, further, that the Company shall promptly (i) notify each Investor in writing of the existence of (but in no event shall the Company disclose to such Investor any of the facts or circumstances regarding) material non-public information giving rise to an Allowed Delay and (ii) advise each Investor in writing to cease all sales under such registration statement until the termination of the Allowed Delay;

(iii) Use its commercially reasonable efforts to prevent the issuance of any stop order or other suspension of effectiveness of a Registration Statement, and, if such an order is issued, to obtain the withdrawal of such order at the earliest possible moment and to notify Investor (and, in the event of an underwritten offering, the managing underwriter) of the issuance of such order and the resolution thereof;

(iv) Cause all shares which are registered in accordance with the provisions herein, to be listed or included for quotation on each exchange on which the Company's shares of Common Stock are then listed or included for quotation;

(v) Provide a transfer agent and registrar for all such shares and CUSIP number for all such shares of Common Stock in each case not later than the effective date of such Registration Statement; and

(vi) Otherwise use its commercially reasonable best efforts to comply with all applicable rules and regulations of the Commission

(vii) In the event of a transfer of the Shares and the Warrant Shares utilizing the prospectus included within any of the Registration Statements covered by this Section 5(B), cause its counsel to issue a legal opinion permitting such transfer and cause its transfer agent to reissue a new certificate representing such Shares and the Warrant Shares without a restrictive legend within five business days, time being of the essence, in each case without charge to the Investor other than customary transfer fees which may be charged by the transfer agent or broker-dealer.

(10) To the extent Investor includes any Shares or Warrant Shares in a registration statement pursuant to the terms hereof, the Company will indemnify and hold harmless Investor, its directors and officers, and each person, if any, who controls Investor within the meaning of the Securities Act, from and against, and will reimburse Investor, its directors and officers and each controlling person with respect to, any and all loss, damage, liability, cost and expense to which Investor or such controlling person may become subject under the Securities Act or otherwise, insofar as such losses, damages, liabilities, costs or expenses are caused by any untrue statement or alleged untrue statement of any material fact contained in such registration statement, any prospectus contained therein or any amendment or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances in which they were made, not misleading; provided, however, that the Company will not be liable in any such case to the extent that any such loss, damage, liability, cost or expense arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission so made in conformity with information furnished by Investor or any such controlling person in writing specifically for use in the preparation thereof.

(11) To the extent Investor includes any Shares or Warrant Shares in a registration statement pursuant to the terms hereof, Investor will indemnify and hold harmless the Company, its directors and officers and any controlling person from and against, and will reimburse the Company, its directors and officers and any controlling person with respect to, any and all loss, damage, liability, cost or expense to which the Company, its directors and officers or such controlling person may become subject under the Securities Act or otherwise, insofar as such losses, damages, liabilities, costs or expenses are caused by any untrue statement or alleged untrue statement of any material fact contained in such registration statement, any prospectus contained therein or any amendment or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances in which they were made, not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was so made in reliance upon and in conformity with written information furnished by or on behalf of the Investor specifically for use in the preparation thereof and provided further, that the maximum amount that may be recovered from Investor shall be limited to the amount of proceeds received by Investor from the sale of such shares of Common Stock.

(12) To the extent any indemnification by an indemnifying party is prohibited or limited by law, the indemnifying party agrees to make the maximum contribution with respect to any amounts for which it would otherwise be liable hereunder to the extent permitted by law, provided that (i) no contribution shall be made under circumstances where the indemnifying party would not have been liable for indemnification pursuant to the provisions hereof, (ii) no seller of securities guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any seller of securities who was not guilty of such fraudulent misrepresentation, and (iii) the amount of the contribution together with any other payments made in respect of such loss, damage, liability or expense, by any seller of securities shall be limited to the net amount of proceeds received by such seller from the sale of such securities.

(13) The Investor will cooperate with the Company in connection with this Subscription Agreement, including timely supplying all information and executing and returning all documents requested by the Company which are required to enable the Company to perform its obligations to register the Shares and the Warrant Shares (which shall include all information regarding the Investor and proposed manner of sale of securities required to be disclosed in any registration statement filed in accordance with this Section 5).

(C) Certain Adjustments. The Shares, Warrants and Warrant Shares shall receive customary adjustment in connection with forward or reverse stock splits, stock dividends, recapitalizations, reclassification, mergers or consolidations and the like. In addition, the Warrants will have certain weighted average anti-dilution rights for issuances below \$2.00 per share as described in the form of Warrant. Specifically excluded from this anti-dilution adjustment provision are shares issued pursuant to options and warrants outstanding as of the date of the Memorandum, options exercised pursuant to grants under the Company's stock option plan, acquisitions and strategic alliances consummated by the Company.

6. Specific State Legends

**FOR NEW HAMPSHIRE RESIDENTS ONLY:** NEITHER THE FACT THAT A REGISTRATION STATEMENT OR AN APPLICATION FOR A LICENSE HAS BEEN FILED WITH THE STATE OF NEW HAMPSHIRE NOR THE FACT THAT A SECURITY IS EFFECTIVELY REGISTERED OR A PERSON IS LICENSED IN THE STATE OF NEW HAMPSHIRE CONSTITUTES A FINDING BY THE SECRETARY OF STATE THAT ANY DOCUMENT FILED UNDER RSA 421-B OF THE NEW HAMPSHIRE UNIFORM SECURITIES ACT IS TRUE, COMPLETE AND NOT MISLEADING. NEITHER ANY SUCH FACT NOR THE FACT THAT AN EXEMPTION OR EXCEPTION IS AVAILABLE FOR A SECURITY OR A TRANSACTION MEANS THAT THE SECRETARY OF STATE HAS PASSED IN ANY WAY UPON THE MERITS OR QUALIFICATIONS OF, OR RECOMMENDED OR GIVEN APPROVAL TO, ANY PERSON, SECURITY OR TRANSACTION. IT IS UNLAWFUL TO MAKE, OR CAUSE TO BE MADE, TO ANY PROSPECTIVE PURCHASER, CUSTOMER OR CLIENT ANY REPRESENTATION INCONSISTENT WITH THE PROVISIONS OF THIS PARAGRAPH.

**FOR FLORIDA RESIDENTS ONLY:** EACH FLORIDA RESIDENT WHO SUBSCRIBES FOR THE PURCHASE OF SECURITIES HEREIN HAS THE RIGHT, PURSUANT TO SECTION 517.06(1)(a)(5) OF THE FLORIDA SECURITIES ACT, TO WITHDRAW HIS SUBSCRIPTION FOR THE PURCHASE AND RECEIVE A FULL REFUND OF ALL MONIES PAID WITHIN THREE BUSINESS DAYS AFTER THE EXECUTION OF THIS SUBSCRIPTION AGREEMENT OR PAYMENT FOR THE PURCHASE HAS BEEN MADE, WHICHEVER IS LATER. WITHDRAWAL WILL BE WITHOUT ANY FURTHER LIABILITY TO ANY PERSON. TO ACCOMPLISH THIS WITHDRAWAL, A SUBSCRIBER NEED ONLY SEND A LETTER OR TELEGRAM TO THE COMPANY AT THE ADDRESS SET FORTH IN THIS SUBSCRIPTION AGREEMENT INDICATING HIS INTENTION TO WITHDRAW.

SUCH LETTER OR TELEGRAM SHOULD BE SENT AND POSTMARKED PRIOR TO THE END OF THE FOREMENTIONED THIRD BUSINESS DAY. IT IS ADVISABLE TO SEND SUCH LETTER BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED, TO ENSURE THAT IT IS RECEIVED AND ALSO TO EVIDENCE THE TIME IT WAS MAILED. IF THE REQUEST IS MADE ORALLY, IN PERSON OR BY TELEPHONE TO AN OFFICER OF THE COMPANY, A WRITTEN CONFIRMATION THAT THE REQUEST HAS BEEN RECEIVED SHOULD BE REQUESTED.

**FOR GEORGIA RESIDENTS ONLY:** THE SECURITIES OFFERED HEREBY ARE BEING ISSUED OR SOLD IN RELIANCE ON PARAGRAPH (13) OF CODE SECTION 10-5-9 OF THE GEORGIA SECURITIES ACT OF 1973, AND MAY NOT BE SOLD OR TRANSFERRED EXCEPT IN A TRANSACTION WHICH IS EXEMPT UNDER SUCH ACT OR PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER SUCH ACT.

**FOR RESIDENTS OF ALL STATES:** THE SECURITIES OFFERED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933 OR THE SECURITIES LAWS OF ANY STATE AND ARE BEING OFFERED AND SOLD IN RELIANCE ON EXEMPTIONS FROM THE REGISTRATION REQUIREMENTS OF SAID ACT AND SUCH LAWS. THE SECURITIES ARE SUBJECT TO RESTRICTIONS

ON TRANSFERABILITY AND RESALE AND MAY NOT BE TRANSFERRED OR RESOLD EXCEPT AS PERMITTED UNDER SAID ACT AND SUCH LAWS PURSUANT TO REGISTRATION OR EXEMPTION THEREFROM. INVESTORS SHOULD BE AWARE THAT THEY WILL BE REQUIRED TO BEAR THE FINANCIAL RISKS OF THIS INVESTMENT FOR AN INDEFINITE PERIOD OF TIME.

THE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION, ANY STATE SECURITIES COMMISSION OR ANY OTHER REGULATORY AUTHORITY, NOR HAVE ANY OF THE FOREGOING AUTHORITIES PASSED UPON OR ENDORSED THE MERITS OF THIS OFFERING. ANY REPRESENTATION TO THE CONTRARY IS UNLAWFUL.

7. No Waiver.

Notwithstanding any of the representations, warranties, acknowledgments or agreements made herein by the undersigned, the undersigned does not thereby or in any manner waive any rights granted to the undersigned under federal or state securities laws.

8. Revocation.

The undersigned agrees that he shall not cancel, terminate or revoke this Subscription Agreement or any agreement of the undersigned made hereunder other than as set forth herein, and that this Subscription Agreement shall survive the death or disability of the undersigned.

9. Termination of Subscription Agreement.

If the Company elects to cancel this Subscription Agreement, provided that it returns to the undersigned, without interest and without deduction, all sums paid by the undersigned, this Offer shall be null and void and of no further force and effect, and no party shall have any rights against any other party hereunder.

10. Miscellaneous.

(A) All notices or other communications given or made hereunder shall be in writing and shall be mailed by registered or certified mail, return receipt requested, postage prepaid, or by overnight courier service to the undersigned at his address set forth on the Investor Signature Page, and to the Company and the Placement Agent at the addresses set forth in the Memorandum.

(B) This Subscription Agreement constitutes the entire agreement among the parties hereto with respect to the subject matter hereof and may be amended only by a writing executed by all parties.

(C) The provisions of this Subscription Agreement shall survive the execution thereof.

(D) This Subscription Agreement shall be governed by the laws of the State of New York as an agreement between residents of New York.

11. Certification.

The undersigned certifies that he has read this entire Subscription Agreement and that every statement on his part made and set forth herein is true and complete.

**INVESTOR SIGNATURE PAGE FOR ORAGENICS, INC. SUBSCRIPTION AGREEMENT**

**Please print or type. Use ink only. (All Parties Must Sign)**

The undersigned investor hereby certifies that he (i) has received and relied solely upon the Confidential Private Placement Memorandum, this Subscription Agreement and their respective exhibits and schedules, (ii) agrees to all the terms and conditions of this Subscription Agreement, (iii) meets the suitability standards set forth herein and (iv) is a resident of the state or foreign jurisdiction indicated below.

Dollar Amount of Units Subscribed for: \$ \_\_\_\_\_

\_\_\_\_\_  
Name of Investor (Print)

\_\_\_\_\_  
Name of Joint Investor (if any) (Print)

\_\_\_\_\_  
Signature of Investor

\_\_\_\_\_  
Signature of Joint Investor (if any)

\_\_\_\_\_  
Capacity of Signatory (If applicable)

\_\_\_\_\_  
Social Security or Taxpayer Identification Number

Investor Address:

\_\_\_\_\_  
Street Address

\_\_\_\_\_  
City State Zip Code

Telephone: ( ) Fax: ( )

Email: \_\_\_\_\_

Address for Delivery of Shares (if different from above):

\_\_\_\_\_  
Street Address

\_\_\_\_\_  
City State Zip Code

Broker:

Westminster Registered Representative \_\_\_\_\_

If other than individual, check one and indicate capacity of signatory under the signature

Trust

Estate

Uniform Gifts to Minors Act, State of \_\_\_\_\_

Attorney-in-fact

Corporation

Other

If Joint Ownership, check one:

Joint Tenants with Right of Survivorship

Tenants in Common

Tenants by the Entirety

Community by Property

**Backup Withholding Statement:**

Please check this box only if the investor is subject to backup withholding

**Foreign Person:**

Please check this box only if the investor is a nonresident alien, foreign corporation, foreign partnership, foreign trust or foreign estate

Country \_\_\_\_\_ Passport # \_\_\_\_\_

ID # \_\_\_\_\_ ID Type \_\_\_\_\_

The investor agrees to the terms of this Agreement and, as required by the Regulations pursuant to the Internal Revenue Code, certifies under penalty of perjury that: (1) the Social Security Number or Taxpayer Identification Number and address provided above is correct, (2) the investor is not subject to backup withholding (unless the Backup Withholding Statement box is checked) either because he has not been notified that he is subject to backup withholding as a result of a failure to report all interest or dividends or because the Internal Revenue Service has notified him that he is no longer subject to backup withholding, and (3) the investor (unless the Foreign Person box above is checked) is not a nonresident alien, foreign partnership, foreign trust or foreign estate.

THE SUBSCRIPTION FOR UNITS OF ORAGENICS, INC. BY THE ABOVE NAMED INVESTOR(S) IS ACCEPTED THIS \_\_\_\_\_ DAY OF \_\_\_\_\_, 2004.

Oragenics, Inc.

By: \_\_\_\_\_

Name: Mente Saponis

Title: President

APPENDIX I

ORAGENICS, INC. REGISTRATION STATEMENT QUESTIONNAIRE

A. Part I

In connection with the preparation of the Registration Statement, please provide us with the following information:

1. Pursuant to the "Selling Stockholder" section of the Registration Statement, please state your or your organization's name exactly as it should appear in the Registration Statement

2. Please provide the number of shares that you or your organization will own immediately after the Closing, including those Shares purchased by you or your organization pursuant to this Subscription Agreement and those shares purchased by you or your organization through other transactions.

3. Have you or your organization had any position, office or other material relationship within the past three years with the Company or its affiliates?

☐ Yes ☐ No

If yes, please indicate the nature of any such relationships below:

B. Part II

Pursuant to Section 3 of the Agreement, please provide us with the following information, and we will use your responses to qualify you for purposes of federal and state securities laws:

ORAGENICS, INC. INVESTOR SUITABILITY QUESTIONNAIRE

ALL INFORMATION FURNISHED IN COMPLETING THIS  
QUESTIONNAIRE WILL BE TREATED CONFIDENTIALLY

I. STATUS AS ACCREDITED INVESTOR

Please confirm whether or not the investor is an "accredited investor" as defined under the Securities Act of 1933, as amended [CHECK AS APPLICABLE]:

The undersigned investor: ☐ IS an accredited investor, by means of the exemption or exemptions listed; or  
☐ IS NOT an accredited investor

If you indicated that you are an accredited investor, please check all applicable boxes to indicate the exemption qualifying you as an accredited investor, as provided in rule 501(a) under the Securities Act of 1933, as amended

Individual Investors

A director or executive officer of the Company,

A person whose individual net worth (or joint net worth with spouse) exceeds \$1 million;

A person who had an individual income in excess of \$200,000 in each of the two most recent years (or joint income with spouse in excess of \$300,000 in each of such years) and has a reasonable expectation of reaching the same income level in the current year.

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#### Non-Individual Investors

\_\_\_\_\_ A corporation, organization described in Section 501(c)(3) of the Internal Revenue Code, a Massachusetts or similar business trust or a partnership, in each case, not formed for the purpose of this investment, with total assets in excess of \$5,000,000;

\_\_\_\_\_ A private business development company as defined in Section 202(a)(22) of the Investment Advisers Act of 1940 [a U.S. venture capital fund which invests primarily through private placements in non-publicly traded securities and makes available (either directly or through co-investors) to the portfolio companies significant guidance concerning management, operations or business objectives];

\_\_\_\_\_ A Small Business Investment Company licensed by the U.S. Small Business Administration under Section 301(e) or (d) of the Small Business Investment Act of 1958;

\_\_\_\_\_ An investment company registered under the Investment Company Act of 1940 or a business development company as defined in Section 2(a)(48) of that Act;

\_\_\_\_\_ A bank as defined in Section 3(a)(2) or a savings and loan association or other institution defined in Section 3(a)(5)(A) of the Securities Act of 1933 acting in either an individual or fiduciary capacity;

\_\_\_\_\_ An insurance company as defined in Section 2(f) of the Securities Act of 1933;

\_\_\_\_\_ An employee benefit plan within the meaning of Title I of the Employee Retirement Income Security Act of 1974 whose investment decision is made by a fiduciary which is either a bank, savings and loan association, insurance company, or registered investment advisor, or whose total assets exceed \$5,000,000 or, if a self-directed plan, a plan whose investment decisions are made solely by persons who are accredited investors;

\_\_\_\_\_ A trust with total assets in excess of \$5,000,000 whose purchase is directed by a sophisticated person as described in rule 506(b)(2)(ii) of the Securities Act of 1933.

\_\_\_\_\_ Other. Describe.

#### II. RESIDENCE INFORMATION

##### Individual Investors

A. Please indicate each state in which you maintained your principal residence during the past three years and the dates during which you resided in each state.

B. Please indicate each state in which you are registered to vote, have a current driver's license or maintain a residence.

##### Non-Individual Investors

Please indicate the jurisdiction in which the entity is chartered and the jurisdiction in which it maintains its principal offices.

#### III. INVESTMENT REPRESENTATION

Are you purchasing the securities offered for your own account and for investment purposes only?

\_\_\_\_\_ Yes \_\_\_\_\_ No

If no, please state for whom you are investing and/or the reason for investing.

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IV. SIGNATURE

The above information is true and correct in all material respects and the undersigned recognizes that the Company and its counsel are relying on the truth and accuracy of such information in reliance on the exemption contained in Subsection 4(2) of the Securities Act of 1933, as amended, and Regulation D promulgated thereunder. The undersigned agrees to notify the Company promptly of any changes in the foregoing information which may occur prior to the investment.

Executed at \_\_\_\_\_, on \_\_\_\_\_, 2004.

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Title if for Entity)

IF THE INVESTMENT WILL BE MADE BY MORE THAN ONE PERSON OR ENTITY, WHETHER OR NOT AFFILIATED, PLEASE COMPLETE A COPY OF THIS QUESTIONNAIRE FOR EACH ENTITY

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

FORM 10-KSB

☒ Annual report under Section 13 or 15(d) of the Securities Exchange Act of 1934 For the fiscal year ended December 31, 2004

☐ Transition report under Section 13 or 15(d) of the Securities Exchange Act of 1934

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

Commission file number 000-50614

ORAGENICS, INC.  
(Name of small business issuer in its charter)

FLORIDA 59-3410522

-----  
(State or Other Jurisdiction of (IRS Employer  
Incorporation or Organization) Identification No.)

13700 PROGRESS BLVD., ALACHUA, FLORIDA 32615

-----  
(Address of Principal Executive Offices) (Zip Code)

(386) 418-4018

-----  
(Issuer's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:  
Common stock, par value \$.001 per share

Securities registered pursuant to Section 12(g) of the Act:  
Common stock, par value \$.001 per share

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 ☐ No

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB ☐

The revenues of registrant for the fiscal year ended December 31, 2004 were \$196,210.

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of March 4, 2005 was approximately \$15,692,932 based upon a last sales price of \$2.38 as reported by the American Stock Exchange.

As of March 4, 2005 there were 14,597,224 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Registrant's Definitive Proxy Statement for its 2005 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-KSB Report except with respect to information specifically incorporated by reference in this Form 10-KSB Report, the Definitive Proxy Statement is not deemed to be filed as a part hereof.

Transitional Small Business Disclosure Format (check one):

Yes \_\_\_ No X

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## PART I

### ITEM 1. DESCRIPTION OF BUSINESS.

This description contains certain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from the results discussed in the forward-looking statements as a result of certain of the risks set forth herein and elsewhere in this Form 10-KSB. We assume no obligation to update any forward-looking statements contained herein.

#### OVERVIEW

We are an early-stage biotechnology company focused on the acquisition and development of novel technologies and products to address significant, unmet medical needs. Our strategy is to in-license and to develop products through human proof-of-concept studies (Phase I and II clinical trials of the U.S. Food and Drug Administration's regulatory process) prior to partnering with major pharmaceutical, biotechnology or healthcare product firms for advanced clinical development and commercialization. Our most advanced product, which we refer to as replacement therapy, is a one-time topical treatment to prevent tooth decay. The FDA has approved our Investigational New Drug application ("IND") for replacement therapy and we plan to begin Phase I trials in 2005.

Since inception, we have funded a significant portion of our operations from the public and private sales of our securities. We have generated no

significant revenues from operations during the last two years. All of our revenues have been from a sponsored research agreement and Small Business Innovation Research ("SBIR") grants which have expired. We have not generated revenues from sales of products.

We are currently developing several products, each of which addresses large market opportunities:

- o REPLACEMENT THERAPY is a single, painless, one-time topical treatment that has the potential to offer lifelong protection against dental caries (tooth decay). Replacement therapy refers to a process which permanently replaces bacteria normally present in the mouth which are strongly associated with tooth decay with a genetically altered strain of bacteria that has been modified so that it no longer contributes to the disease. Present in the normal flora of the mouth, *Streptococcus mutans* converts dietary sugar to lactic acid; the lactic acid, in turn, causes the erosion of tooth enamel that results in the destruction of the tooth surface and eventually the entire tooth. Replacement therapy permanently replaces resident acid-producing *Streptococcus mutans* with a patented, genetically engineered strain of *Streptococcus mutans* that does not produce lactic acid. Applied topically to tooth surfaces with a swab, the therapy requires only one application. We plan to begin Phase I clinical trials in early 2005 and partner with a major healthcare products or pharmaceutical company prior to initiating later stages of clinical testing.
- o PROBIOTICS are live microorganisms that confer health benefits to the host when administered in adequate amounts; the use of yogurt containing live *Lactobacillus* cultures is an example of a probiotic application. We have identified three natural strains of bacteria that provide significant protection against the causative organisms of periodontal disease and dental caries. We are developing a formulation and method of delivery of these beneficial bacteria that we plan to commercialize as a dental care probiotic. Because probiotic treatments may be marketed as "health supplements" without the need for extensive regulatory oversight, we believe that we may achieve commercialization of our probiotic product in certain markets in 2006. If successfully developed, our oral probiotic product will be one of the first probiotics to be marketed for the maintenance of oral health.
- o MUTACIN 1140 is a highly potent bactericidal peptide produced by *Streptococcus mutans*. This proprietary peptide was discovered by our researchers during the course of developing replacement therapy and is a novel antibiotic that has broad-spectrum antimicrobial activity against essentially all Gram-positive bacteria including vancomycin-resistant *Staphylococcus aureus*. The antibiotic currently is in preclinical stages of development. We currently plan to begin animal studies in 2005.

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- o IVIAT AND CMAT are technologies we licensed from iViGene Corporation (a company related to us by common ownership). These technologies enable the simple, fast identification of novel and potentially important gene targets associated with the natural onset and progression of infections, cancers and other diseases in humans and other living organisms, including plants. This licensed technology offers 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 and tuberculosis, as well as agricultural and other non-human uses.

We were founded in 1996, became operational in 1999 and currently employ 18 full-time employees. Our registered office is located at 4730 S.W. 103rd Way, Gainesville, Florida 32608, and our headquarters are located at 13700 Progress Boulevard, Alachua, Florida 32615.

## OUR BUSINESS STRATEGY

Our strategy is to develop novel technologies through human proof-of-concept studies (Phase I or II clinical trials) prior to partnering with major pharmaceutical, biotechnology or health care product firms for advanced clinical development and commercialization. Upon successful completion of proof-of-concept studies, we intend to consider sublicensing our licensed, patented technologies to one or more strategic partners that would be responsible for advanced clinical development, completing the U.S. Food and Drug Administration's ("FDA") approval process, and manufacturing and marketing our products. We plan to structure our agreements with strategic partners sublicensing our technology to include an upfront licensing fee upon execution of the agreement, milestone payments upon achievement of specific product development goals and royalties from product sales.

In pursuing this strategy, we expect to avoid the high cost of later stage clinical trials and generate revenues in the form of license fees from our technologies sooner than if we were to complete the lengthy FDA approval-process ourselves. Once one or more of our technologies are successfully licensed, we plan to license additional promising technologies within our field of expertise from leading academic institutions and other biotechnology companies. There can be no assurance that we will be able to enter into such sublicenses.

## OUR TECHNOLOGIES

### REPLACEMENT THERAPY

Dental caries (tooth decay) is a worldwide epidemic that affects the majority of populations in industrialized and developing countries. According to the World Health Organization, tooth decay is the most prevalent infectious disease, affecting approximately 5 billion people. Much of the tooth decay in low-income countries remains untreated until the teeth are extracted.

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

Our replacement therapy technology employs a genetically modified strain of *Streptococcus mutans* that does not produce lactic acid. When applied to the teeth, this non acid-producing organism displaces and permanently replaces the indigenous acid-producing strains of *Streptococcus mutans*, thereby potentially providing lifelong protection against most forms of tooth decay.

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

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We submitted an IND for replacement therapy to the FDA in 1998 seeking permission to begin Phase I clinical trials. In March 2003, we submitted a new IND. In November 2004, the FDA approved our clinical design and protocol for the Phase I clinical trial. In March 2005, we initiated enrollment in the clinical trial.

### TECHNICAL BACKGROUND

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

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

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

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

#### REGULATORY STATUS

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

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

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

The initial study will be conducted in eleven couples and an additional four unattached males at Hill Top Research in West Palm Beach, Florida and will look at the safety of Replacement Therapy and the potential for horizontal transmission of the Replacement Therapy organism to the non-treated member of each couple. All of the participants in the trial must be without teeth, with full sets of dentures, and under the age of 55. The study will involve four days of pretreatment with an antibiotic (chlorhexidine) to kill resident *S. mutans* in each participant's mouth. Male study subjects will then receive Replacement Therapy. The non-treated member of each couple will be tested repeatedly to see if there is any horizontal transmission of the Replacement Therapy organism from

one person to another. The investigators will determine the genetic stability of the Replacement Therapy organism over time. Seven days after treatment, the subjects will undergo an eradication phase of the study for one month, using the same antibiotic and the withholding of a D-alanine amino acid supplement that the Replacement Therapy organism requires for its survival. The investigators will subsequently follow each study participant for three months to ensure that the eradication was effective.

## PRECLINICAL STUDIES

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

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

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

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

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

- o Does not cause significant tooth decay in rats;
- o Persistently and preemptively colonizes the tooth surfaces of rats;
- o Displaces other strains of *Streptococcus mutans*;
- o Is genetically stable in the laboratory and in rats;
- o Shows no toxicity in acute and chronic tests; and
- o Does not disrupt the normal flora of the mouth

## INTELLECTUAL PROPERTY

We have exclusively licensed the intellectual property for our replacement therapy from the University of Florida Research Foundation, Inc. The license is dated August 4, 1998 and was amended on September 15, 2000, July 10, 2002, September 25, 2002 and March 17, 2003. The agreement provides us with an exclusive worldwide license to make, use and sell products and processes covered by Patent No. 5,607,672, which is dated March 4, 1997 and will expire on March 3, 2014. Our license is for the period of the patent, subject to the performance of terms and conditions contained therein. The patent covers the genetically

altered strain of Streptococcus mutans which does not produce lactic acid, a pharmaceutical composition for administering the genetically altered strain and the method of preventing tooth decay by administering the strain. The University of Florida Research Foundation, Inc. has reserved for itself and the University of Florida the right to use and sell such products and services for research purposes only. Our license also provides the University of Florida Research Foundation, Inc. with a license, for research purposes only, to any improvements that we make to the products and processes covered by the patent.

Under the terms of the license, we have entered into an Equity Agreement with the University of Florida Research Foundation, Inc. under which we issued 599,940 shares of our common stock as partial consideration for the license. We are obligated to pay 5% of the selling price of any products developed from the licensed technology to the University of Florida Research Foundation, Inc. and, if we sublicense the license, we are obligated to pay 20% of all amounts received from the sublicensee. On December 31, 2005 and each year thereafter we are obligated to make a minimum royalty payment of \$50,000. We spent in excess of \$600,000 in 2003 and \$1,000,000 in 2004 which were the minimum amounts required under our license in order to maintain it. In each future calendar year, we are obligated to spend, or cause to be spent, an aggregate of \$1,000,000 on the research, development and regulatory prosecution of our replacement therapy and mutacin 1140 technologies combined, until a product which is covered wholly or partially by the claims of the patent, or is manufactured using a process which is covered wholly or partially by the claims of the patent, is sold commercially. If we fail to make these minimum expenditures, the University of Florida Research Foundation, Inc. may terminate our license.

We must also pay all patent costs and expenses incurred by the University of Florida Research Foundation, Inc. for the preparation, filing, prosecution, issuance and maintenance of the patents beyond \$105,000. We have paid \$100,000 to the University of Florida Research Foundation, Inc. for patent expenses already incurred. We have agreed to indemnify and hold the University of Florida Research Foundation, Inc. harmless from any damages caused as a result of the production, manufacture, sale, use, lease, consumption or advertisement of the product. Further, we are required to maintain liability insurance coverage appropriate to the risk involved in marketing the products, for which we obtained liability insurance in the amount of \$2,000,000 that expires in August, 2005. There is no assurance that we can obtain continued coverage on reasonable terms.

We received notification from B.C. International Corporation on July 29, 2002 that a gene utilized in its licensed, patented strain of Streptococcus mutans infringes a patent which it holds under a license. Their notification did not state that they intended to pursue legal remedies. We do not believe that the gene in question infringes that patent and we sent them correspondence setting out our position. We have received no further communication from them.

#### MANUFACTURING, MARKETING AND DISTRIBUTION

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

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

#### MARKET OPPORTUNITY

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

- o increasing consumption of dietary sugar;

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

During the last 20 years, sugar consumption has increased. Higher dietary intake of sugar predisposes individuals to higher rates of tooth decay. Moreover, according to the Beverage Marketing Corporation, by 2005 consumers will drink more bottled water than any other alcoholic or non-alcoholic

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beverage, with the exception of carbonated soft drinks. Since bottled water generally does not contain fluoride, the protective effects of fluoridated public water systems are lost. With the aging of the population, the incidence and frequency of tooth decay is likely to further increase as most of the baby boomers upon reaching retirement age will have a relatively intact dentition unlike previous generations. Teeth lose density with age and become more susceptible to decay. Therefore, more teeth will be at risk for tooth decay.

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

## COMPETITION

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

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

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

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## PROBIOTICS

Probiotics are live microorganisms that confer a health benefit to their host when administered in adequate amounts. In probiotic therapy, beneficial microorganisms are colonized in areas normally colonized by pathogens. By being better adapted to their ecosystem than the pathogens, these beneficial bacteria crowd out harmful bacteria and inhibit colonization and growth of the disease-causing pathogens. Examples of common probiotic applications are the use of yogurt containing live cultures to improve digestion, immune system response, and vaginal and urinary tract health.

The oral cavity provides an ecological niche for 400 -500 bacterial species, some of which are responsible for periodontal disease (gum disease) and dental caries (tooth decay). Of all of the bacteria normally residing in a person's mouth, only about half a dozen are the primary cause of periodontal disease and dental caries. Our oral rinse probiotics' technology employs three natural strains of beneficial bacteria which promote oral health and inhibit the growth of harmful bacteria that cause periodontal disease and tooth decay.

## TECHNICAL BACKGROUND

Through our research, we have developed a probiotic product containing three natural strains of beneficial bacteria that promote oral health. The three bacterial strains are *Streptococcus oralis* and *Streptococcus uberis* for the maintenance of periodontal health and *Streptococcus rattus* for the maintenance of dental health.

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

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

## PRECLINICAL STUDIES

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

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

Dental caries. We believe probiotics can also be used to suppress levels of *Streptococcus mutans*, the principal cause of tooth decay. *Streptococcus mutans* converts dietary refined sugar to lactic acid. The lactic acid, in turn, erodes the mineral in enamel and dentin, which weakens the tooth

resulting in tooth decay. Research conducted by our scientists have led to the discovery of a close relative of *Streptococcus mutans*, a strain of *Streptococcus rattus*, which is naturally deficient in its ability to produce lactic acid and thus unable to cause tooth decay. Because *Streptococcus rattus* is very closely related to *Streptococcus mutans*, *Streptococcus rattus* reduces the number of *Streptococcus mutans* by competing for nutrients, attachment sites, and other important colonization factors. As animal studies have revealed, daily treatment

with this beneficial strain can promote dental health by significantly reducing the numbers of dental caries-causing *Streptococcus mutans*.

We are currently performing acute and chronic toxicity tests of our probiotic technology in laboratory rats. Further work will involve studies to determine an appropriate and stable delivery system, and to determine the optimum dosage levels to be used in human clinical trials.

## REGULATORY STATUS

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

## INTELLECTUAL PROPERTY

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

## MANUFACTURING, MARKETING AND DISTRIBUTION

Manufacturing methods used to produce probiotic strains are the standard fermentation methods which involve culturing bacteria in large vessels and harvesting them when mature by centrifuge or filtration. These methods are relatively commonplace and readily available within the pharmaceutical industry. We intend to seek one or more strategic partners for the manufacturing, marketing and distribution of our oral probiotic technology in Asia and Europe. Product launch in select markets is currently expected to occur in 2006 and 2007.

## MARKET OPPORTUNITY

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

## COMPETITION

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

## MUTACIN 1140

Most clinical isolates of *Streptococcus mutans* secrete peptides, called mutacins, which exhibit antimicrobial activity against closely related streptococcal species and other Gram-positive bacteria. Research suggests that these mutacins play a key role in enabling *Streptococcus mutans* to effectively colonize the oral cavity.

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

## TECHNICAL BACKGROUND

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

Currently, mutacin 1140 is in the early stages of preclinical development and we have not yet filed an Investigational New Drug application with the FDA, however, such filing is expected after successful completion of animal studies that are currently expected to begin in 2005.

## PRECLINICAL STUDIES

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

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

## REGULATORY STATUS

Mutacin 1140 currently is in preliminary stages of development. We currently plan to initiate animal studies in 2005. Upon completion of the animal studies, we will submit an Investigational New Drug application for mutacin 1140 to the FDA.

## INTELLECTUAL PROPERTY

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

## MANUFACTURING, MARKETING AND DISTRIBUTION

Once we are able to establish large-scale production capabilities, we currently plan to begin animal studies in 2005. Upon successful completion of animal studies, we will file an IND application for mutacin 1140 with the FDA.

Once the FDA has approved an IND and we have completed Phase I clinical trials, we would expect to seek a strategic partner for further clinical development and commercialization.

## MARKET OPPORTUNITY

The need for novel antibiotics is increasing as a result of the growing resistance of target pathogens. The Center for Disease Control estimates that

bacteria resistant to known antibiotics cause 44% of hospital infections. Vancomycin, introduced in 1956, serves as the last line of defense against certain life-threatening infections. Unfortunately, certain bacteria have developed strains which resist even vancomycin.

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

## COMPETITION

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

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

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

## IVIAT AND CMAT

In March 2004, we licensed from iviGene Corporation, a company whose major shareholders also own a significant number of shares of our common stock, applications of a novel technology that enables the simple, fast identification of novel and potentially important gene targets associated with the natural onset and progression of cancers and other diseases in humans and other living organisms, including plants. This licensed technology 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.

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

## TECHNICAL BACKGROUND

This technology platform was developed by our founder and chief scientific officer, Jeffrey D. Hillman, and University of Florida scientists. It is called in vivo induced antigen technology (IVIAT). IVIAT can quickly and easily identify in vivo induced genes in human infections without the use of

animal models, facilitating the discovery of new targets for the development of vaccines, antimicrobials and diagnostics. Dr. Hillman and his collaborators have further developed methods based on this approach to create Change Mediated Antigen Technology (CMAT). CMAT can be used to identify gene targets associated with the onset and progression of cancerous processes and autoimmune diseases. It can also be used to identify novel genes in plant diseases, including genes expressed by the pathogen when it causes the disease and genes expressed by the plant in response to the disease.

## INTELLECTUAL PROPERTY

Our license provides us with exclusive worldwide rights to this broad platform technology in the areas of cancer and tuberculosis, as well as agricultural and other non-human uses. In return, we will pay royalties on revenues we are able to generate from any products developed using the technology, including royalties on sublicense fees, milestone payments and future product sales. Under the terms of our license with iviGene we are not obligated to make any payments to iviGene until we have achieved certain milestone or royalty payments. However, we are required to pay all patent-related expenses and commit two full-time staff or spend at least \$200,000 toward product development annually to maintain our license.

## FEDERAL FOOD AND DRUG ADMINISTRATION (FDA) REGULATION

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

## GENERAL

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

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

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

## PRECLINICAL TRIALS AND INVESTIGATIONAL NEW DRUG APPLICATION

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

## CLINICAL TRIALS

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

### PHASE I

Phase I clinical trials consist of administering the drug and testing for safety and tolerated dosages as well as preliminary evidence of efficacy in humans. They are concerned primarily with learning more about the safety of the drug, though they may also provide some information about effectiveness. Phase I testing is normally performed on healthy volunteers. The test subjects are paid

to submit to a variety of tests to learn what happens to a drug in the human body; how it is absorbed, metabolized and excreted, what effect it has on various organs and tissues; and what side effects occur as the dosages are increased. The principal objective is to determine the drug's toxicity.

## PHASE II

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

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impaired. A number of patients with the disease or illness will receive the treatment while a control group will receive a placebo. At the conclusion of Phase II trials, we and the FDA will have a clear understanding of the short-term safety and effectiveness of our technologies and their optimal dosage levels.

## PHASE III

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

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

## PHARMACEUTICAL DEVELOPMENT

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

## NEW DRUG APPLICATION

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

## POST MARKETING SURVEYS

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

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

## COMPETITION

**Industry.** The pharmaceutical and biotechnology industries are characterized by intense competition, rapid product development and technological change. Competition is intense among manufacturers of dental therapeutics and prescription pharmaceuticals. Most of our potential competitors are large, well established pharmaceutical, chemical or healthcare companies with considerably greater financial, marketing, sales and technological resources than are available to us. Academic institutions, government agencies and other public and private research organizations may also conduct research, seek patent protection and establish collaborative arrangements for discovery, research and clinical development of technologies and products similar to ours.

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Many of our potential competitors have research and development capabilities that may allow them to develop new or improved products that may compete with products based on our technologies. Products developed from our technologies could be rendered obsolete or made uneconomical by the development of new products to treat the conditions to be treated by products developed from our technologies, technological advances affecting the cost of production, or marketing or pricing actions by our potential competitors. This could materially affect our business, financial condition and results of operations. We cannot assure you that we will be able to compete successfully.

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

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

## RESEARCH AND DEVELOPMENT COSTS

We have spent \$1,990,979 and \$929,355 on research and development of our technologies in 2004 and 2003, respectively.

## COSTS OF ENFORCING OUR LICENSES

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

## OUR EMPLOYEES

We are an early-stage biotechnology research and development company and currently have 18 full-time employees, none of whom is represented by a labor union. We believe that our relationship with our employees is excellent.

## AVAILABLE INFORMATION

Our website is [www.oragenics.com](http://www.oragenics.com). On our website we make available at no cost our annual reports on Form 10-KSB, quarterly reports on Form 10-QSB, current reports on Form 8-K and amendments to those reports filed or furnished as soon as reasonably practicable after we electronically file such material with, or furnish them to, the United States Securities and Exchange Commission ("SEC"). The information contained on our website is not a part of this annual report on Form 10-KSB.

### ITEM 2. DESCRIPTION OF PROPERTY.

Our administrative office and laboratory facilities are located at 13700 Progress Boulevard, Alachua, Florida 32615. We began leasing this property pursuant to a five-year operating lease in November 2004. The facility is approximately 5,300 square feet of which approximately 60% is laboratory space

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and the remainder is office space and common areas. The twelve months rental will be \$76,850, net of insurance, taxes and utilities that are paid by us. Lease payments in subsequent years escalate by 3% annually. In 2004, we paid approximately \$469,000 for leasehold improvements to outfit this facility. Such improvements included equipping the building with sufficient air-handling and building laboratory stations. We believe our facilities are sufficient for our current needs, however, we expect to purchase an additional \$700,000 of equipment for use in the laboratories and offices in 2005.

### ITEM 3. LEGAL PROCEEDINGS.

As of the date hereof, we are not a party to any material legal proceedings.

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

None during the fourth quarter of the fiscal year covered by this report.

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## PART II

### ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

Our common stock began trading on the American Stock Exchange under the symbol ONI on May 20, 2004. Previously it was traded on the TSX Venture Exchange under the symbol ORA.U. We voluntarily de-listed from the TSX Venture Exchange on October 12, 2004. The following sets forth the high and low closing bid prices for the common stock on the TSX Venture Exchange from the beginning of 2004 through May 19, 2004 and on the American Stock Exchange from May 20, 2004 through the end of 2004. Such prices represent prices between dealers without adjustment for retail mark ups, mark downs, or commissions and may not necessarily represent actual transactions.

	2004		2003	
	High	Low	High	Low
COMMON STOCK				
First quarter	\$4.35	\$3.20	N/A	N/A
Second quarter	\$4.40	\$2.80	\$2.30	\$1.80
Third quarter	\$3.75	\$2.00	\$4.45	\$2.62
Fourth quarter	\$4.45	\$2.65	\$4.40	\$3.50

On March 4, 2005, the closing bid price of the common stock, as reported by the American Stock Exchange, was \$2.38. As of March 4, 2005, there were approximately 19 record holders of our common stock according to our transfer agent. The number of record holders does not reflect the number of beneficial owners of the common stock for whom shares are held by banks, brokerage firms and others.

#### EQUITY COMPENSATION PLAN INFORMATION

The Company has reserved an aggregate of 1,500,000 shares of the Company's common stock for issuance pursuant to its 2002 Stock Option and Incentive Plan. The per share exercise price of each stock option or similar award granted under these plans must be at least equal to the closing fair market value of the stock on the date of grant. The following table represents the number of shares issuable upon exercise and reserved for future issuance under these plans as of December 31, 2004.

<TABLE>

<CAPTION>

PLAN CATEGORY	NUMBER OF SECURITIES REMAINING AVAILABLE FOR FUTURE ISSUANCE UNDER EQUITY COMPENSATION PLANS (EXCLUDING SECURITIES REFLECTED IN COLUMN (a))		
	NUMBER OF SECURITIES TO BE ISSUED UPON EXERCISE OF OUTSTANDING OPTIONS, WARRANTS AND RIGHTS	WEIGHTED-AVERAGE EXERCISE PRICE OF OUTSTANDING OPTIONS, WARRANTS AND RIGHTS	
-----	-----	-----	
(a)	(b)	(c)	
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<S>	<C>	<C>	<C>
EQUITY COMPENSATION PLANS APPROVED BY SECURITY HOLDERS	1,070,000	\$2.52	430,000
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EQUITY COMPENSATION PLANS NOT APPROVED BY SECURITY HOLDERS	276,180(1) 37,500(2)	1.25 3.00	-- --
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TOTAL	1,383,680	\$2.28	430,000
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</TABLE>

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- (1) Represents outstanding underwriter warrants issued in connection with the Company's initial public offering to acquire shares of common stock at an exercise price of \$1.25. See Note 5 to the Company's Financial Statements.
  - (2) Represents warrants issued to the placement agent in connection with the initial closing of the Company's recent private placement to acquire 25,000 shares of common stock at an exercise price of \$2.75, subject to adjustment and 12,500 shares of common stock at an exercise price of \$3.50, subject to adjustment based upon the following formula:  $NEP = OEP \times [OB + X] / OA$ , where NEP = the New Exercise Price; OEP = the existing Exercise Price immediately before the new Issue ("Old Exercise Price"); OB = the total outstanding shares of Common Stock immediately before the new issue; X = number of shares issuable at the Old Exercise Price (applicable to the Warrant Shares as to which the calculation is being made) for the total consideration to be received for the new issue; OA = the total outstanding shares of Common Stock immediately after the new issue.

#### DIVIDENDS

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

financing agreements entered into in the future may preclude payment of dividends.

## RECENT SALES OF UNREGISTERED SECURITIES

On November 30, 2004, we issued a total of 250,000 shares of our common stock and warrants to purchase 162,500 shares of our common stock in a private placement to three accredited investors and a placement agent. The issuance of the shares of common stock and warrants was made pursuant to the exemptions from registration provided by Section 4(2) of the Securities Act and Regulation D promulgated thereunder. We received gross proceeds of \$687,500 in the private placement and incurred costs of approximately \$142,500 resulting in net proceeds of approximately \$545,000. Warrants representing 125,000 shares of common stock are exercisable by the three accredited investors over a four-year period at a price of \$3.50 per share. The placement agent received warrants exercisable over a four-year period to purchase 25,000 and 12,500 shares of common stock at prices of \$2.75 and \$3.50 per share, respectively.

The subscription agreements we entered into with the investors in connection with the above referenced private placement grant certain resale registration rights to the investors. In the event a registration statement for resale of the shares issued to the investors is not filed within 30 days of closing, is not declared effective within 120 days of the closing, or in certain other events of default, the terms of the subscription agreements provide that each investor (pro rated on a daily basis) is entitled to compensatory payment from us of an amount equal to one percent of the amount invested by that investor, and thereafter one percent for each successive month or any portion of that month until the registration statement is effective or we have cured the other events of default. The subscription agreement also provides that compensatory payments may be made in cash or in stock, at our option, and shall be paid no later than the fifth business day following the month in which such registration default occurred. The payment of any compensatory amounts does not, however, relieve us of our obligation to register the shares. If the compensatory payments are made in stock, such stock is also required to be included in a subsequently filed registration statement. The subscription agreement further provides that if a compensatory payment is not timely made, we will also be obligated to pay the investor interest at the rate of 12% per annum, or the highest rate permitted by law, if less, until such amounts have been paid in full. To date, we have not filed a registration statement nor have we made any compensatory payments to any investors under the subscription agreements.

We are permitted to suspend the use of the registration statement on no more than two occasions for a period not more than 30 consecutive calendar days (or a total of not more than seventy-five (75) calendar days in any twelve month period) under certain circumstances relating to pending corporate developments, public filings with the SEC and similar events. We will pay all the expenses in connection with the filing of the registration statement, other than underwriting commissions and discounts of the selling shareholders. The

selling shareholders will not pay any of the expenses that are incurred in connection with the registration of the shares, but will pay all commissions, discounts, and any other compensation to any securities broker-dealers through whom they sell any of the shares.

## USE OF PROCEEDS

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.

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 our common stock and warrants to purchase 500,000 shares of our common stock at \$1.25 per share until June 24, 2005. As of December 31, 2004, 223,820 underwriter warrants were exercised providing proceeds to us of \$279,775. With respect to the remaining 276,180 unexercised underwriter warrants which expire in June 2005, we maintain an effective registration statement for the resale of shares of common stock underlying the warrants. The costs associated with maintaining this registration statement totaling \$62,421 through December 31, 2004 are netted against proceeds and recorded as a component of stockholders' equity.

Through December 31, 2004 we have applied a total of \$4,982,411 of the \$7,886,166 in net proceeds from our initial public offering as follows:

Payment 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	237,540
Mutacin 1140 production research	444,345
Pre-clinical research	1,532,409
General and administration costs	1,480,105
Purchase of computer and laboratory equipment	715,047
	-----
	\$ 4,982,411
	=====

Other than normal and recurring compensation, the deferred compensation payments and payments 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 two financial institutions and invested overnight in U. S. Government securities. We believe we have used, and continue to use, the net proceeds from the offering consistent with our business strategy.

## ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION.

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

### OVERVIEW

We are an emerging, early-stage biotechnology company aimed at adding value to novel technologies and products sourced from innovative research at the University of Florida and other academic centers. Our strategy is to in-license and to develop products through human proof-of-concept studies (Phase I and II clinical trials of the U.S. Food and Drug Administration's regulatory process) prior to partnering with major pharmaceutical, biotechnology or healthcare product firms for advanced clinical development and commercialization. Since inception, we have funded a significant portion of our operations from the public and private sales of our securities. We have generated no significant revenues from operations during the last two years. All of our revenues have been from a sponsored research agreement and SBIR grants

which have expired. We have not generated revenues from sales of products.

We are currently developing several products, each of which addresses large market opportunities:

REPLACEMENT THERAPY is a single, painless one-time topical treatment that has the potential to offer lifelong protection against dental caries (tooth decay). The therapy is based on genetically altering the bacterium, *Streptococcus mutans*, which is the primary etiologic agent in tooth decay. Present in the normal flora of the mouth, *Streptococcus mutans* converts dietary sugar to lactic acid; the lactic acid, in turn, causes the erosion of tooth enamel that results in the destruction of the tooth surface and eventually the entire tooth. Replacement therapy permanently replaces resident acid-producing *Streptococcus mutans* with a patented, genetically engineered strain of *Streptococcus mutans* that does not produce lactic acid. Applied topically to tooth surfaces with a swab, the therapy requires only one application. We plan to begin Phase I clinical trials in 2005 and partner with a major healthcare products or pharmaceutical company prior to initiating later stages of clinical testing.

PROBIOTICS are live microorganisms that confer health benefits to the host when administered in adequate amounts; the use of yogurt containing live *Lactobacillus* cultures is an example of a probiotic application. We have identified three natural strains of bacteria that provide significant protection against the causative organisms of periodontal disease and dental caries. Because probiotic treatments may be marketed as "health supplements" without the need for extensive regulatory oversight, we believe that we may achieve commercialization of our probiotic product in certain markets in 2006. If successfully developed, our oral rinse product will be one of the first probiotics to be marketed for the maintenance of oral health.

MUTACIN 1140 is a highly potent bactericidal peptide that is produced by our strain of *Streptococcus mutans*. Our proprietary mutacin bacteria was discovered by our researchers during the course of developing replacement therapy and is a novel antibiotic that has broad-spectrum antimicrobial activity against essentially all Gram-positive bacteria including vancomycin-resistant *Staphylococcus aureus*. The antibiotic currently is in preclinical stages of development. We currently plan to begin animal studies in 2005.

IVIAT AND CMAT are technologies we licensed from iviGene Corporation, a company related to us by common ownership. These technologies enable the simple, fast identification of novel and potentially important gene targets associated with the natural onset and progression of infections, cancers and other diseases in humans and other living organisms, including plants. This licensed technology offers 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 and tuberculosis, as well as agricultural and other non-human uses.

A more detailed discussion of our technologies is provided in Item 1 above beginning on page 4.

## BUSINESS OBJECTIVES AND MILESTONES

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

### REPLACEMENT THERAPY

1. Successfully complete Phase I clinical trials.
2. Obtain FDA approval for a pivotal trial.

#### 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. Develop appropriate manufacturing and packaging systems.
2. Complete one human study.

#### IVIAT AND CMAT

1. 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 undertake and complete. To the extent our current capital limits our ability to pursue all of our technologies under development concurrently, we would expect to concentrate our available resources on replacement therapy and oral probiotics in the near-term. We currently believe that we will be able to begin to generate ongoing revenue from our development efforts with our oral probiotics technology sometime in the next eighteen to twenty-four months. This time period could change depending on the progress of our development efforts and our ability to negotiate a partnering arrangement, as well as our efforts to raise additional capital.

#### 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. The preparation of financial statements in accordance with Accounting Principles Generally Accepted in the United States requires us to make estimates and assumptions that affect reported amounts and related disclosures. We consider an accounting estimate to be critical if it requires assumptions to be made that were uncertain at the time the estimate was made; and changes in the estimate or different estimates that could have been made could have a material impact on our results of operations or financial condition. Our financial statements do not include any significant estimates that would have a material impact on our results of operations or financial condition.

#### NEW ACCOUNTING PRONOUNCEMENTS

In December 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004), Share-Based Payment ("Statement 123(R)"), a revision of FASB Statement No. 123, Accounting for Stock-Based Compensation. Statement 123(R) supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and amends FASB Statement No. 95, Statement of Cash Flows. Statement 123(R), which we expect to adopt in the first quarter of 2006, is generally similar to Statement 123, however, it will require all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values. Thus, pro forma disclosure will no longer be an alternative to financial statement recognition. We do not believe the adoption of Statement 123(R) will have a material impact on our results of operations or financial position.

#### RESULTS OF OPERATIONS

##### Operating Results Summary

THREE MONTHS ENDED DECEMBER 31

	2004	2003
Revenue	\$ 33,333	\$ --
Operating expenses:		
Research and development	742,557	333,150
General and administration	565,181	296,036
Total operating expenses	1,307,738	629,186
Loss from operations	(1,274,405)	(629,186)
Other income (expense):		
Interest income	15,831	3,599
Interest expense	(442)	(1,884)
Total other income, net	15,389	1,715
Loss before income taxes	(1,259,016)	(627,471)
Income tax benefit	--	--
Net loss	\$(1,259,016)	\$ (627,471)

YEARS ENDED DECEMBER 31

	2004	2003
Revenue	\$ 196,210	\$ --
Operating expenses:		
Research and development	1,990,979	929,355
General and administration	1,329,983	738,596
Total operating expenses	3,320,962	1,667,951
Loss from operations	(3,124,752)	(1,667,951)
Other income (expense):		
Interest income	47,306	7,874
Interest expense	(442)	(12,877)
Total other income (expense), net	46,864	(5,003)
Loss before income taxes	(3,077,888)	(1,672,954)
Income tax benefit	--	--
Net loss	\$(3,077,888)	\$(1,672,954)

FOR THE QUARTERS ENDED DECEMBER 31, 2004 AND 2003

We had revenues of \$33,333 in the three months ended December 31, 2004 and no revenues in the same period in 2003. The increase is a result of having a Small Business Innovation Research ("SBIR") Grant from the National Institute of Health in 2004. Our operating expenses increased 108% to \$1,307,738 in the three months ended December 31, 2004 from \$629,186 in same period in 2003. Research and development expenses increased 123% to \$742,557 in the three months ended December 31, 2004 from \$333,150 in the same period in 2003, reflecting the hiring of additional research personnel, expensing of stock option compensation, payments to research consultants and increased consumption of laboratory supplies. General and administration expenses increased 91% to \$565,181 in the three months ended December 31, 2004 from \$296,036 in same period in 2003. This increase reflects additions to personnel, expensing of stock option compensation, increased coverage in directors' and officers' liability insurance

and higher facility costs related to moving to our new location.

Interest income increased 340% to \$15,831 in the three months ended December 31, 2004 from \$3,599 in the same period in 2003 as a result of higher cash balances and interest rates in 2004. Interest expense decreased 77% to \$442 in the three months ended December 31, 2004 from \$1,884 during the same period in 2003, reflecting the pay-off of shareholder notes in December 2003.

Our net loss increased 101% to \$1,259,016 during the three months ended December 31, 2004 from \$627,471 in the same period in 2003. The increase in our net loss was principally caused by the hiring of additional personnel, expensing of stock option compensation, increased fees paid to outside professionals, increased use of supplies and higher facility costs.

#### FOR THE YEARS ENDED DECEMBER 31, 2004 AND 2003

We had revenues of \$196,210 in the year ended December 31, 2004 and no revenues in 2003. This is a result of having a two Small Business Innovation Research Grants for our Mutacin 1140 and IVIAT technologies in 2004. Our operating expenses increased 99% to \$3,320,962 in the year ended December 31, 2004 from \$1,667,951 in 2003. Research and development expenses increased 114% to \$1,990,979 in 2004 from \$929,355 in 2003, reflecting the hiring of research personnel, increased consumption of laboratory supplies and the costs associated with preparing for human clinical trials. General and administration expenses increased 80% to \$1,329,983 in 2004 from \$738,596 in 2003, reflecting the hiring of personnel, the hiring of outside professionals for investor and public relations, costs associated with public entity filings and increased coverage in directors' and officers' liability insurance.

Interest income increased 501% to \$47,306 in the year ended December 31, 2004 from \$7,874 in 2003, which was a result of the higher interest rates and higher average cash balances maintained in 2004 due to the exercise of Series A and Series B common stock warrants in December 2003 and March 2004, respectively. Interest expense decreased 97% to \$442 in the year ended December 31, 2004 from \$12,877 in 2003 as a result of the pay-off of shareholder notes in December 2003.

Our net loss increased 84% to \$3,077,888 in the year ended December 31, 2004 from \$1,672,954 in 2003. The increase in our net loss was principally caused by the hiring of additional personnel, increased fees paid to outside professionals for clinical trial preparation and public entity filings, and the increased use of supplies.

#### LIQUIDITY AND CAPITAL RESOURCES

Our operating activities used cash of \$2,745,243 for the twelve months ended December 31, 2004 and \$1,218,910 for the twelve months ended December 31, 2003. Our working capital was \$3,345,512 as of December 31, 2004. Cash used by operations in the twelve months ended December 31, 2004 resulted primarily from operating losses from operations of \$3,077,888.

Our investing activities used cash of \$690,548 for the twelve months ended December 31, 2004 for the acquisition of property and equipment.

Our financing activities provided \$3,518,278 in cash for the twelve months ended December 31, 2004, which consists primarily of \$3,035,788 in proceeds from exercised warrants. On November 30, we issued a total of 250,000 shares of our common stock and warrants to purchase 125,000 shares of our common stock pursuant to a subscription agreement between us and three investors. We received gross proceeds of \$687,500, and incurred offering costs of approximately \$142,500 resulting in net proceeds of approximately \$545,000. Westminster Securities Corp., a member of the National Association of Securities Dealers, Inc. and a registered broker-dealer, acted as the placement agent in connection with this private placement transaction. The private placement agreement and offering was terminated by mutual assent of the Company and the placement agent because a sufficient level of funding was not being achieved. Each warrant is exercisable on or before November 30, 2008 to acquire one share of common stock at a price of \$3.50 per share. The issuance of the shares of common stock and warrants was made pursuant to the exemption from registration provided by Section 4(2) of the Securities Act. Each investor is accredited

under the Securities Act and the securities were sold without any general solicitation. As the placement agent, Westminster received (i) \$35,000 (ii) commission of 8% on the gross proceeds to us, and (iii) a warrant to purchase 25,000 shares of common stock at a purchase price of \$2.75 per share and a warrant to purchase 12,500 shares of common stock at 3.50. In addition to Westminster's fee and commission, we incurred further expenses in connection with the offering of approximately \$52,500. We anticipate that direct costs in 2005 associated with preparing for and conducting clinical testing on our replacement therapy technology will be approximately \$1,700,000. Such costs are expected to consist of approximately \$875,000 for manufacturing clinical materials, \$475,000 for conducting the clinical trials and \$350,000 for employee salaries, fringe benefits, supplies and other related direct costs. We also anticipate spending approximately \$525,000 performing animal studies on our mutacin 1140 technology. Such costs are expected to consist of approximately \$175,000 for contract research, \$200,000 for employee salaries and fringe benefits and \$150,000 for laboratory supplies and other related direct costs.

We anticipate that our capital expenditures in 2005 will be less than \$700,000 for the acquisition of laboratory and business equipment. This amount is subject to change, however, depending upon the nature and the amount of the development of our technologies and capital raising efforts. On February 24, 2005, we entered into a Business Loan Agreement with a bank that will fund approximately \$615,000 of laboratory equipment purchases. The loan has a term of 37 months with the first month payment of interest only and the remaining monthly payments of principal and interest of approximately \$18,900 per month. Interest will be calculated at the prime rate as published in the Wall Street Journal (currently 5.5%) plus 1.00%. Interest can never be below 5.75% or above 17.5%. The loan is collateralized by the equipment being purchased, as well as all equipment currently owned by us.

Our business is based on commercializing entirely new and unique technologies, and our current business plan contains a variety of assumptions and expectations that are subject to uncertainty, including assumptions and expectations about manufacturing capabilities, clinical testing cost and pricing, continuing technology improvements, strategic licensing relationships and other relevant matters. These assumptions take into account recent financings, as well as expected but currently unidentified additional financings. We have experienced losses from continuing operations during the last two fiscal years and have an accumulated deficit of \$5,471,984 as of December 31, 2004. Cash used in continuing operations for the years ended December 31, 2004 and December 31, 2003 was \$2,745,243 and \$1,218,910, respectively, and cash flow from continuing operations was negative throughout 2004. At December 31, 2004, our principal source of liquidity was \$3,666,244 of cash and cash equivalents. These operating results occurred while we are developing and attempting to commercialize and manufacture products from entirely new and unique technologies. Our business plan requires significant spending related to start-up costs and clinical testing expenditures. These

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

Our capital requirements during the next twelve months will depend on numerous factors, including the success of our research and development, the resources we devote to develop and support our technologies, and the success of pursuing strategic licensing and funded product development relationships with external partners. We expect to incur substantial expenditures to further develop each of our technologies including continued increases in personnel and costs related to research, preclinical testing and clinical studies, as well as significant costs associated with being a public company. We believe our working capital at December 31, 2004 will not be sufficient to meet our business objectives as presently structured beyond September 2005. We will require substantial funds to conduct research and development and preclinical and Phase I clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase II and III clinical testing and manufacture and marketing of any products that are approved for commercial sale. We recognize that we must generate additional capital resources or consider modifications to our technology development plans to enable us to continue as a going concern. Our plans include seeking financing, alliances or other partnership agreements with entities interested in our technologies, or other

business transactions that would generate sufficient resources to assure continuation of our operations and research and development programs.

We intend to seek additional funding through sublicensing arrangements, joint venturing or partnering, sales of rights to technology, government grants and through public or private financings. During 2004, we conducted a private placement to raise capital. In February 2005, we entered into an agreement with an investment advisory firm to assist us in raising additional capital by acting as a financial advisor and placement agent. There can be no assurance that additional financing will be available to us on acceptable terms, or at all. Our future success depends on our ability to raise capital and ultimately generate revenue and attain profitability. We cannot be certain that additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to us or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current stockholders may experience dilution. If we are unable to obtain funds when needed or on acceptable terms, we may be required to curtail our current development programs, cut operating costs and forego future development and other opportunities. Without sufficient capital to fund our operations, we will be unable to continue as a going concern.

## RISK FACTORS

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

### RISKS ASSOCIATED WITH OUR COMPANY

WE 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. OUR INDEPENDENT REGISTERED CERTIFIED PUBLIC ACCOUNTANTS HAVE EXPRESSED SUBSTANTIAL DOUBT AS TO OUR ABILITY TO CONTINUE AS A GOING CONCERN. WE MUST CONTINUE TO RAISE MONEY FROM INVESTORS AND SEEK PARTNERS AND/OR SUB-LICENSORS 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 \$5,465,000 through December 31, 2004. Since inception, we have substantially funded our operations from the public and private sales of our securities. 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. At December 31, 2004 we had approximately \$3,346,000 in available working capital and our budgeted expenditures for 2005 currently exceed our available working capital. We believe, absent any additional funds, our existing cash will be sufficient to enable us to continue in operation until September 2005. Thereafter, we anticipate that we will need additional financing to continue our operations. There is no assurance that such capital will be available to us or, if available, will 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. In addition, if adequate funds are not available we may be required to delay, scale back or eliminate the development of one or more of our products which could harm 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. We will be unable to continue as a going concern without sufficient capital to fund our operations.

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 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

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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 WE ARE UNABLE TO MAINTAIN REGULATORY CLEARANCE OR OBTAIN APPROVAL FOR OUR TECHNOLOGIES, WE WILL BE UNABLE TO GENERATE REVENUES AND MAY HAVE TO CEASE OPERATIONS.

Only our replacement therapy technology has been granted clearance to begin Phase 1 human clinical trials by the FDA. Clinical trials on our replacement therapy are expected to take 4-5 years to fully complete. Our other technologies have not been cleared for testing in humans. Our technologies have not been cleared for marketing by the FDA or foreign regulatory authorities and they will not be able to be commercially distributed in the United States or any international markets until such clearances are obtained. Before regulatory approvals can be obtained, our 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. If we are unable to resolve the FDA's concerns, we will not be able to proceed further to obtain regulatory approval for that technology. If we fail to maintain regulatory clearance for our replacement therapy or fail to obtain FDA clearance for our other 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 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 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 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 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.

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WE RELY ON THE SIGNIFICANT EXPERIENCE AND SPECIALIZED EXPERTISE OF OUR SENIOR MANAGEMENT AND MUST RETAIN AND ATTRACT QUALIFIED SCIENTISTS AND OTHER HIGHLY SKILLED PERSONNEL IN A HIGHLY COMPETITIVE JOB ENVIRONMENT TO MAINTAIN AND GROW OUR BUSINESS.

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

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

IT IS POSSIBLE THAT OUR REPLACEMENT THERAPY AND ORAL PROBIOTIC TECHNOLOGIES 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 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 to find such a method, we will be unable to generate revenues from this technology and we may have to cease operations.

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

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

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

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

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

WE INTEND TO CONSIDER RELYING ON THIRD PARTIES TO PAY THE MAJORITY OF COSTS RELATING TO REGULATORY APPROVALS NECESSARY TO MANUFACTURE AND SELL PRODUCTS USING OUR TECHNOLOGIES. IF WE ARE UNABLE TO OBTAIN AGREEMENTS WITH THIRD PARTIES TO FUND SUCH COSTS, WE WILL HAVE TO FUND THE COSTS OURSELVES. WE MAY BE UNABLE TO DO SO, AND IF WE ARE NOT, WE MAY HAVE TO CEASE OPERATIONS.

We intend to consider sublicensing our technologies to strategic partners prior to commercialization. If we do so, our 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

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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. Our management 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 United States. In the United States more stringent FDA oversight in product clearance and enforcement activities could result in our experiencing longer approval cycles, more uncertainty, greater risk, and higher expenses. Even if regulatory approval of a product is granted, this approval may entail limitations on uses for which the product may be labeled and promoted. It is possible, for example, that we may not receive FDA approval to market products based on our licensed, patented technologies for broader or different applications or to market updated

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

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

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

WE CAN OFFER YOU NO ASSURANCE THE GOVERNMENT AND THE PUBLIC WILL ACCEPT OUR LICENSED PATENTED TECHNOLOGIES. IF THEY DO NOT, WE WILL BE UNABLE TO GENERATE SUFFICIENT REVENUES FROM OUR TECHNOLOGIES, WHICH MAY CAUSE US TO CEASE OPERATIONS.

The commercial success of our 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 MARKETING 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, IT COULD LIMIT OUR REVENUE.

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

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:

- 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 escrow 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 December

31, 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 December 31, 2004, there were 14,594,924 shares of our common stock outstanding, with another 276,180 shares of common stock issuable upon exercise of our underwriter warrants, 1,070,000 shares issuable upon exercise of options issued and an additional 430,000 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 and may be resold into the market. We had approximately 3,960,317 shares of common stock held in escrow pursuant to Canadian law and underwriter requirements in connection with our initial public offering pursuant to escrow agreements. 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 3,690,344 are held by principals of the Company and 269,973 are held by the University of Florida Research Foundation, Inc. Through December 31, 2004, approximately 4,510,421 shares held by principals (including a former director) and 329,967 shares held by the University of Florida Research Foundation, Inc. were released from escrow. The released shares held by the principals (excluding the former director) may now be resold into the market under Rule 144. This could cause the market price of our common stock to drop significantly. The shares held by the University of Florida Research Foundation, Inc. are 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 de-listed 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 shareholders 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.

#### WE MUST MAINTAIN A CURRENT PROSPECTUS AND REGISTRATION STATEMENT IN CONNECTION WITH SHARES AND WARRANTS ISSUED IN CONNECTION WITH OUR PRIVATE PLACEMENT.

We may need to meet state registration requirements for sales of securities in states where an exemption from registration is not otherwise available. There are currently 276,180 shares of common stock issuable upon exercise of the underwriter warrants at \$1.25 per share that were issued in connection with our initial public offering and expire on June 24, 2005. In addition, there are 162,500 shares of common stock issuable upon exercise of warrants issued in connection with our private placement, 25,000 at an exercise price of \$2.75 and 137,500 at an exercise price of \$3.50 expiring November 30, 2008. We are obligated to maintain an effective registration statement in connection with the resale of shares issued and acquired upon exercise of warrants issued in connection with our private placement. It is possible that we may be unable to cause a registration statement covering the common stock underlying these shares and shares issuable upon exercise of the warrants to be

effective or to maintain the effectiveness of such registration. There can be no assurance that we will be able to maintain an effective registration statement relating to the resale of our common stock. If we are unable to maintain an effective registration for the resale of common stock issued in connection with our private placement and upon exercise of the warrants, we may be subject to

claims by the holders of such shares and warrants.

WE HAVE LIMITED RESOURCES WHICH EXPOSES US TO POTENTIAL RISKS RESULTING FROM NEW INTERNAL CONTROL REQUIREMENTS UNDER SECTION 404 OF THE SARBANES-OXLEY ACT OF 2002.

We are evaluating our internal controls in order to allow management to report on, and our independent registered certified public accounting firm to attest to, our internal controls, as required by Section 404 of the Sarbanes-Oxley Act of 2002. We may encounter unexpected delays in implementing the requirements relating to internal controls, therefore, we cannot be certain about the timing of completion of our evaluation, testing and remediation actions or the impact that these activities will have on our operations since there is no precedent available by which to measure the adequacy of our compliance. We also expect to incur additional expenses and diversion of management's time as a result of performing the system and process evaluation, testing and remediation required in order to comply with the management certification and auditor attestation requirements. We are a small company with limited resources that will make it difficult for us to timely comply with the requirements of Section 404. If we are not able to timely comply with the requirements set forth in Section 404, we might be subject to sanctions or investigation by regulatory authorities. Any such action could adversely affect our business and financial results. The requirement to comply with Section 404 of the Sarbanes-Oxley Act of 2002 will become effective for our fiscal year ending December 31, 2006.

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

#### 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, 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.

Incorporated by reference to pages F-1 to F-17 at the end of this report.

#### ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

#### ITEM 8A. CONTROLS AND PROCEDURES.

##### EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES

Within 90 days prior to the date of this report, we carried out an evaluation (the "Evaluation"), under the supervision and with the participation of our President and Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), of the effectiveness of the design and operation of our disclosure controls and procedures ("Disclosure Controls"). Based on the Evaluation, our CEO and CFO concluded that, subject to the limitations noted below, our Disclosure Controls are effective in timely alerting them to material information required to be included in our periodic SEC reports.

##### CHANGES IN INTERNAL CONTROLS

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

##### LIMITATIONS ON THE EFFECTIVENESS OF CONTROLS

Our management, including our CEO and CFO, does not expect that our Disclosure Controls and internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management or board override of the control.

The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

##### CEO AND CFO CERTIFICATIONS

Appearing immediately following the Signatures section of this report there are Certifications of the CEO and the CFO. The Certifications are required in accordance with Section 302 of the Sarbanes-Oxley Act of 2002 (the Section 302 Certifications). This Item of this report, which you are currently reading is the information concerning the Evaluation referred to in the Section 302 Certifications and this information should be read in conjunction with the Section 302 Certifications for a more complete understanding of the topics presented.

#### ITEM 8B. OTHER INFORMATION.

None.

Certain information required by Part III is omitted from this Report in that we expect to file a definitive proxy statement with the Securities and Exchange Commission (the "Commission") within 120 days after the end of its fiscal year pursuant to Regulation 14A, as promulgated by the Commission, for our 2005 annual meeting of shareholders (the "Proxy Statement"), and certain information included in the Proxy Statement will be incorporated herein by reference.

#### ITEM 9. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

The information required by this Item 9 with respect to identification of our directors will be included under the captions "Proposal I Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" is incorporated herein by reference to our Proxy Statement. We have adopted a Code of Business Conduct and Ethics (the "Code") that applies to all of our Directors, officers and employees, including our principal executive officer and principal financial officer. The Code is posted on our website at [www.oragenics.com](http://www.oragenics.com). We intend to disclose any amendments to the Code by posting such amendments on our website. In addition, any waivers of the Code for Directors or executive officers of the Company will be disclosed in a report on Form 8-K.

#### ITEM 10. EXECUTIVE COMPENSATION.

The information required by this Item 10 with respect to management remuneration and transactions is incorporated herein by reference to our Proxy Statement under the heading "Executive Compensation."

#### ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.

The information required by this Item 11 with respect to the security ownership of certain beneficial owners and management is incorporated herein by reference to our Proxy Statement under the heading "Security Ownership of Certain Beneficial Owners and Management."

#### ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

The information required by this Item 12 with respect to transactions between us and certain related entities is incorporated herein by reference to our Proxy Statement under the heading "Certain Relationships and Related Transactions."

#### ITEM 13. EXHIBITS AND REPORTS ON FORM 8-K.

##### (a) Exhibits.

Incorporated by reference to the Exhibit Index immediately following the signature page.

##### (b) Reports on Form 8-K:

We filed Form 8-K's on October 7, 2004, October 13, 2004, November 30, 2004 and December 1, 2004, relating to (i) our de-listing from the TSX Venture Exchange; (ii) our presentation at the Rodman and Renshaw Techvest 6th Annual Healthcare Conference; (iii) FDA lifting its clinical hold for our technology for the prevention of dental caries; and, (iv) the closing on a private financing raising \$687,500 and the disclosure of financial estimates used in the financing document.

#### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information required by this Item 14 is incorporated herein by reference to our Proxy Statement under the heading "Principal Accountant Fees and Services."

Oragenics, Inc.

Financial Statements

Years ended December 31, 2004 and 2003

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Report of Independent Registered Certified Public Accounting Firm on Financial  
Statements

The Board of Directors and Shareholders of  
Oragenics, Inc.

We have audited the accompanying balance sheet of Oragenics, Inc. as of December 31, 2004, and the related statements of operations, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Oragenics, Inc. at December 31, 2004, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2004, in conformity with accounting principles generally accepted in the United States.

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

January 28, 2005 except for Note 11, as to  
which the date is February 24, 2005

Tampa, Florida

Certified Public Accountants

## Oragenics, Inc.

Balance Sheet  
December 31, 2004

## ASSETS

## Current assets:

Cash and cash equivalents	\$ 3,666,244
Prepaid expenses and other current assets	108,895

Total current assets 3,775,139

Property and equipment, net 690,932

Total assets \$ 4,466,071

## LIABILITIES AND STOCKHOLDERS' EQUITY

## Current liabilities:

Accounts payable and accrued expenses	\$ 429,627
---------------------------------------	------------

Total current liabilities 429,627

## Stockholders' equity:

Preferred stock, no par value; 20,000,000 shares authorized; none issued and outstanding	--
Common stock, \$0.001 par value; 100,000,000 shares authorized; 14,594,924 shares issued and outstanding	14,595
Additional paid in capital	9,493,833
Accumulated deficit	(5,471,984)

Total stockholders' equity 4,036,444

Total liabilities and stockholders' equity \$ 4,466,071

See accompanying notes.

## Oragenics, Inc.

## Statements of Operations

&lt;TABLE&gt;

&lt;CAPTION&gt;

	YEAR ENDED DECEMBER 31	
	2004	2003
	-----	
	<C>	<C>
<S>		
Revenue	\$ 196,210	\$ --
Operating expenses:		
Research and development	1,990,979	929,355
General and administration	1,329,983	738,596
	-----	
Total operating expenses	3,320,962	1,667,951
	-----	
Loss from operations	(3,124,752)	(1,667,951)
Other income (expense):		
Interest income	47,306	7,874
Interest expense	(442)	(12,877)

Total other income (expense), net	46,864	(5,003)
Loss before income taxes	(3,077,888)	(1,672,954)
Income tax benefit	--	--
Net loss	\$ (3,077,888)	\$ (1,672,954)
Basic and diluted net loss per share	\$ (0.22)	\$ (0.15)
Shares used to compute basic and diluted net loss per share	14,118,129	10,814,198

</TABLE>

See accompanying notes.

F-4

Oragenics, Inc.

# Statements of Changes in Stockholders' Equity (Deficit)

<TABLE>

<CAPTION>

	COMMON STOCK		ADDITIONAL PAID IN CAPITAL		TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	
	SHARES	AMOUNT		DEFICIT		
<S>	<C>	<C>	<C>	<C>	<C>	
Balance at December 31, 2002		9,425,704	\$ 9,426	\$ 628,234	\$ (721,142)	\$ (83,482)
Issuance of common stock and warrants		2,500,000	2,500	2,280,112	--	2,282,612
Exercise of common stock warrants		1,370,500	1,370	2,628,817	--	2,630,187
Compensation expense relating to option issuances	--	--	283,534	--	283,534	
Net loss	--	--	--	(1,672,954)	(1,672,954)	
Balance at December 31, 2003		13,296,204	13,296	5,820,697	(2,394,096)	3,439,897
Exercise of common stock warrants		1,048,720	1,049	3,034,724	--	3,035,773
Costs associated with filing initial public offering post effective amendment	--	--	(62,421)	--	(62,421)	
Issuance of common stock and warrants		250,000	250	544,676	--	544,926
Compensation expense relating to option issuances	--	--	156,157	--	156,157	
Net loss	--	--	--	(3,077,888)	(3,077,888)	
Balance at December 31, 2004		14,594,924	\$ 14,595	\$ 9,493,833	\$(5,471,984)	\$ 4,036,444

</TABLE>

See accompanying notes.

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Oragenics, Inc.

# Statements of Cash Flows

<TABLE>

<CAPTION>

	YEAR ENDED DECEMBER 31	
	2004	2003
	<C>	<C>

## OPERATING ACTIVITIES

Net loss	\$(3,077,888)	\$(1,672,954)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	41,987	12,545
Non-cash issuance of common stock and common stock options	--	54,000
Stock-based compensation expense	156,157	229,534
Changes in operating assets and liabilities:		
Costs associated with initial public offering	--	271,937
Prepaid expenses and other current assets	(84,258)	(15,896)
Accounts payable and accrued expenses	289,013	(92,197)
Accrued interest	(25,582)	8,120
Deferred compensation	(44,672)	(13,999)
Net cash used in operating activities	(2,745,243)	(1,218,910)

## INVESTING ACTIVITY

Purchases of property and equipment	(690,548)	(50,258)
Net cash used in investing activity	(690,548)	(50,258)

## FINANCING ACTIVITIES

Proceeds from notes payable to stockholders	--	175,000
Payment of notes payable to stockholders	--	(260,454)
Net proceeds from issuance of common stock	3,518,278	4,912,799
Net cash provided by financing activities	3,518,278	4,827,345

Net increase in cash and cash equivalents	82,487	3,558,177
Cash and cash equivalents at beginning of year	3,583,757	25,580
Cash and cash equivalents at end of year	\$ 3,666,244	\$ 3,583,757

## SUPPLEMENTAL DISCLOSURE OF NON-CASH FINANCING ACTIVITIES

Common stock and common stock options issued in connection with investment bank and related financing services	\$ --	\$ 54,000
--	-------	-----------

## SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Interest paid	\$ 26,024	\$ 4,757
---------------	-----------	----------

</TABLE>

See accompanying notes.

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Oragenics, Inc.

Notes to Financial Statements

December 31, 2004

## 1. ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES

Oragenics, Inc. is dedicated to developing technologies associated with oral health, broad spectrum antibiotics and other general health benefits. The Company has licensed two unique technologies from the University of Florida: replacement therapy for the prevention of tooth decay and mutacin 1140, a novel antibiotic. The Company has also developed a probiotics technology to provide protection against the causative organisms of periodontal disease and has licensed two related platform technologies that enable the simple, fast identification of gene targets associated with the natural onset and progression of infections, cancers and other diseases.

## BASIS OF PRESENTATION

The financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States including the assumption of a going concern basis which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company incurred a net loss of \$3,077,888 for the year ended December 31, 2004 and as of that date had an accumulated deficit of \$5,471,984. Cash used in operations for the years ended December 31, 2004 and December 31, 2003 was \$2,745,243 and \$1,218,910, respectively, and cash flow from operations was negative throughout 2004. The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes the working capital at December 31, 2004 will be insufficient to meet the business objectives as presently structured. Management recognizes that the Company must generate additional capital resources or consider modifications to its technology development plans to enable it to continue as a going concern. Management's plans include seeking financing, alliances or other partnership agreements with entities interested in the Company's technologies, or other business transactions that would generate sufficient resources to assure continuation of the Company's operations and research and development programs.

The Company intends to seek additional funding through sublicensing arrangements, joint venturing or partnering, sales of rights to technology, government grants and public or private financings. During 2004 the Company conducted a private placement to raise capital. During 2005 the Company expects to raise additional capital through selling additional debt or equity securities on terms acceptable to the Company. There can be no assurance that additional financing will be available to the Company on acceptable terms, or at all. The Company's future success depends on its ability to raise capital and ultimately generate revenue and attain profitability. The Company cannot be certain that additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to it or, if available, will be on terms acceptable to the Company. If the Company issues additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of its common stock, and the Company's current stockholders may experience dilution. If the Company is unable to obtain funds when needed or on acceptable terms, the Company may be required to curtail their current development programs, cut operating costs and forego future development and other opportunities. Without sufficient capital to fund their operations, the Company will be unable to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

#### CONCENTRATIONS OF CREDIT RISK

The Company's cash and cash equivalents are deposited in two financial institutions and consist of demand deposits and overnight repurchase agreement investments.

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Oragenics, Inc.

Notes to Financial Statements (continued)

#### 1. ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

##### USE OF ESTIMATES

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

##### FAIR VALUE OF FINANCIAL INSTRUMENTS

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

## CASH EQUIVALENTS

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

## PROPERTY AND EQUIPMENT

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

## BUSINESS SEGMENTS

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

## STOCK-BASED COMPENSATION

The Company has a stock-based employee compensation plan, which is described more fully in Note 5. The Company accounts for the plan under the recognition and measurement principles of APB Opinion No. 25, Accounting for Stock Issued to Employees, and related Interpretations. The following table illustrates the effect on net loss per share if the Company had applied the fair value recognition provisions of SFAS No. 123, Accounting for Stock-Based Compensation, to stock-based employee compensation.

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Oragenics, Inc.

Notes to Financial Statements (continued)

## 1. ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

<TABLE>

<CAPTION>

	YEARS ENDED DECEMBER 31	
	2004	2003
<hr/>		
<S>	<C>	<C>
Net loss, as reported	\$ (3,077,888)	\$ (1,672,954)
Add: Total stock-based employee compensation expense reported in net loss	156,157	229,534
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(152,545)	(44,371)
	<hr/>	<hr/>
Pro forma net loss	\$ (3,074,276)	\$ (1,487,791)
	<hr/>	<hr/>
Loss per share:		
Basic and diluted - as reported	\$(0.22)	\$(0.15)
Basic and diluted - pro forma	\$(0.22)	\$(0.14)
Shares used to compute basic and diluted net loss per share	14,118,129	10,814,198

</TABLE>

## NET LOSS PER SHARE

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

amounts are the same for the periods presented.

#### REVENUE RECOGNITION

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

#### IMPAIRMENT OF LONG-LIVED ASSETS

The Company reviews their long-lived assets for impairment and reduces the carrying value to fair value whenever events or changes in circumstances indicate that the carrying value may not be recoverable. There were no impairment losses recorded during the years ended December 31, 2004 and 2003.

#### RESEARCH AND DEVELOPMENT EXPENSES

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

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Oragenics, Inc.

Notes to Financial Statements (continued)

### 1. ORGANIZATION AND SIGNIFICANT ACCOUNTING POLICIES (CONTINUED)

#### INCOME TAXES

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

#### RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123 (revised 2004) "Share Based Payment" ("FAS 123(R)", which is a revision of FASB Statement No. 123 "Accounting for Stock Based Compensation" ("Statement 123"). This statement supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees" ("Opinion 25") which allowed companies to use the intrinsic value method of valuing share-based payment transactions and amends FAS Statement No. 95, "Statement of Cash Flows". FAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. The Company expects to adopt Statement 123 (R) on January 1, 2006.

FAS 123(R) permits public companies to adopt its requirements using one of two methods. A "modified prospective" method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of FAS 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees prior to the effective date of FAS 123(R) that remain unvested on the effective date. A "modified retrospective" method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under Statement 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption. The Company will determine which method to adopt prior to the effective date of FAS 123(R).

The impact of adoption of FAS 123(R) cannot be accurately predicted at this time

since it will depend on levels of share-based payments granted in the future. However, had the Company adopted FAS 123(R) in prior periods, the impact of the standard would have approximated the impact of FAS 123 as described in the disclosure of pro forma net loss and loss per share in Note 1 to the financial statements. Statement 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. While the Company cannot estimate what those amounts will be in the future (because they depend on, among other things, when employees exercise stock options), there were no amounts of operating cash flows recognized in prior periods for such excess tax deductions in 2003 and 2004.

As permitted by Statement 123, the Company currently accounts for share-based payments using Opinion 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options.

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Oragenics, Inc.

Notes to Financial Statements (continued)

## 2. PROPERTY AND EQUIPMENT

Property and equipment consists of the following as of December 31, 2004:

Leasehold improvements	\$ 469,327
Laboratory equipment	226,070
Office and computer equipment	54,127
	-----
	749,524
Accumulated depreciation	(58,592)
	-----
	<u>\$ 690,932</u>
	=====

Depreciation expense for 2004 and 2003 was \$41,987 and \$12,545, respectively.

## 3. OBLIGATIONS TO STOCKHOLDERS

The Company issued promissory notes for cash to two stockholders in the amounts of \$69,604 and \$15,000 in 2001 and 1999, respectively. These notes were payable upon demand and accrued interest at 7% per year. The principal portion of the notes was repaid in December 2003 and related accrued interest totaling \$18,452 was paid in January 2004.

In 2003, the Company issued two demand promissory notes to a stockholder in the amounts of \$100,000 and \$75,000 bearing interest at 10% per annum. Both notes and interest totaling \$4,757 were repaid in June 2003.

At December 31, 2004 and 2003, \$75,000 was owed and included in accounts payable and accrued expenses for consulting services provided by a stockholder of the Company in prior years. In January 2005, \$20,000 was paid on this obligation. No interest is being accrued on this outstanding debt.

## 4. DEFERRED COMPENSATION

During 2000, the Company entered into a two-year employment agreement with an officer and shareholder. The agreement provided for the deferral of compensation until a certain level of investment funding was received and required the Company to accrue interest on the deferred balance at 7% per year. Beginning July 1, 2001, the agreement was amended whereby the deferral of compensation ceased. No compensation expense was recognized in 2004 or 2003 and interest expense relating to the employment agreement for the years ended December 31, 2004 and 2003 was \$0 and \$2,409, respectively. In January 2004, payments totaling \$41,539 were made in settlement of this obligation.

Between December 2002 and June 2003, compensation payments totaling \$149,263 to three officers of the Company were deferred due to limited cash flow of the Company. As of December 31, 2003, payments of \$139,000 were made and the balance of \$10,263 was paid in January 2004. There was no provision to pay interest on these deferred compensation payments.

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Oragenics, Inc.

Notes to Financial Statements (continued)

## 5. STOCKHOLDERS' EQUITY

### COMMON STOCK

On June 24, 2003, the Company completed the filing of 2,400,000 units at \$1.25 per unit as an initial public offering (IPO) for gross proceeds of \$3,000,000. Each unit consisted of one share of the Company's common stock, one-half Series A Common Share Purchase Warrant and one-half Series B Common Share Purchase Warrant. One whole Series A warrant allowed the holder to purchase a share of the Company's stock at \$2.00 per share until December 24, 2003. All Series A warrants were exercised before the expiration date providing proceeds to the Company of \$2,400,000. One whole Series B warrant allowed the holder to purchase a share of the Company's stock at \$3.00 per share until March 24, 2004. A total of 995,400 Series B warrants were exercised on or before March 24, 2004 providing proceeds of \$2,986,200 and the remaining 204,600 Series B warrants expired unexercised on March 24, 2004. In addition to receiving a cash commission for each share sold, the underwriting agent for the IPO received 100,000 shares of common stock of the Company and warrants to purchase 500,000 shares of common stock of the Company at \$1.25 per share until June 24, 2005. As of December 31, 2004, 223,820 underwriter warrants were exercised providing proceeds to the Company of \$279,775. The cost of the IPO, including the filing of a post effective amended registration statement in October 2004, was \$779,809 including the agent's commission.

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

### STOCK COMPENSATION PLAN

The Company's 2002 Stock Option and Incentive Plan (the Plan) was adopted by the Board of Directors (the Board). The purpose is to advance the interests of the Company by affording certain employees and directors of the Company and key consultants and advisors an opportunity to acquire or increase their proprietary interests in the Company. The Plan authorizes the grant of stock options (incentive and non-statutory), stock appreciation rights and restricted stock. As of December 31, 2004, the Company had not awarded stock appreciation rights or restricted stock under the Plan. The Company has reserved an aggregate of 1,500,000 shares of common stock for grants under the Plan, of which 430,000 shares are available for future grants as of December 31, 2004. The exercise price of each option shall be determined by the Board and an option's maximum term is five years.

In September 2002, the Company issued 195,000 options that were re-priced upon the change in the initial public offering price. As a result, these options were subjected to variable accounting treatment. In accordance with Financial Accounting Standards Board Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation (FIN 44), stock options must be accounted for as variable under such circumstances. Variable accounting requires companies to re-measure compensation costs for the variable options until the options are exercised, cancelled, or forfeited without replacement. Compensation is dependent on fluctuations in the quoted stock prices for the Company's common stock. Such compensation costs will be recognized over a three-year vesting schedule until the options are fully vested, exercised, cancelled, or forfeited, after which time the compensation will be recognized immediately at each

reporting period. During 2004 and 2003, the Company recognized compensation expense of \$156,157 and \$229,534, respectively.

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Oragenics, Inc.

Notes to Financial Statements (continued)

## 5. STOCKHOLDERS' EQUITY (CONTINUED)

A summary of the status of the Company's outstanding stock options, including employee stock options discussed above, as of December 31, 2004 and 2003 and changes during the periods ending on those dates is presented below:

		WEIGHTED AVERAGE OPTION PRICE	EXERCISE PRICE	
OPTIONS	PER SHARE			
-----				
Outstanding at January 1, 2003	315,000	\$ 1.25	\$ 1.25	
Granted	285,000	\$ 2.65 - 4.00	\$ 3.29	
-----				
Outstanding at December 31, 2003	600,000	1.25 - 4.00	2.22	
Forfeited	(20,000)	2.65	2.65	
Granted	175,000	3.30 - 4.25	3.83	
Granted	315,000	2.25 - 2.65	2.38	
-----				
Outstanding at December 31, 2004	1,070,000	1.25 - 4.25	\$ 2.52	
=====				
Exercisable at end of year	246,667	\$ 1.25 - 4.00	\$ 1.89	
=====				

The range of exercise price is \$1.25 to \$4.25 per share. The weighted-average per option fair value of options granted during 2004 and 2003 was \$1.48 and \$1.26, respectively, and the weighted average remaining contractual life of those options is 4.3 years. Options vest over a period of three to four years from respective grant dates and the options expire 5 years after the date of grant. The fair value of these options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions: weighted average risk-free interest rate of 1.00-2.87%; dividend yields of 0%; weighted-average volatility factors of the expected market price of the Company's common stock of 55%; and an expected life of the option of four years.

## 6. LICENSES

The Company has two license agreements with the University of Florida Research Foundation, Inc. ("UFRF") for their technologies. The Company issued 599,940 shares of common stock as partial consideration. The license agreements provide for, among other things, the Company to make minimum annual research expenditures of \$600,000 in 2003 and \$1,000,000 thereafter, to adhere to specific milestones and pay royalties on product sales, which beginning December 31, 2005 will be a minimum of \$50,000 annually per agreement. The agreement also required the Company to pay \$100,000 to UFRF as reimbursement for patent filing costs upon the closing of any financing in excess of \$1,000,000. If the Company fails to perform certain of its obligations, UFRF may terminate the license agreements. Upon completion of the initial public offering in June 2003, the Company paid UFRF \$100,000.

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Oragenics, Inc.

## 6. LICENSES (CONTINUED)

In March 2004, the Company licensed from iviGene Corporation, a company whose major shareholders also own a significant number of shares of the Company's common stock, applications of two novel technologies referred to as IVIAT and CMAT. Our license provides us with exclusive worldwide rights to this broad platform technology in the areas of cancer and tuberculosis, as well as agricultural and other non-human uses. In return, we will pay royalties on revenues we are able to generate from any products developed using the technology, including royalties on sublicense fees, milestone payments and future product sales. Under the terms of our license with iviGene we are not obligated to make any payments to iviGene until we have achieved certain milestone or royalty payments, however, we are required to spend up to \$200,000 annually on these technologies to maintain our license. To support the research for this technology in 2004, we received a Phase I Small Business Innovation Research Grant from the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) that paid to us \$96,210.

## 7. RETIREMENT PLAN

In January 2004, the Company established a defined contribution retirement plan, replacing the previous plan that had been established in 2001. The new plan covers all employees and provides for a Company match of up to 3% of all employee contributions to the plan. During 2004, employee contributions are limited to \$9,000 except for individuals 50 years or older for which the contribution limitation is \$10,500. Total matching contributions made by the Company in 2004 were \$28,315. There were no contributions made under the prior plan in 2003.

## 8. INCOME TAXES

At December 31, 2004, the Company had temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and their respective income tax bases, as measured by enacted state and federal tax rates, as follows:

Deferred tax assets:	
Net operating loss carryforward	\$ 1,833,321
Consulting services	28,223
Non qualified stock options	64,977
Tax credits	129,275
	-----
Total deferred tax assets	2,055,796
Less valuation allowance	(2,055,796)
	-----
Total net deferred taxes	\$ --
	=====

## 8. INCOME TAXES (CONTINUED)

The following is a reconciliation of tax computed at the statutory federal rate to the income tax benefit in the statements of operations for the years ended December 31, 2004 and 2003:

YEAR ENDED DECEMBER 31	
2004	2003
-----	-----

Income tax benefit computed at statutory federal rate of 34%	\$(1,046,482)	\$ (568,804)
State income tax benefits, net of federal expense/benefit	(111,727)	(60,728)
Change in valuation allowance	1,178,040	596,049
Non-deductible expenses	60,721	60,303
Research and development credit	(80,552)	(32,512)
Other	--	5,692
	-----	
Total	\$ --	\$ --
	=====	

SFAS No. 109, Accounting for Income Taxes, requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all of the evidence, both positive and negative, management has determined that a valuation allowance of \$2,055,796 at December 31, 2004 is necessary to reduce the deferred tax assets to the amount that will more likely than not be realized. The change in the valuation allowance for the year ended December 31, 2004 was \$1,178,040. At December 31, 2004, the Company has available net operating loss carryforwards of \$4,871,968 that begin to expire in 2022.

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

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Oragenics, Inc.

Notes to Financial Statements (continued)

## 9. COMMITMENTS AND CONTINGENCIES

The Company leased its laboratory and office space, as well certain equipment, under a 12-month cancelable operating lease with annual renewal options. Total rent expense under this lease was \$47,376 and \$33,583 for the years ended December 31, 2004 and 2003, respectively. The lease agreement ended in November 2004 when the Company moved into its new facility that is being leased from a real estate developer for a term of five years subject to renewal provisions. This operating lease agreement required the Company to pay a deposit of \$6,400 and provides for monthly lease payments of \$6,400, exclusive of utilities, insurance, sales taxes and real estate taxes. Total rent expense under this lease was \$10,184 for the year ended December 31, 2004.

In addition, the Company has entered into certain operating leases for office equipment. Future annual minimum payments under all noncancelable operating leases are approximately as follows:

Year ended:	
2005	\$ 84,200
2006	86,600
2007	88,600
2008	87,800
2009	82,600
Thereafter	--
	-----
	\$ 429,800
	=====

## 10. UNAUDITED QUARTERLY FINANCIAL INFORMATION

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

2004

	FIRST	SECOND	THIRD	FOURTH
Revenue .....	\$ --	\$ 44,235	\$ 118,642	\$ 33,333
Total operating expenses ..	544,461	723,202	745,561	1,307,738
Net loss .....	(537,440)	(667,662)	(613,770)	(1,259,016)

Loss per share:

Basic and Diluted ..... \$ 0.04 \$ 0.05 \$ 0.04 \$ 0.09

2003

	FIRST	SECOND	THIRD	FOURTH
Total operating expenses ..	\$ 207,899	\$ 432,440	\$ 398,426	\$ 629,186
Net loss .....	(211,442)	(437,319)	(396,722)	(627,471)

Loss per share:

Basic and Diluted ..... \$ 0.02 \$ 0.05 \$ 0.03 \$ 0.05

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Oragenics, Inc.

Notes to Financial Statements (continued)

# 11. SUBSEQUENT EVENT

On February 24, 2005, the Company entered into a Business Loan Agreement with a bank that will fund approximately \$615,000 of laboratory equipment purchases. The loan has a term of 37 months with the first month payment of interest only and the remaining monthly payments of principal and interest of approximately \$18,900 per month. Interest will be calculated at the prime rate as published in the Wall Street Journal (currently 5.5%) plus 1.00%. Interest can never be below 5.75% or above 17.5%. The loan is collateralized by the equipment being purchased, as well as all equipment currently owned by the Company.

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## SIGNATURES

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 11, 2005

ORAGENICS, INC.  
(Registrant)

By: /s/ Mento A. Sponis

-----  
Mento A. Sponis, Chief Executive  
Officer and President

By: /s/ Paul A. Hassie

-----  
Paul A. Hassie, Chief Financial Officer,  
Secretary and Treasurer (Principal  
Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE -----	TITLE -----	DATE ----
/s/ Mento A. Sponis ----- Mento A. Sponis	Chief Executive Officer and President	March 11, 2005
/s/ Paul A. Hassie ----- Paul A. Hassie	Chief Financial Officer	March 11, 2005
/s David J. Gury ----- David J. Gury	Chairman	March 11, 2005
/s/ Brian Anderson ----- Brian Anderson	Director	March 11, 2005
/s/ Jeffrey D. Hillman ----- Jeffrey D. Hillman	Director	March 11, 2005
/s/ Robert T. Zahradnik ----- Robert T. Zahradnik	Director	March 11, 2005

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# EXHIBIT INDEX

<TABLE>

<CAPTION>

## INCORPORATED BY REFERENCE

EXHIBIT NUMBER -----	EXHIBIT DESCRIPTION -----	FORM -----	FILING FILE NO -----	FILED EXHIBIT -----	DATE	HEREWITH
<S>	<C>	<C>	<C>	<C>		
3.1	Amended and Restated Articles of Incorporation	SB-2	333-100568	3.3	10/16/02	
3.2	Bylaws	SB-2	333-100568	3.2	10/16/02	
4.1	Specimen Stock Certificate	SB-2	333-100568	4.1	10/16/02	
4.2	Specimen initial public offering underwriter's warrant certificate	SB-2	333-100568	4.4	10/16/02	
4.3	Form of private placement warrant				X	
4.4	Form of private placement Subscription Agreement (including registration rights)				X	
10.1	License Agreement between the Company and the University of Florida Research Foundation, Inc. effective August 4, 1998 for Replacement Therapy for Dental Caries (the "Replacement Therapy License Agreement")	SB-2	333-100568	10.1	10/16/02	
10.2	First Amendment to Replacement Therapy License Agreement dated September 15, 2000	SB-2	333-100568	10.2	10/16/02	
10.3	Second Amendment to Replacement Therapy License Agreement dated June 2002	SB-2	333-100568	10.3	10/16/02	
10.4	Third Amendment to Replacement Therapy License Agreement dated September 25, 2002	SB-2	333-100568	10.4	10/16/02	
10.5	Fourth Amendment to Replacement Therapy License Agreement and Mutacin 1140 License Agreement dated March 2003	SB-2/A-3	333-100568	10.36	4/9/03	
10.6	License Agreement between the Company and the University of Florida Research Foundation, Inc. effective June 22, 2000 (the "Mutacin 1140 License Agreement")	SB-2	333-100568	10.5	10/16/02	
10.7	First Amendment to the Mutacin 1140 License	SB-2	333-100568	10.6	10/16/02	

Agreement dated September 15, 2000					
10.8	Second Amendment to the Mutacin 1140 License Agreement dated June 10, 2002	SB-2	333-100568	10.7	10/16/02
Third Amendment to the Mutacin 1140 License Agreement dated September 25, 2002					
10.10	Equity Agreement between the Company and the University of Florida Research Foundation dated August 4, 1998 (including registration rights)	SB-2/A-2	333-100568	10.8	2/10/03
10.11	Escrow Agreement between our principals, ourselves and Computershare Trust Company	SB-2	333-100568	99.10	10/16/02

</TABLE>

<TABLE>

<CAPTION>

EXHIBIT NUMBER	EXHIBIT DESCRIPTION	FORM	FILING FILE NO	FILED EXHIBIT	DATE	HEREWITH
-----	-----	-----	-----	-----	-----	-----
<S>	<C>	<C>	<C>	<C>	<C>	
10.12	Value Escrow Agreement between ourselves, the University of Florida Research Foundation, Inc. and Computershare Trust Company	SB-2	333-100568	99.11	10/16/02	
10.20+	2002 Stock Option and Incentive Plan	SB-2	333-100568	99.16	10/16/02	
10.21+	Amendment No. 1 to the 2002 Stock Option and Incentive Plan	DEF 14A	333-100568	App. E	4/22/04	
10.22	Warrant Agent and Registrar Agreement between the Company and Computershare Trust Company	SB-2/A-1	333-100568	10.28	12/23/02	
10.31	Proprietary Information Agreements between ourselves and Brian Anderson, Brian McAlister, Robert Zahradnik, Howard Kuramitsu, and Steven Projan	SB-2	333-100568	99.23	10/16/02	
10.32*	Proprietary Information and Invention Agreement between the Company and Jeffrey D. Hillman	SB-2	333-100568	99.4	10/16/02	
10.42*	Employment agreement of Mento Soponis	10-KSB	000-50614	10.42	3/17/04	
10.43*	Employment agreement of Jeffrey Hillman	10-KSB	000-50614	10.43	3/17/04	
10.44*	Employment agreement of Paul Hassie	10-KSB	000-50614	10.44	3/17/04	
10.45	Memorandum of Agreement - License Agreement between iviGene Corporation and the Company	10-QSB	000-50614	10.1	8/11/04	
10.46	Lease Agreement between the Company and Hawley-Wiggins LLC dated January 28, 2004; Subordination Agreement dated April 14, 2004; and First Amendment dated November 15, 2004					X
23.1	Consent of Ernst & Young LLP					X
31.1	Rule 13a-14(a)/15d-14(a) Certification					X
31.2	Rule 13a-14(a)/15d-14(a) Certification					X
32.1	Section 1350 Certifications					X
32.2	Section 1350 Certifications					X

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\* management contract

+ compensatory plan or arrangement

</TABLE>

## LEASE

THIS LEASE AGREEMENT (Lease) is made this 28th day of January, 2004 between "Landlord" and "Tenant" hereafter set forth.

## WITNESSETH:

## 1. DEFINITIONS:

- (a) "Landlord": Hawley-Wiggins, L.L.C, a Florida limited company  
Address:
- (b) "Tenant": Oragenics, Inc., a Florida Corporation Address:
- (c) "Premises": A building consisting (which landlord represents consists) of approximately 5,300 square feet of gross rentable area as described in the Exhibit "A" attached hereto. The Premises are located in the Progress Corporate Park. If lessor has available additional space for lease, lessee shall be given a Right of First Refusal to lease said additional space at landlords then current lease rate.
- (d) "Use of Premises": Office and laboratory use
- (e) "Commencement Date": The later of June 1, 2004 ("the anticipated Commencement Date"), or the date Landlord can deliver possession of the Premises, but in no event later than September 1, 2004. In the event Premises can not be delivered by September 1, 2004, Tenant shall have the option to cancel this lease and receive a refund of monies paid hereunder. In the event the Commencement Date is not delayed, this lease shall expire on May 31, 2009. (unless sooner terminated or extended as provided herein)
- (f) "Term": Not less than sixty months commencing on the Commencement Date, this Lease to end on the last day of the sixtieth month after the Commencement Date.
- (g) "Rent":

(1) "Annual Net Rent" shall be per rentable square foot per Lease year as scheduled below:

Lease Year:	Annual Net Rent/RSF:	Annual Net Rent:	Monthly Payment Rent:
1	14.50	76,850.00	6,404.16
2	14.94	79,156.00	6,596.33
3	15.38	81,514.00	6,792.83
4	15.85	84,005.00	7,000.42
5	16.32	86,496.00	7,208.00

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Rent and other sums payable by Tenant to Landlord under this Lease, plus any applicable tax, shall be paid to Landlord, without deduction or offset at its management office presently located at 13709 Progress Boulevard, Box 10, Alachua, Florida 32615 or at such other place as Landlord may hereafter specify in writing.

(h) "Security Deposit": The sum of Six Thousand Four Hundred Four and 16/100 Dollars (\$6,404.16).

2. PREMISES AND TERM: Landlord, in consideration of the Rent hereinafter reserved to be paid and of the covenants, conditions and agreements to be kept and performed by Tenant, hereby leases, lets and demises to Tenant, and Tenant hereby leases and hires from Landlord, that certain space called the Premises as described above.

If Landlord, for any reason whatsoever, cannot deliver possession of the

Premises to Tenant on or before the anticipated Commencement Date, this Lease shall not be void or voidable, nor shall Landlord be liable to Tenant for any loss or damage resulting therefrom, but in that event, there shall be an abatement of Rent covering the period between the anticipated Commencement Date and the time the Landlord can deliver possession, the date when the Landlord can deliver possession being deemed to be the "Commencement Date" (Commencement Date) The ending date of this Lease shall be extended for not less than an identical period of time that transpired between the anticipated Commencement Date and the date Landlord delivered possession (Commencement Date), it being the parties' intent that this Lease have not less than a complete term as described and contemplated in Item 1, Section (f) above. To this end, if the actual Commencement Date is a day other than the first day of a particular month, the term of the Lease shall not expire until the last day of the last month of the proposed term as described in Item 1, Section (f). If the Commencement Date is other than the anticipated Commencement Date, the parties' representatives shall execute a letter amendment to this Lease (which they are hereby authorized to do) whereby the Commencement Date and expiration date of this Lease will be specified. By occupying the Premises, Tenant shall be conclusively deemed to have accepted the Premises as complying fully with Landlord's covenants and obligations.

3. RENT: Tenant covenants and agrees to pay, without deduction or offset, to Landlord Rent for the Premises as described in the Definitions above, on or before the first (1st) day of the first (1st) full calendar month of the term hereof and on or before the first (1st) day of each and every successive calendar month thereafter during the full term of this Lease, subject to the adjustments as provided hereinafter along with any applicable tax, at the then current rate. In the event the Commencement Date occurs on a day other than the first (1st) day of a calendar month, the first Rent payment shall be in the amount of the prorated Rent for the calendar month in which the term of this Lease commences, such payment to be due on the Commencement Date. If Tenant shall fail to pay any rents, additional rents or other charges within ten (10) (business) days after the same become due and payable, then Tenant shall also pay to Landlord a late payment service charge of ONE HUNDRED DOLLARS (\$100.00), excepting such payments that are contested by Tenant.

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Whenever under the terms of this Lease any sums of money is required to be paid by Tenant in addition to the Rent herein reserved, whether or not such sum is herein described as "Additional Rent", said sum shall nevertheless, at Landlord's option, if not paid when due, be deemed Additional Rent and shall be collectible as such with the first installment of Rent thereafter falling due hereunder.

3.1 PERSONAL PROPERTY TAXES: Tenant shall be liable for all taxes levied against personal property and trade fixtures placed by Tenant in the Premises.

3.2 REAL ESTATE TAXES: Tenant shall pay to Landlord, as Additional Rent (its proportionate share of) the (real estate) taxes payable by Landlord with respect to the (building and the land on which it is situated) (premises). Tenant will pay to Landlord its share of real estate taxes within fifteen (15) days after demand in one lump sum, or, at Landlord's option, divided by twelve (12) and collected with monthly rent. The tax payment will be due each anniversary after the initial tax bill is issued and collectible as Additional Rent. In addition, Tenant shall make timely payment of (or reimburse Landlord for) all taxes and assessments levied against or attributable to Tenant's furniture, equipment, supplies, fixtures and other personal property located in the Premises, regardless of whether title to such improvements shall be held by Tenant or Landlord

3.3 PROPERTY INSURANCE: Tenant shall pay the cost to Landlord to maintain liability insurance, multi peril hazard insurance with extended coverage, and other insurance on the Premises with coverage and in amounts not less than those which are from time to time acceptable to a prudent owner of which the property is located. Tenant's share of such insurance premiums shall be payable monthly in advance along with Tenant's payment of rent, and shall be computed by dividing the total amount of premiums for the previous year by twelve (12). If at the end of each lease year, there shall be a variance between the amount collected as Tenant's share of insurance and the amount actually due, Landlord shall furnish to Tenant a statement of any such variance. If the amount

of insurance due is in excess of the amount collected, Tenant shall make a lump sum payment to the Landlord for the difference with fifteen (15) days of receipt of such statement. If the amount of insurance actually due is less than the collected amount, Landlord shall make a lump sum payment to Tenant in the amount of such difference, along with the statement of variance. Upon written request, Tenant shall be permitted to inspect at Landlord's office during normal business hours, all records concerning such insurance.

Even though the term of the Lease has terminated or expired and Tenant has vacated the Leased Premises, when a final determination is made of Tenant's share of the taxes and insurance premiums for the year in which this Lease terminates, Tenant shall immediately pay any increase due over the estimated Tenant's Share of such taxes and insurance premiums previously paid, and conversely, any overpayment made shall be immediately rebated by Landlord to Tenant.

3.4 COMMON AREA ASSESSMENTS: Tenant shall pay to Landlord, as Additional Rent (its proportionate) (the) share of Common Area Assessments (related to the Premises) due Progress Corporate Park Owners Association, Inc. when due. Tenant will pay to Landlord within fifteen (15) days after demand in one lump sum, or at Landlord's option divided by twelve (12) and collected with monthly rent.

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4. COST FOR UPGRADES: The rental rate is for basic space as described in the plans prepared by Paul Stresing Associates, Inc., project No.: 03-118. This rate does not include any upgrades for electrical, plumbing, heating and air conditioning, special exhausts, or lab fixtures or equipment. All upgrade costs related to the design and construction, requested by Tenant, shall be paid by Tenant at the time they are incurred during construction of the premises.

5. LANDLORD'S REPAIRS: Landlord, at Landlord's expense, shall deliver the Premises to the Tenant in good, sound, and watertight condition. Upon Tenant taking possession of the Leased Premises, Tenant hereby acknowledged that it has accepted the Premises "As Is" and thereafter shall be responsible for all maintenance and/or repairs of the premises. Landlord, however, shall be responsible for the maintenance and repair of the building structure, plumbing, sewer, and electrical.

6. TENANT'S REPAIRS: Tenant, at Tenant's expense, shall make all ordinary wear and tear repairs and replacements to keep and maintain the Premises in good condition, including, but not limited to, the heating, hot water, air conditioning and other mechanical installations serving the Premises, all doors, all windows including hardware and other appurtenances, and the parking areas, landscaped areas, sidewalks, access routes, light facilities, and all other portions of the Premises, including but not limited to, stripe painting, repaving, patching, mowing, and the removal of standing water, snow and ice therefore, and the removal of rubbish and other refuse and debris. Any and all items that Tenant shall replace during the term of this Lease shall be of equal type and style than the item being replaced. Tenant shall not permit any waste, damage or injury to the Premises. Tenant shall keep in full force and effect a contract with a reputable heating contractor for not less than the quarterly inspection, maintenance and repair of the air-conditioning and heating systems servicing the Premises, including oiling, filter changes, belt repair and/or replacements, refills of freezing compound to the air conditioning and similar maintenance and minor repair procedures. Landlord, however, shall be responsible for any major air conditioning or heating system repairs, which exceed \$1,000.00. Tenant shall furnish a copy of said contract to Landlord upon request. Tenant shall further keep the Premises clean, attractive and free of rubbish, rubble, debris, insects, rodents and other pests. Tenant shall not do, order of cause any work to be done or installations to be made in, on or to the roof of the Premises without first obtaining Landlord's prior written consent. Tenant shall be responsible for any damage as a result of misuse or neglect of the sewer system.

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7. TENANT'S ALTERATIONS: Tenant shall have the right, at its sole expense, from time to time, to redecorate the Premises and to make such alterations, additions, improvements and changes in such parts thereof as Tenant shall deem

expedient or necessary for its purposes, subject to Landlord's prior approval; provided, however, that such alterations, additions, improvements and changes when completed shall neither impair the structural soundness nor diminish the value of the Premises. Upon the expiration of this Lease, Tenant may, at its option, remove all such redecorations, alterations, additions, improvements and changes. Tenant shall repair all damage caused by such removal. Notwithstanding the foregoing, all floor and wall coverings, sinks, vanities, light fixtures (other than special decorative lighting fixtures), and the complete electrical, plumbing, air conditioning and heating systems, including ducts, diffusers, grills, controls and all other equipment and parts related to such systems, shall be and remain in the Premises at all times for the benefit of Landlord. All such alterations, additions, or improvements shall be done in accordance with all applicable laws, rules regulations, and orders, including applicable building codes. Landlord shall execute and deliver upon request of Tenant such instrument or instruments embodying the approval of Landlord which may be required by any public or quasi public authority for the purpose of obtaining any licenses or permits for the making of such alterations, additions, improvements, changes and/or installations in, to or upon said Premises and Tenant agrees to pay for such licenses or permits. Tenant will indemnify and hold Landlord harmless from and against all claims by reason of such alterations, additions, or improvements which may be made by Tenant on the Premises, and Tenant shall promptly repair any damage to the Premises caused by any such alterations, additions, improvements, or changes. Anything contained in this Section to the contrary notwithstanding, Tenant shall not make changes to the exterior or structural portions for the Premises without Landlord's prior approval, which approval shall not be withheld or delayed unreasonably.

8.MECHANICS' LIENS: Tenant shall not suffer any mechanics' lien to be filed against the Premises by reason of work, labor, services or materials performed or furnished to Tenant in connection with any alterations, additions, or improvements to the Premises by Tenant hereunder. If any such mechanics' lien shall at any time be filed against the Premises, Tenant shall have the right to contest and any and all such liens; provided, however, that Tenant shall cause the same to be discharged of record by payment, bond, order of a court of competent jurisdiction or otherwise within thirty (30) days written notice by Landlord. If Tenant shall fail to cause such lien to be discharged within such thirty (30) day period, then, in addition to any other right or remedy, Landlord may, but shall not be obligated to discharge the same by paying the amount claimed to be due or by bonding or other proceeding deemed appropriate by Landlord, and the amount so paid by Landlord and/or all reasonable costs and expense, including reasonable attorneys' fees, incurred by Landlord in procuring the discharge of such lien, together with interest thereon at the Default Rate from the date paid until repaid by Tenant to Landlord, shall be deemed to be additional rent for the Premises and shall be due and payable by Tenant to Landlord on the first day of the next following month.

9. UTILITIES: Tenant shall pay all charges for water, gas, heat, electricity, sewer and any other utility used upon or furnished to the Premises. Tenant shall keep the Premises sufficiently heated to avoid the freezing or bursting of all pipes therein. The obligation of Tenant to pay for such utilities shall commence as of the Commencement Date.

10. USE OF PREMISES. Tenant shall use and occupy the Premises for purposes of office and/or laboratory use. Landlord represents that the Premises may lawfully be used for such purposes.

11. TENANT'S COVENANTS. Tenant covenants and agrees as follows:

(a) Tenant shall procure any and all licenses and permits required for Tenant's use of the Premises, and upon the expiration or termination of this Lease, Tenant shall remove its goods and effects and those of all persons claiming under it and shall yield up the same peaceably to Landlord in good order, repair and condition in all respects, except for damage by fire and casualty, which is either insured against or required to be insured against hereunder, structural defects (not caused by Tenant's use of the Premises), required repairs by landlord, and reasonable wear and tear.

(b) Tenant shall permit Landlord and its agents on reasonable notice and at reasonable times to examine the Premises and to show the

Premises to prospective purchasers, mortgagees, and/or tenants (but only during the last twelve (12) months of the term with respect to prospective tenants), provided that Landlord shall not thereby unreasonably interfere with the conduct of Tenant's business. During the last three (3) months of the Term of this Lease, Landlord shall have the right to display on the Premises a "for rent" and/or "for sale" sign, which notice shall not be removed, obliterated, or hidden by Tenant.

(c) Tenant shall use and occupy the Premises in a careful, safe and proper manner and shall keep the Premises in a clean, safe and health condition in accordance with local ordinances and lawful directions of proper public officers. Tenant shall not permit the Premises to be used for any unlawful purpose, commit any waste thereof, or commit any nuisance. Notwithstanding the foregoing, Tenant shall have the right to contest the legality of any law, order, rule, regulations or requirement applicable to Tenant's use of the Premises, and Tenant shall indemnify and hold Landlord harmless from any liabilities, suits or penalties that may result from any such contest. Upon the final determination of any such contest, Tenant shall comply with any such law, order, ordinance, rule, regulation or requirements to the extent held to be valid or legal.

(d) (i) Tenant covenants that except in compliance with all laws and regulations, Tenant will not use hazardous substances within the Premises as defined by any law or regulation now or hereafter enacted or promulgated by any governmental authority and that there shall be no hazardous wastes or biomedical materials or waste generated within the Premises as defined by any law or regulation now or hereafter enacted or promulgated by any governmental authority, without Landlord's prior consent. Tenant agrees to manage and dispose of all hazardous substances, hazardous wastes biomedical materials and wastes in accordance with all federal, state and local laws, regulations and rules. Notwithstanding the foregoing, Landlord acknowledges that Tenant will be using biomedical materials in the leased premises and approves of such use in accordance with all governmental regulations.

(ii) Tenant agrees not to store any hazardous wastes or biomedical materials or waste within the Premises (except in compliance with all laws and regulations).

(iii) Upon the expiration of the term of the Lease or the earlier termination hereof, Tenant shall remove all hazardous wastes and/or biomedical materials or waste generated by Tenant from any portion of the Premises. Landlord shall have the right to inspect the Premises with regard to the management and disposal of hazardous substances and wastes at all reasonable times during the term of this Lease.

(e) Tenant acknowledges that the leased premises are part of an office park development subject to covenants, conditions and restrictions as recorded in Official Records Book 1588, at Page 2207, as amended, Alachua County, Florida, together with rules and regulations governing the office park which Tenant shall comply with and be subject to.

In addition, the Tenant shall promptly execute and comply with all statutes, ordinances, rules, orders, regulations and requirements of the Federal, State and City Government and of any and all their Departments and Bureaus applicable to said premises, for the correction, prevention, and abatement of nuisances or other grievances, in, upon, or connected with said premises during said term; and shall also promptly comply with and execute all rules, orders and regulations of the applicable fire prevention codes for the prevention of fires, at Tenant's own cost and expense.

12. ASSIGNMENT AND SUBLETTING: Tenant shall not assign, transfer, mortgage or encumber this Lease in whole or in part, nor sublet all or any part of the Premises, nor suffer or permit the occupation of all or any part thereof by any other party, without the prior written consent of the Landlord, which consent shall not be unreasonably withheld or delayed. The consent by Landlord to any assignment or subletting shall not constitute a waiver of the necessity for such consent to any subsequent assignment or subletting. (Tenant shall be entitled to

assign or sublease this to an affiliated entity provided that Tenant remains liable for performance of the lease.)

13. CHANGE IN CONTROL: Any transfers of company interests in Tenant which results in change of control shall be deemed an assignment of this Lease.

14. TENANT TO REMAIN LIABLE. If, at any time during the term of this Lease, Tenant sublets all or any part of the Premises or assigns this Lease as provided herein, Tenant shall nevertheless remain fully liable under all the terms and conditions of this Lease.

15. FIXTURES: All equipment and all other trade and light fixtures installed by or at the expense of Tenant in or on the Premises shall remain the property of Tenant and Tenant may, but shall not be obligated to, remove the same or any part thereof within thirty (30) days after the end of the term hereof, and provided that Tenant, at its sole cost and expense, shall make any repairs occasioned by such removal.

16. INDEMNITY: Tenant shall indemnify and hold Landlord harmless from any claims, damages, liabilities and expenses (including attorneys' fees and costs) for damage or injury to any person or any property occurring on the Premises, or any part thereof, arising as a result of the tortious or negligent acts or commissions of Tenant, its agents, employees, independent contractors and invitees.

17. LIABILITY INSURANCE: During the Term of this Lease, Tenant shall maintain comprehensive public liability insurance, including insurance against the assumed or contractual liability of Tenant hereunder, to afford protection to the limit for each occurrence of not less than \$1,000,000.00 combined single limit for bodily injury, death and \$300,000.00 for damage to the property. The policy carried by Tenant hereunder shall name Landlord (and Landlord's mortgagee) as an additional insured, and such policy shall provide that no cancellation, reduction or other material changes therein shall be effective until at least thirty (30) days after mailing of written notice thereof to Landlord (and Landlord's mortgagee). Certificates evidencing all such insurance shall be delivered to Landlord prior to the Commencement Date, and prior to the expiration of any such policies.

18. PROPERTY INSURANCE. During the term of this Lease, Tenant shall maintain all-risk property casualty insurance, written at replacement cost value and with replacement cost endorsement, including coverage against vandalism and malicious mischief, covering all of Tenant's personal property in the Premises (including, without limitation, inventory, trade fixtures, all and floor coverings, furniture and other personal property), and all leasehold improvements installed in the Premises by Tenant.

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19. DESTRUCTION OF PREMISES. Upon the performance by the Tenant of all the covenants and agreements hereinabove set forth, in case the leased premises or any part thereof shall at any time be destroyed or so damaged as to be unfit for occupancy or use by the Tenant, then, and in that event, the Landlord shall have to option: (1) to terminate this Lease; (2) to repair and rebuild the said premises remitting rents hereby reserved or a fair and just proportion thereof according to the damage sustained, until the said premises are reinstated and made fit for occupancy and use and in the event the Landlord elects to exercise the option to repair and rebuild, the same shall be done and completed within one hundred eighty (180) days from the date said damage occurred; otherwise, the Tenant shall have the option to terminate this Lease.

20. DAMAGE TO TENANT'S PROPERTY. The Tenant assumes all risks of any damage or loss to Tenant's property that may occur by reason of water or the bursting or leaking of any pipes or waste water about said premises, or from any act of negligence of any co-Tenant or occupants of the building, or fire, or hurricane, or other Act of God, or from any cause whatsoever. The Landlord shall not be liable for any damage so incurred.

21. TOTAL TAKING: If the whole of the Premises shall be taken under power of eminent domain by any public or private authority, or conveyed by Landlord to said authority in lieu of such taking, then this Lease shall terminate as of the date of such taking.

22. PARTIAL TAKING: Landlord or Tenant may, at their election, terminate this Lease upon the occurrence of any condemnation or conveyance in lieu of condemnation, which affects any portion of the floor area of the Premises. Upon the occurrence of such event, either party shall give the other party notice of such election within thirty (30) days after receipt of notice of such pending condemnation. If either party fails to give the other party such written notice within such thirty (30) day period, such party shall be conclusively deemed to have elected not to terminate this Lease. Notwithstanding any termination of this Lease hereunder, Tenant, at its election, may continue to occupy the Premises, subject to the terms and provisions of this Lease, for the period between the date of such taking and the date when possession of the Premises shall be taken by the appropriate authority.

23. RESTORATION. If this Lease is not terminated under Section 22 above, Landlord, at Landlord's sole cost and expense, shall promptly negotiate and settle its claim for compensation with the condemning authority and upon receipt of the condemnation award shall promptly restore the remaining portions of the Premises, including any and all improvements made theretofore, to an architectural whole in substantially the same condition that the same were in prior to such taking. Upon any condemnation of a portion of the Premises, the Rent and any other charges payable by Tenant hereunder shall be proportionately reduced based upon the floor area of the Premises remaining after said taking.

24. THE AWARD. All compensation awarded for any taking, whether for the whole or a portion of the Premises, shall be the sole property of Landlord whether such compensation shall be awarded for diminution in the value of, or loss of, the leasehold or for diminution in the value of, or loss of the fee, or otherwise, and Tenant hereby assigns to Landlord all of Tenant's right and title to and

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interest in any and all such compensation; provided, however, Landlord shall not be entitled to and Tenant shall have the sole right to retain any separate award made by the appropriating authority to Tenant for the cost of removal of leasehold improvements, fixtures, and personalty improvements installed in the Premises by, or at the expense of, Tenant and for relocation expenses, and any separate award made by the appropriating authority directly to Tenant.

25. RELEASE. In the event of any termination of this Lease as the result of the provisions of Sections 21 or 22 above, Rent and any other charges, if any, paid in advance by Tenant shall be refunded to Tenant, and the Parties, effective as of such termination, shall be released from all liability and obligations thereafter arising under this Lease.

26. EVENTS OF DEFAULT; REMEDIES. If Tenant shall at any time be in default in the payment of rental or any other charges hereunder or in the performance of any of the covenants of this Lease, and Tenant shall fail to remedy such default within (a) fifteen (15) days after receipt of written notice thereof from Landlord if such default is as to payment of Rent, or any other charges payable by Tenant hereunder, or (b) within fifteen (15) days after receipt of written notice thereof if such default is nonmonetary (but Tenant shall not be deemed in default if such default cannot be cured in fifteen (15) days and Tenant commences to remedy such default within said fifteen (15) day period and proceeds therewith with due diligence until completion), or if Tenant shall be adjudged a bankrupt or shall make an assignment for the benefit of creditors, or if a receiver of any property of Tenant in or upon the Premises be appointed in any action, suit or proceeding by or against Tenant and not removed within sixty (60) days after appointment, or if the interest of Tenant in the Premises shall be sold under execution or other legal process, or if the Premises are sublet or this Lease is assigned without Landlord's consent, or if Tenant shall commit waste, Landlord may terminate this Lease, or without terminating this Lease, re-enter the Premises by summary proceedings, proceedings in forcible entry and detainer, eviction, or otherwise, and may dispossess Tenant.

27. LANDLORD'S RIGHT TO RELIEF. If Tenant abandons the Premises and/or if Landlord elects to terminate Tenant's right to possession only without terminating this Lease as above provided, Landlord may remove from the Premises any and all property found therein and such repossession shall not release Tenant from Tenant's obligation to pay the rental herein. After any such repossession by Landlord without termination of the Lease, Landlord may relet the Premises or any part thereof to any person, firm or corporation and for such time and upon such terms as Landlord in Landlord's sole discretion may

determine. Landlord may make repairs, alterations and additions in and to the Premises and redecorate the same to the extent deemed by Landlord necessary or desirable and Tenant, upon demand in writing, shall pay the reasonable cost thereof, (excluding tenant improvements for the replacement tenant) together with Landlord's reasonable expenses of reletting, including any commissions and attorneys' fees relative thereto. If the rents collected by Landlord upon any such reletting are not sufficient to pay monthly the full amount of the monthly rent and other charges reserved herein, together with the reasonable costs of such repairs, alterations (excluding tenant improvements for any replacement tenant), additions, redecorating, and expenses, Tenant shall pay to Landlord the amount of each monthly deficiency upon demand in writing.

28. DAMAGES. Tenant agrees to be liable for and to pay to Landlord (i) all rent and other charges and sums due under this Lease at the time of termination of this Lease or upon the termination of Tenant's right of possession, as the case

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may be, and (ii) damages equal to the present value (discounted at the annual rate of interest then being paid on U.S. Treasury Bonds which mature upon the expiration of this Lease) of the excess amount, if any, of the rent and all other charges and sums due under this Lease for the entire term over the rental received by Landlord for the Premises for such term, which damages shall be payable at such time as said damages as discounted by agreement of Landlord and Tenant, or by judicial decision, or at such time that said rent and other charges are payable under this Lease, which liability shall survive the termination of this Lease, the re-entry into the Premises by Landlord, and the commencement of the action to secure possession of the Premises.

29. LANDLORD'S RIGHT TO REMOVE CHATTELS. Any and all property which may be removed from the Premises by Landlord in accordance with the terms of this Lease may be handled, removed, stored or otherwise disposed of by Landlord at the risk and expense of Tenant, and Landlord in no event shall be responsible for the preservation of safekeeping thereof. Tenant shall pay to Landlord upon demand in writing, any and all reasonable expenses incurred in connection with such removal and all storage charges against such property so long as the same shall be in Landlord's possession or under Landlord's control. If any property shall remain in the Premises or in the possession of Landlord and shall not be retaken by Tenant within a period of thirty (30) days from and after the time when the Premises are either abandoned by Tenant or repossessed by Landlord under the terms of this Lease, said property shall conclusively be deemed to have been forever abandoned by Tenant.

30. CONDITION OF PREMISES. If this Lease be terminated for any reason whatsoever or if Landlord should re-enter the Premises as a result of any breach of Tenant hereunder without terminating the Lease, Tenant covenants, any other covenant herein to the contrary notwithstanding (except where this Lease is terminated following eminent domain proceedings), that (a) the Premises shall then be in the condition required by all applicable provisions of this Lease, and (b) Tenant shall perform any covenant contained in this Lease for the making of any repair, improvement, alteration or betterment to the Premises or for restoring or rebuilding any part thereof. For the breach of either of the foregoing obligations Landlord shall be entitled to recover and Tenant shall pay forthwith, without notice or other action by Landlord, the then cost of performing such obligation(s), together with interest at the Default Rate.

31. LANDLORD'S NONWAIVER. No failure by Landlord to insist upon the strict performance of any agreement, term, covenant or condition hereof or to exercise any right or remedy consequent upon a breach thereof, and no acceptance of full or partial rent during the continuance of any such breach, shall constitute a waiver of any such breach or of such agreement, term, covenant, or condition. No agreement, term, covenant, or condition hereof to be performed or complied with by Tenant, and no breach thereof, shall be waived, altered or modified except by a written instrument executed by Landlord. No waiver of any breach shall affect or alter this Lease, but each and every agreement, term, covenant and condition hereof shall continue in full force and effect with respect to any other then existing or subsequent breach thereof. No surrender of the Premises shall be effected by Landlord's acceptance of rent, or by Landlord's acceptance of the keys of the Premises, or by any other means whatsoever, unless the same is evidenced by Landlord's written agreement to accept surrender of the Premises; and if Landlord does accept surrender of the Premises, Tenant's obligations to pay rents and to perform the duties and provisions of this Lease required of

Tenant hereunder shall not be released or terminated but shall continue for the remainder of the term of this Lease.

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32. REMEDIES CUMULATIVE. Each right and remedy provided for in this Lease shall be cumulative and shall be in addition to every other right or remedy provided for in this Lease or now or hereafter existing at law or in equity or by statute or otherwise, and the exercise or beginning of the exercise by Landlord of any one or more of the rights or remedies provided for in this Lease or now or hereafter existing at law or in equity or by statute or otherwise shall not preclude the simultaneous or later exercise by Landlord of any or all other rights or remedies provided for in this Lease or now or hereafter existing at law or in equity or by statute or otherwise. In the event of a default or threatened default by Tenant of any of the terms, provisions, covenants, conditions, rules and regulations of this Lease, Landlord shall have the right to injunction and the right to invoke any remedy permitted to Landlord in law or in equity.

33. SELF-HELP. If Tenant shall default in the performance or observance of any agreement or condition in this Lease contained on its part to be performed or observed and shall not cure such default within any applicable cure period set forth herein, Landlord may, at its option, without waiving any claim for damages for breach of agreement, at any time thereafter cure such default for the account of Tenant, and any amount paid or any contractual liability incurred by Landlord in so doing shall be deemed paid or incurred for the account of Tenant and Tenant agrees to immediately reimburse Landlord therefor and save Landlord harmless therefrom; provided that Landlord may cure any such default as aforesaid prior to the expiration of said waiting period, without notice to Tenant, if any emergency situation exists, or after notice to Tenant, if the cure of such default prior to the expiration of said waiting period is reasonably necessary to protect the Premises or Landlord's interest therein, or to prevent injury to damage to persons or property. If Tenant fails to reimburse Landlord upon demand for any amount paid for the account of Tenant hereunder, said amount (and all accrued interest thereon) shall be added to and become due as a part of the next payment of rent due hereunder.

34. BANKRUPTCY. Should the Tenant at anytime during the term of this Lease directly or indirectly suffer or permit an involuntary or voluntary petition in any proceedings under the Federal Bankruptcy Act to be filed against it, or should Tenant voluntarily file any proceedings under any insolvency laws, or should a receiver or trustee be appointed for the Tenant's property, or should any order of any Court of competent jurisdiction be entered continuing the Tenant in possession of the leased premises in any Federal or State proceedings, or should the Tenant's leasehold interest be levied upon and the lien of said levy remain undischarged for thirty (30) days after said levy has been made, or should the Tenant fail to promptly make the necessary returns and reports required by State and Federal Law, or should the Tenant fail to promptly pay when due all taxes of whatever kind required to be paid to the Federal or State governments or any subdivision thereof, then and upon the happening of either or any of the aforesaid events, the Landlord shall have the right, at its election, to consider the same a material default on the part of the Tenant of the terms and provisions hereof, and in the event such default is not cured by the Tenant within thirty (30) days after written notice by Landlord to the Tenant of the existence of such default, the Landlord shall have the option to declare this Lease terminated and the interest of the Tenant therein forfeited, or the Landlord may exercise any other options herein conferred upon it. The pendency of any proceedings under the Bankruptcy Act or of any proceedings under State Insolvency Law to which the Tenant shall be a party shall not preclude the Landlord from exercising the option herein conferred upon it. Upon termination

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of the Lease at the Landlord's option and/or as herein otherwise provided, the parties agree that the Court having jurisdiction of the cause may require and direct the re-delivery to the Landlord of the entire leased premises, without

notice to Tenant (which said Tenant hereby waives), upon motion or application of the Landlord. All revenues derived from or accruing from the leased premises subsequent to the date of the termination of said Lease shall constitute the property of the Landlord and the same is hereby declared to be a trust fund and shall not constitute an asset of the Tenant or its estate.

35. RECEIVERSHIP. The Tenant pledges and assigns unto the Landlord all of the rents, revenues, issues and profits which might otherwise accrue unto the Tenant for the use, enjoyment and operation of the leased premises. In connection with the aforementioned pledges and assigns, the Tenant covenants and agrees with the Landlord that if the Landlord, upon the default of the Lease and after giving proper notice to the Tenant as provided in this Lease, elects to file a suit in any Court having jurisdiction to enforce the Lease and protect the Landlord's rights thereunder, then the Landlord may, ancillary to such suit, apply to the appropriate Court for the appointment of a receiver of all and singular, the leased premises and the improvements and building(s) located thereon, and thereupon it is expressly covenanted and agreed that in such event, Tenant consents to the appointment of said receiver and that the Court, without notice to Tenant, may appoint a receiver with the usual powers and duties of receivers in like cases, and such appointment shall be made by such Court as a matter of strict right to the Landlord and without reference to the adequacy or inadequacy of the value of the property which is subject to the Landlord's lien, or to the solvency or insolvency of the Tenant, and without reference to the commission of waste.

36. SUBORDINATION. Tenant hereby subordinates this Lease to the lien of any deed of trust, mortgage or mortgages now or hereafter placed upon Landlord's interest in the Premises; provided, however, that Landlord shall procure from any such mortgagee an agreement, in writing, in form and substance reasonably acceptable to Tenant, which acceptance shall be deemed given if such agreement provides in substance that so long as Tenant substantially performs the obligations imposed upon Tenant hereunder within the applicable grace or cure period, its tenancy will not be disturbed, nor its rights under this Lease affected by, any default under such mortgage nor shall Tenant be named as a defendant in any foreclosure proceeding, and such agreement is otherwise customary in form and substance.

37. QUIET ENJOYMENT. Landlord covenants and agrees with Tenant that upon Tenant paying the Rent and observing and performing all of the terms, covenants and conditions on Tenant's part to be observed and performed hereunder, Tenant may peaceably and quietly have, hold, occupy and enjoy the Premises without hindrance or molestation from Landlord or any persons lawfully claiming through Landlord.

38. SECURITY DEPOSIT. Tenant herewith deposits with Landlord the sum of Six Thousand Four Hundred Four and 16/100 Dollars (\$6,404.16) as a guarantee of the fulfillment of the terms and conditions of this Lease. Said deposit shall remain with the Landlord upon the same terms if Tenant exercises its option to renew this Lease. Tenant shall have the security deposit refunded at the end of the lease, assuming all payments due to Landlord have been made and the property is returned to the Landlord in clean condition, ordinary wear and tear excepted.

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39. HOLDING OVER. In the event that Tenant or anyone claiming under Tenant shall continue occupancy of the Premises after the expiration of the original or renewal term of this Lease without any agreement in writing between Landlord and Tenant with respect thereto, and Landlord has not given its written consent to said continued occupancy, such occupancy shall not be deemed to extend or renew the term of this Lease, but such occupancy shall continue as a tenancy from month to month upon the covenants, provisions and conditions herein contained and at two hundred percent (200%) of the Rental in effect upon the expiration of the term, prorated and payable for the period of such occupancy, and Landlord shall have the right to terminate such tenancy upon five (5) days' written notice to Tenant.

40. WAIVERS. Failure of either party to complain of any act or omission on the part of the other party, no matter how long the same may continue, shall not be deemed to be a waiver by said party of any of its rights hereunder. No waiver by either party at any time, express or implied, of any breach of any provision of this Lease shall be deemed a waiver of a breach of any other provisions of this Lease or a consent to any subsequent breach of the same or any other provisions. If any action by either party shall require the consent or approval of the other

party, the other party's consent to or approval of such action on any one occasion shall not be deemed a consent to or approval of said action on any subsequent occasion or a consent to or approval of any other action on the same or any subsequent occasion.

41. NOTICES. All notices and other communications authorized or required hereunder shall be in writing and shall be given by mailing the same by certified mail or registered mail, return receipt requested, postage prepaid, and any such notice or other communication shall be deemed to have been given when received by the party to whom such notice or other communication shall be addressed, or on the date noted that the addressee has refused delivery or on the date that the notice is returned to sender due to the inability of the postal authorities to deliver. Notices shall be mailed to the address hereinabove set forth or such other address as either party may hereafter designate by notice to the other.

42. COST INCURRED BY BREACH. The Tenant shall be liable to the Landlord for all costs, expenses, reasonable attorney's fees and damages which may be incurred or sustained by the Landlord by reason of the Tenant's breach of any of the provisions of this Indenture. Any sums due the Landlord under the provisions of this Item shall constitute a lien against the interest of the Tenant in the leased premises to the same extent and on the same conditions as delinquent rent would constitute a lien on said premises. The Landlord shall be liable to the Tenant for any costs, expenses, reasonable attorney's fees and damages which may be incurred or sustained by the Tenant by reason of the Landlord's breach of any of the covenants herein contained, providing Tenant asserts a claim therefore in the appropriate Court and secures a judgment thereon.

43. FORCE MAJEURE. In the event that Landlord or Tenant shall be delayed or hindered in or prevented from the performance of any act (other than Tenant's obligation to make payments of Rent and other charges required hereunder), by reason of strikes, lockouts, unavailability of materials, failure of power, restrictive governmental laws or regulations, riots, insurrections, the act, failure to act, or default of the other party, war or other reason beyond its control, then performance of such act shall be excused for the period for the

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delay and the period of the performance of such act shall be extended for a period equivalent to the period of such delay. Notwithstanding the foregoing, lack of funds shall not be deemed to be a cause beyond control of either party.

44. ESTOPPEL CERTIFICATES. At any time and from time to time, Landlord and Tenant each agree, within five (5) days after request in writing from the other, to execute, acknowledge and deliver to the other or to any person designated by the other a statement in writing certifying that this Lease is unmodified and is in full force and effect, or if there have been modifications, that the same is in full force and effect as modified (stating the modifications), that the other party is not in default in the performance of its covenants hereunder, or if there have been such defaults, specifying the same and the dates to which the rent and other charges have been paid, and such other matters as the requesting party may reasonably request.

45. INVALIDITY OF PARTICULAR PROVISION. If any term or provision of this Lease or the application hereto to any person or circumstance shall, to any extent, be invalid or unenforceable, the remainder of this Lease, or the application of such term or provision to persons or circumstances other than those as to which it is held invalid or unenforceable shall not be affected thereby, and each term and provision of this Lease shall be valid and be enforced to the fullest extent permitted by law.

46. CORPORATE TENANCY If Tenant is a corporation, the undersigned officer of Tenant hereby warrants and certifies to Landlord that Tenant is a corporation in good standing and is authorized to do business in the State of Florida. The undersigned officer of Tenant hereby further warrants and certifies to Landlord that he or she, as such officer, is authorized and empowered to bind the corporation to the terms of this Lease by his or her signature thereto. Landlord, before it accepts and delivers this Lease, may require Tenant to supply it with a certified copy of the corporate resolution authorizing the execution of this Lease by Tenant. If Tenant is a corporation (other than one whose shares are regularly and publicly traded on a recognized stock exchange), Tenant represents that the ownership and power to vote its entire outstanding

capital stock belongs to and is vested in the officer or officers executing this Lease or members of his, her or their immediate family. If there shall occur any change in the ownership and/or power to vote the majority of the outstanding capital stock of Tenant, whether such change of ownership is by sale, assignment, bequest, inheritance, operation of law or otherwise, without the prior written consent of Landlord, then Landlord shall have the option to terminate this Lease upon thirty (30) days' written notice to Tenant, furthermore, Tenant shall have an affirmative obligation to notify immediately Landlord of any such change.

46. CAPTIONS AND DEFINITIONS. The captions of the Sections of this Lease are for convenience only and are not a part of this Lease and do not in any way limit or amplify the terms and provisions of this Lease. The word "Landlord" and the pronouns referring thereto, shall mean, where the context so admits or requires, the persons, firm or corporation made herein as landlord or the mortgagee in possession for the time being of the land and building comprising of the Premises. Any pronoun shall be read in the singular or plural number and in such gender as the context may require. Except as in this Lease otherwise provided, the terms and provisions of this Lease shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns.

47. ENTIRE AGREEMENT. This instrument contains the entire and only agreement between the parties and no oral statement or representations or prior written matter not contained in this instrument shall have any force and effect. This Lease shall not be modified in any way except by a writing executed by both parties.

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48. NO PARTNERSHIP. Landlord is not and shall not become by this Lease or by any rights granted or reserved herein a partner or joint venturer of or with Tenant in the conduct of Tenant's business or otherwise.

49. LIABILITY OF LANDLORD.

(a) If Landlord should sell or otherwise transfer Landlord's interest in the Premises, Tenant agrees that Landlord shall thereafter have no liability to Tenant under this Lease or any modification or amendment thereof or extensions or renewals thereof, except for such liabilities which might have accrued prior to the date of such sale or transfer of Landlord's interest. Landlord shall be liable under this Lease only while owner of the Premises provided that any successor in interest to Landlord hereunder shall assume such obligations and liabilities as of the date Landlord's interest in the Premises is sold, assigned, or otherwise transferred hereunder.

(b) If Landlord shall fail to perform any covenant, term or condition of this Lease upon Landlord's part to be performed or if Landlord shall be liable to Tenant in any way arising out of this Lease, or pursuant to statute, law, ordinance or regulation, or under the common law, and, as a consequence, if Tenant shall recover a money judgment against Landlord, such judgment shall be satisfied only out of the proceeds received at a judicial sale upon execution and levy against the right, title and interest of Landlord in the Premises. If Landlord is an individual, a trustee of a trust or a company, Landlord's obligations hereunder shall not be binding upon, nor shall there be any personal liability by, Landlord individually, the trustees of said trust, the beneficiaries of said trust, the company, or the partners of the company.

50. OPTION TO RENEW: Provided that Tenant is not in default under this Lease, Tenant shall have the option to renew this Lease for an additional term of Sixty (60) months commencing on the expiration of the initial term. All of the terms and conditions of this lease shall apply during the renewal term except that the monthly rent shall be increased by three (3) % over the previous year's monthly rental during each year of the renewal. This renewal option shall be exercised by Tenant by written notice given to Landlord not less than 45 days prior to the expiration of the initial term.

51. EARLY TERMINATION: Tenant may terminate this lease at any time after the first 12 months of this Lease upon payment to landlord of a sum

equal to 12 months rent in which event both parties shall be released from any further liability or obligation under this lease.

IN WITNESS WHEREOF, the parties hereto have executed this Lease the day and year first above written.

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WITNESSES: LANDLORD:  
HAWLEY WIGGINS, L.L.C,  
A FLORIDA LIMITED COMPANY

/s/ Darryl J. Tompkins BY: /s/ Phillip L. Hawley  
-----  
Printed Name: Darryl J. Tompkins ITS: Manager

/s/ Marlene Pendergast  
-----  
Printed Name: Marlene Pendergast

TENANT:  
ORAGENICS INC., A FLORIDA CORPORATION

/s/ Darryl J. Tompkins BY: /s/ Mento A. Soponis  
-----  
Printed Name: Darryl J. Tompkins ITS: President

/s/ Rebecca Budny  
-----  
Printed Name: Rebecca Budny

STATE OF FLORIDA  
COUNTY OF ALACHUA

The foregoing instrument was acknowledged before me this 28th day of January, 2004, by Phillip L. Hawley as Manager on behalf of Hawley Wiggins, L.L.C, a Florida limited company, who is personally known to me or who has produced \_\_\_\_\_ as identification and who did take an oath.

/s/ Marlene Pendergast  
-----  
NOTARY PUBLIC STATE OF FLORIDA  
My Commission DD248314  
Expires September 9, 2007  
Printed Name: Marlene Pendergast

STATE OF FLORIDA  
COUNTY OF ALACHUA

The foregoing instrument was acknowledged before me this 28th day of January, 2004 by Mento Soponis as President on behalf of Oragenics Inc., a Florida corporation who is personally known to me or who has produced FL Drivers License as identification and who did take an oath.

/s/ Marlene Pendergast  
-----  
NOTARY PUBLIC STATE OF FLORIDA  
My Commission DD248314  
Expires September 9, 2007  
Printed Name: Marlene Pendergast

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EXHIBIT B

## LEASEHOLD IMPROVEMENTS

Landlord agrees that, subject to delays due to causes beyond Landlord's control, it will, at its own expense, do the following work to the Premises:

As provided in plans prepared by Paul Stresing Associates, Inc.,  
project No.: 03-118.

## LEASE SUBORDINATION AGREEMENT

THIS AGREEMENT made as of the 14th day of April, 2004 by and between Oragenics, Inc., a Florida corporation ("Lessee"); Hawley-Wiggins, L.L.C., a Florida limited liability company ("Lessor") and SunTrust Bank, a Georgia Banking Corporation authorized to transact business in the State of Florida, ("Mortgagee").

### W I T N E S S E T H:

WHEREAS, Lessee is the lessee under a certain Business Property Lease (the "Lease") between Lessor, as lessor and Lessee, as lessee, dated January 28, 2004, renting the premises described therein which is a part of the property described in Exhibit "A" hereto (the "Premises") and the improvements thereon.

WHEREAS, Mortgagee has committed to make a loan to Lessor; said loan to be secured by a first mortgage on the Premises (the "Mortgage"); and

WHEREAS, Mortgagee has required the execution of this Subordination Agreement in order to perfect the Mortgage as a first lien on the Premises:

NOW, THEREFORE, in consideration of the premises and the sum of Ten Dollars (\$10.00), receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Lessee hereby covenants and agrees with Mortgagee that all of the Lessee's rights under the Lease shall hereby be and shall continue to be subject and subordinate to the lien of the Mortgage and to all advances heretofore made or which hereafter may be made thereunder (including but not limited to all sums advanced for the purposes of paying brokerage commissions, mortgage recording taxes, documentary stamps, fees for examination of title, surveys and other disbursements and charges in connection therewith), and to any extensions, renewals or modifications thereof, including any future advances made thereunder.

2. Lessee, by the execution of this Agreement, shall not become responsible or liable for the payment of any sum or sums due under the note to be secured by the Mortgage.

3. Mortgagee hereby covenants and agrees that so long as the Lessee shall not be in default under the provisions of said Lease, said Lease shall not be cut off nor shall any of Lessee's rights and obligations under said Lease be disturbed by any steps or proceedings taken by the Mortgagee in the exercise of any of its rights under the Mortgage or Note secured thereby. In the event the Mortgagee or any other person in the exercise of any rights under the Mortgage becomes owner of the leased premises, the undersigned Lessee shall recognize such new owner as lessor under the Business Property Lease; the new owner to have all the rights including, but not limited to, the right to receive and collect rent from the Lessee, granted to Lessor and all the duties imposed upon the lessor named as such in the Lease.

4. Lessee agrees to send to Mortgagee a copy of any notice of default given to Lessor in connection with the Lease, said notice being only for the purpose of informing Mortgagee of Lessor's default. Said notice shall not be construed as placing any obligations on Mortgagee.

5. This Agreement may not be changed or terminated orally. This Agreement shall bind and inure to the benefit of the parties hereto, their respective successors and assigns and may be recorded in the Public Records of Alachua County, Florida.

IN WITNESS WHEREOF, the undersigned have duly executed this Agreement the day and year first above written.

In the presence of: "LESSEE"

ORAGENICS, INC., a Florida Corporation  
(SEAL)

/s/ Sandra Allen BY: /s/ Mento A. Saponis  
Witness:

/s/ James W. Sharpe ITS: President & CEO  
Witness:

"LESSOR"

HAWLEY-WIGGINS, L.L.C.,  
a Florida limited liability company  
(SEAL)

/s/ Rebecca Budny BY: /s/ Phillip L. Hawley  
Witness: PHILLIP L. HAWLEY  
ITS: Managing Member

/s/ Marlene Pendergast  
Witness: "MORTGAGEE"

SUNTRUST BANK, a Georgia Banking  
Corporation(SEAL)

/s/ Rebecca Budny BY: /s/ Nathan R. Garcia  
Witness: NATHAN R. GARCIA  
/s/ Marlene Pendergast ITS: Assistant Vice President  
Witness:

STATE OF FLORIDA )  
) SS:  
COUNTY OF )

The foregoing instrument was acknowledged before me this \_\_\_\_ day of April, 2004 by \_\_\_\_\_ on behalf of Oragenics, Inc., a Florida Corporation ("Lessee") who is personally known to me or who has produced \_\_\_\_\_ as identification and who did not take an oath.

-----  
NOTARY PUBLIC  
Printed Name: \_\_\_\_\_  
My commission expires:

STATE OF FLORIDA )  
) SS:  
COUNTY OF ALACHUA )

The foregoing instrument was acknowledged before me this 14 day of April, 2004 by Phillip L. Hawley, as Managing Member of Hawley-Wiggins, L.L.C., a Florida limited liability company ("Lessor") who is personally known to me or who has produced \_\_\_\_\_ as identification and who did not take an oath.

/s/ Rebecca Budny  
-----  
NOTARY PUBLIC  
Printed Name: Rebecca Budny  
My commission expires: Dec. 17, 2004  
Comm. No. DD 243843

STATE OF FLORIDA )  
) SS:  
COUNTY OF )

The foregoing instrument was acknowledged before me this 14 day of April, 2004 by Nathan R. Garcia as Assistant Vice President, on behalf of SunTrust Bank, a Georgia Banking corporation, ("Mortgagee") who is personally known to me or who has produced his Florida Drivers License as identification and who did not take an oath.

/s/ Rebecca Budny

-----  
NOTARY PUBLIC

Printed Name: Rebecca Budny

My commission expires: Dec. 17, 2004

Comm. No. DD 243843

#### FIRST AMENDMENT TO LEASE

WHEREAS, Hawley-Wiggins, LLC, a Florida limited company as "Landlord" and Oragenics, Inc., a Florida corporation as "Tenant" have entered into that certain Lease dated the 28th day of January, 2004, for that certain real property described on the attached Exhibit "A".

and;

WHEREAS, Landlord and Tenant have requested an amendment to the Lease.

NOW, THEREFORE, the Landlord and Tenant agree as follows:

(1) The Lease is modified to read as follows:

1. (e) "Commencement Date": The later of November 15, 2004 ("the anticipated Commencement Date") or the date Landlord can deliver possession of the Premises, but in no event later than December 15, 2004. In the event Premises cannot be delivered by December 15, 2004, Tenant shall have the option to cancel this lease and receive a refund of monies paid hereunder. In the event the Commencement Date is not delayed, this lease shall expire on November 30, 2009. (Unless sooner terminated or extended as provided herein)

All provisions of the original Agreement not amended herein shall remain unchanged and in full force and effect.

IN WITNESS WHEREOF, the parties have set their hands and seals this 15th day of November, 2004.

In the presence of: "LANDLORD"

Hawley-Wiggins, LLC, a Florida limited company

/s/ Phillip L. Hawley

-----  
Printed Name: \_\_\_\_\_ By: PHILLIP L. HAWLEY  
Its: Manager

-----  
Printed Name: \_\_\_\_\_

"TENANT"

Oragenics, Inc., a Florida corporation

/s/ Mento A. Soponis

-----  
Printed Name: \_\_\_\_\_ By: Mento A. Soponis  
-----  
Its: President and CEO

-----  
Printed Name: \_\_\_\_\_

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

- (i) Form S-8 No. 333-110646 pertaining to Orogenics, Inc. 2002 Stock Incentive Plan; and
- (ii) Post Effective Amendment No. 1 to the Registration Statement on Form S-3 to Form SB-2 (No. 333-100568) and related Prospectus of Orogenics, Inc. for the registration of 297,724 shares of its common stock issuable upon exercise of warrants;

of our report dated January 28, 2005, with respect to the financial statements of Orogenics, Inc. included in this Annual Report (Form 10-KSB) for the year ended December 31, 2004.

/s/ Ernst & Young LLP  
Certified Public Accountants

Tampa, Florida  
February 28, 2005

EXHIBIT 31.1

CERTIFICATION

I, Mento A. Soponis, certify that:

1. I have reviewed this annual report on Form 10-KSB 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: March 11, 2005

/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 annual report on Form 10-KSB 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: March 11, 2005

/s/ Paul A. Hassie

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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 Annual Report of Orogenics, Inc. (the "Company") on Form 10-KSB for the period ended December 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 March 11, 2005.

/s/ Mento A. Soponis

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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 Annual Report of Oragenics, Inc. (the "Company") on Form 10-KSB for the period ended December 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 March 11, 2005.

/s/ Paul A. Hassie

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Paul A. Hassie  
Chief Financial Officer