

SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

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FORM SB-2/A-6  
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933  
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**ORAGENICS, INC.**

(Name of small business issuer in its charter)

**Florida**  
(State or Other Jurisdiction of  
Organization)

**2836**  
(Primary Standard Industrial  
Classification Code)

**59-3410522**  
(IRS Employer Identification #)

**ORAGENICS, INC.**  
**12085 Research Drive**  
**Alachua, Florida 32615**  
**(386) 418-4018**

**Mento A. Soponis**  
**4730 SW 103d Way**  
**Gainesville, FL 32608**  
**Tel: (386) 418-4018**

(Address and telephone of registrant's executive  
office)

(Name, address and telephone number of agent  
for service)

Copies of all communications and notices to:

**Conrad C. Lysiak, Esq.**  
**601 West First Avenue**  
**Suite 503**  
**Spokane, Washington 99201**  
**Tel: (509) 624-1475**  
**Fax: (509) 747-1770**

**Ronald A. Fleming, Jr.**  
**Pillsbury Winthrop LLP**  
**One Battery Park Plaza**  
**New York, New York 10004**  
**Tel: (212) 858-1000**  
**Fax: (212) 858-1500**

**S. Campbell Fitch**  
**Miller Thomson LLP**  
**Robson Court**  
**1000 - 840 Howe Street**  
**Vancouver, B.C. V6Z 2M1**  
**Tel: (604) 687-2242**  
**Fax: (604) 643-1200**

**APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC:**

The effective date of this registration statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the *Securities Act of 1933*, as amended (the "Securities Act") check the following box. [ X ]

If this Form is filed to register additional securities for an offering under Rule 462(b) of the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed under Rule 462(c) of the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed under Rule 462(d) of the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  
[ ]

If delivery of the prospectus is expected to be made under Rule 434, please check the following box. [ ]

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**CALCULATION OF REGISTRATION FEE**

<b>Securities to be Registered</b>	<b>Amount to be Registered</b>	<b>Offering Price Per Share[1]</b>	<b>Aggregate Offering Price[1]</b>	<b>Registration Fee</b>
Units consisting of:	2,400,000	\$ 1.25	\$ 3,000,000	\$ 276.00
One share of common stock [2]	2,400,000			
One half of one Series A warrant [3]	1,200,000			
One half of one Series B warrant [3]	1,200,000			
Shares of common stock issuable upon exercise of Series A warrants	1,200,000	2.00	2,400,000	\$ 220.80
Shares of common stock issuable upon exercise of Series B warrants	1,200,000	3.00	3,600,000	\$ 331.20
Redeemable warrants we will issue to our underwriter [4]	500,000			
Shares of common stock issuable upon exercise of redeemable warrants	500,000	1.25	625,000	\$ 57.50
Shares of common stock to be issued to our underwriter [4]	100,000			
<b>Totals:</b>	<b>10,700,000</b>		<b>9,625,000</b>	<b>\$ 885.50</b>

- [1] Estimated solely for purposes of calculating the registration fee under Rule 457(a)
- [2] Upon completion of our offering, the shares of common stock will be separable from the units and represented by certificates different from those representing the Series A and B warrants. The shares of common stock will trade on the TSX Venture Exchange.
- [3] Upon completion of our offering, the Series A and B warrants will be separable from the units, and represented by certificates different from those representing the shares of common stock. The Series A and B warrants will be non-transferable and will not trade on any stock exchange or quotation service.
- [4] In connection with the sale of the units, the registrant will issue to its underwriter, Haywood Securities Inc., 100,000 shares of common stock and warrants to purchase 500,000 shares of common stock.

**REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE SECURITIES ACT OF 1933, OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING UNDER SAID SECTION 8(A), MAY DETERMINE.**

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**SUBJECT TO COMPLETION DATED MAY 12, 2003**

**The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities in any state where the offer or sale is not permitted.**

**Prospectus**

**ORAGENICS, INC.**  
**2,400,000 Units**  
**Consisting of One Share of Common Stock,**  
**One Half of One Series A Warrant and**  
**One Half of One Series B Warrant**  
**500,000 Redeemable Warrants**  
**100,000 Shares of Common Stock**

Before this offering, there has been no public market for the common stock.

Each unit consists of one share of common stock, one half of one non-transferable Series A warrant and one half of one non-transferable Series B warrant. Each whole Series A warrant entitles the holder to purchase one share of common stock at a price of \$2.00 for 6 months from the date of closing of the offering of the units. Each whole Series B warrant entitles the holder to purchase one share of common stock at a price of \$3.00 for 9 months from the closing date. If the warrants are not exercised by such times, they will expire and cannot be exercised thereafter. The shares of common stock and Series A and B Warrants are separable from the units. Each will be represented by different certificates. We are offering 2,400,000 units in the Canadian provinces of British Columbia and Alberta only through our underwriter, Haywood Securities Inc. The offering price is \$1.25 per unit. Our offering is a "best efforts" offering on an "all or none" basis, completion of our offering is subject to the sale of all the units. There are no minimum purchase requirements. The offering will commence on the effective date of this registration statement, which will occur concurrently with or after the date of issue of a MRRS Decision Document evidencing the issue of receipts for the Canadian prospectus in Alberta and British Columbia by the British Columbia Securities Commission, and will continue for a period of 90 days from the date of issue of an MRRS Decision Document. There are no arrangements to place the funds in an escrow, trust or similar account.

**Investing in our common stock involves risks. See "Risk Factors" on page 9.**

	<b>Price to Public</b> <sup>[1]</sup>	<b>Underwriter's Commission</b> <sup>[2]</sup>	<b>Proceeds to Us</b> <sup>[3]</sup>
<b>Per unit</b>	\$ 1.25	\$ 0.09375	\$ 1.15625
<b>Total</b>	\$ 3,000,000	\$ 225,000	\$ 2,775,000

[1] The price per unit was established by negotiation between us and our underwriter, Haywood Securities Inc.

[2] We will pay Haywood a commission of 7.5% of the gross proceeds of the offering. We will also issue 500,000 warrants each exercisable for two years from the closing date to purchase one share of our common stock, at a price of \$1.25 per share, and 100,000 shares of our common stock, to Haywood.

[3] Before expenses of the offering, estimated at \$350,000.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. It is illegal to tell you otherwise.**

The information in this prospectus is not complete and may be changed. We will not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to

sell securities, and is not soliciting an offer to buy these securities, in any jurisdiction where the offer or sale is not permitted.

There is no public trading market for our units, shares of common stock, or warrants. These securities will not be listed on any national securities exchange in the United States. The Series A and B warrants are non-transferable and will not be listed on any stock exchange.

The date of this prospectus is \_\_\_\_\_.

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9. We must spend at least \$600,000 in 2003 and \$1 million annually following 2003 on development of our technologies under our license agreements with the University of Florida Research Foundation, Inc. We may be unable to raise the financing necessary to do so. We must also comply with certain other conditions of our licenses. If we are not, we will lose our licenses to our technologies, and may have to cease operations.	11
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13. There is uncertainty relating to favorable third-party reimbursement in the United States. If we can't obtain third party reimbursement for products based on our technologies, we may have to cease operations.	12
14. Although Dr. Jeffrey Hillman is our Chief Scientific Officer, he will devote only approximately 75% of his working time to the affairs of our company and he has agreed to	12

assign to our company only those inventions that he may conceive or discover which relate to our existing proprietary intellectual rights. If he should conceive of or discover further inventions which do not relate to our existing intellectual property rights, we will not get the economic benefit of those inventions. If Dr. Hillman conceives of or discover inventions which do not relate to our intellectual property rights which compete with our technologies, we may earn less revenue from our technologies.

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## **SUMMARY OF OUR OFFERING**

The following is a summary of the principal features of this offering and should be read together with the more detailed information and financial data and statements contained elsewhere in this prospectus. You should read the entire prospectus carefully, especially the discussion of the risks of purchasing our securities in "Risk Factors" on page 9.

### **Our Business**

We were incorporated in Florida in 1996. Our executive office is located at 12085 Research Drive, Alachua, Florida 32615. This is also our mailing address. Our telephone number is (386) 418-4018. Our corporate website is at [www.rogenics.com](http://www.rogenics.com). We do not intend the reference to our web address to incorporate by reference in this prospectus the information on our website. The information on our website is not intended to be part of this prospectus and you

should not rely on it when making a decision to invest in our securities.

We are a biotechnology research and development company seeking to commercialize two technologies developed by our founder and Chief Scientific Officer, Dr. Jeffrey Hillman. Dr. Hillman is a Harvard-trained Professor at the University of Florida College of Dentistry. He is presently on indefinite leave from his post at the University of Florida. He did the early development work on our technologies at the Forsyth Dental Center and the University of Florida. The technologies are the property of the University, and the University has obtained patents relating to the technologies. We have obtained exclusive licenses of the technologies from the University.

The first technology is a genetically altered strain of a species of bacteria called *S. mutans* which occurs naturally on teeth in human beings. We refer to this technology as replacement therapy. The strains of this species of bacteria which occur naturally produce lactic acid from sugar in our diets. Lactic acid is the principal cause of tooth decay. Our preliminary animal studies indicate that our licensed, patented strain of this bacteria produces harmless chemicals instead of lactic acid[1], and therefore does not cause tooth decay. [2] We hope further testing will confirm these results.

The second technology is an antibiotic known as *mutacin* 1140 which is produced by our licensed, patented strain of bacteria. Our preliminary *in vitro* [3] laboratory tests of mutacin 1140 have demonstrated its effectiveness against all tested Gram-positive bacteria [4]. Gram-positive bacteria cause many human ailments, such as pneumonia, pharyngitis and others. We hope further testing will confirm these results.

We have made an investigational new drug application to the Federal Food and Drug Administration, which we refer to as the FDA in this prospectus, in respect of our replacement therapy technology. The FDA has placed our application on clinical hold. This means that we may not begin human clinical trials under our application until the FDA gives us permission to do so. On March 19, 2003, we submitted to the FDA a new investigational drug application. Our new investigational drug application relates to a modified strain of our licensed, patented strain of *s. mutans* which we developed in order to respond to the FDA's concerns with our previous investigational new drug application, and incorporates our previous investigational new drug application by reference. The FDA has put our new investigational drug application on clinical hold. We have not yet made an investigational new drug application in respect of our *mutacin* 1140 technology. In order to sell products based on our licensed, patented technologies, we must obtain approval from the FDA for investigational new drug applications, complete Phase I, II and III clinical trials, and obtain FDA approval for new drug applications. If we are successful in obtaining regulatory approval for one or both of our licensed, patented technologies, we will attempt to license other technologies, from the University of Florida or elsewhere, to which we believe members of our team such as Dr. Hillman can add value.

[1] Hillman et al, Construction and Characterization of an Effector Strain of *Streptococcus mutans* for Replacement Therapy of Dental Caries, *Infection and Immunity* (2000) Vol. 68, No. 2, pp. 543-549.

[2] Hillman et al, Construction and Characterization of an Effector Strain of *Streptococcus mutans* for Replacement Therapy of Dental Caries, *Infection and Immunity* (2000) Vol. 68, No. 2, pp. 543-549.

[3] Studies carried out in isolation from a living organism.

[4] Wojciehowski, Byers and Hillman, Regulation of Expression of the Structural Gene for Mutacin 1140 and Characterization of its Antibacterial Properties (2002), submitted for publication and Hillman et al, Isolation of a *Streptococcus mutans* strain producing a Novel Bacterium, *Infection and Immunity* (1984) Vol. 44, No. 1, pp. 141-144.

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## The Offering

Following is a brief summary of this offering:

Securities being offered by us

2,400,000 units. Each unit consists of one share of common stock, one half of one Series A warrant, and one half of one Series B warrant. Each whole Series A warrant may be exercised to purchase a further share of common stock at a price of \$2.00 per share for 6 months from the closing of the offering. Each whole Series B warrant may be exercised to purchase a further share of common stock at a price of \$3.00

per share for 9 months from the closing of the offering.

Offering price per unit	\$1.25
Net proceeds to us	\$2,775,000, before expenses of the offering, estimated at \$350,000.
Number of shares outstanding before the offering	9,425,704
Number of shares outstanding after the offering	11,925,704[1]

[1] Excludes shares which may be issued on exercise of outstanding options, the Series A and B warrants, and the warrants we will issue to Haywood.

### Selected Financial Data

The following selected financial data for the three years ended December 31, 2002 are derived from our audited financial statements, which have been audited by Ernst & Young LLP, independent certified public accountants. Ernst & Young LLP's report on the financial statements for the three years ended December 31, 2002, which appears elsewhere herein, includes an explanatory paragraph which describes an uncertainty about our ability to continue as a going concern.

	December 31, 2002 [1]	December 31, 2001 [1]	December 31, 2000 [1]
<b>Balance Sheet</b>			
Total Assets	\$ 310,916	\$ 201,265	\$ 14,423
Total Liabilities	394,398	215,292	42,039
Total Long Term Liabilities	nil	nil	nil
Cash Dividends Per Share	nil	nil	nil
Stockholders' (Deficit)	(83,482)	(14,027)	(27,616)
<b>Income Statement</b>			
	2002	Year Ended December 31 2001	2000
Total Revenue	- 0 -	303,912	53,875
Total Expenses	709,700	270,465	69,318
Income (Loss) from Operations	(709,700)	33,447	(15,443)
Net Income (Loss)	(699,603)	13,473	(16,912)
Net Income (Loss) per Share-basic and diluted	(0.08)	0.00	0.00

[1] Our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, conform in all material respects with accounting principles generally accepted in Canada.

### RISK FACTORS

**An investment in our securities involves significant risks. Please consider the following risk factors before deciding to invest in our securities.**

## **Risks Associated with Our Company**

***1. Our auditors have issued a going concern opinion. This means we may not be able to achieve our objectives and may have to suspend or cease operations.***

Our auditors have issued a going concern opinion. This means that there is doubt that we can continue as an ongoing business. At April 30, 2003 we had an estimated working capital deficit of \$(284,000).

***2. We have experienced a history of losses and expect to incur future losses. Therefore, we must continue to raise money from investors to fund our operations. If we are unable to fund our operations, we will cease doing business.***

We have recorded minimal revenue to date and we have incurred a cumulative operating loss of \$714,000 through December 31, 2002. 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 pre-clinical 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 are a development stage company focused on product development and we have not generated any revenues from sales to date. Until we receive FDA approval for sales of products incorporating our licensed, patented technologies, we cannot sell our products and will not have revenues from sales. That is because we are spending money on research and development of our technologies, but cannot sell products to the public at the present time. Consequently, we must raise money from investors to fund our operations. If we can't fund our operations through investments by third parties, we will have to cease operations. We expect that when we receive the net proceeds from this offering, we will have the cash we need for operations during the next twelve months.

***3. We have a limited operating history. We have generated extremely limited revenue from our operations, and no revenue from sales. If we do not generate revenues from our operations, we may have to cease operations.***

We have a limited operating history. We commenced operations in 1999. Since commencing operations, we have generated very limited revenue from our operations. We have not generated any revenue from sales. If we cannot generate revenues from our operations in the future, and are unable to obtain further financing to cover our expenses, we will have to cease operations.

***4. The FDA has put our investigational new drug application for our replacement therapy technology on clinical hold. If we are unable to obtain or maintain regulatory clearance or approval for our technologies, we will be unable to generate revenues and will have to cease operations.***

Our technologies have not been cleared for marketing by the FDA or foreign regulatory authorities and cannot be commercially distributed in the United States or any international markets until such clearance is obtained. Before regulatory approvals can be obtained, our technologies will be subject to extensive pre-clinical and clinical testing. These processes are lengthy and expensive. We can offer you no assurance that such trials will demonstrate the safety or effectiveness of our technologies. There is a risk that our replacement therapy and mutacin 1140 technologies may be found to be unsafe or ineffective or otherwise fail to satisfy regulatory requirements. The FDA has put our investigational new drug application for our replacement therapy technology on clinical hold. This means that we may not begin human clinical trials under our application until the FDA gives us permission to do so. We have amended our investigational new drug application three times to respond to the FDA's concerns. We filed a new investigational new drug application in March of 2003. This investigational new drug application has also been placed on hold until we satisfy the FDA's safety concerns. If we are unable to resolve the FDA's concerns, we will not be able to proceed further to obtain regulatory approval for that technology. If we fail to obtain or maintain FDA clearance for one or both of our technologies we may have to cease operations.

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***5. 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 will have to cease operations.***



Our only two product candidates are in the preliminary development state. Although we have current data which indicates the promise of the concept of our replacement therapy and *mutacin* 1140 technologies, we can offer you no assurance that the technologies will be effective at a level sufficient to support a profitable business venture. If they are not, we will be unable to create marketable products, we will not generate revenues from our operations, and we will have to cease operations. The science on which our replacement therapy and *mutacin* 1140 technologies are based may also fail due to flaws or inaccuracies on which the data are based, or because the data is totally or partially incorrect, or not predictive of future results. The science upon which our business is based may prove to be totally or partially incorrect. Because our science may be flawed or incorrect, we may never be able to create a marketable product. If our science fails, we will not be able to create a marketable product. If we are unable to do so, we will not generate revenues, we will have to cease operations and you will lose your entire investment.

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

We intend to continue with research and development of our technologies for the purpose of obtaining regulatory approval to produce and market them. Research and development activities, by their nature, preclude definitive statements as to the time required and costs involved in reaching certain objectives. Actual costs may exceed the amounts we have budgeted and actual time may exceed our expectations. If research and development requires more funding than we anticipate, then we may have to reduce technological development efforts or seek additional financing from loans or the sale of our stock. 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. If we are unable to receive additional financing, you may lose all or a portion of your investment. Equity financing could result in substantial dilution to existing shareholders. We anticipate we will remain engaged in research and development for a considerable period of time.

***7. It is possible that our replacement therapy technology will be less effective in humans than it has been shown to be in animals. It is possible our mutacin 1140 technology will be shown to be ineffective or harmful in humans. If either of our technologies are shown to be ineffective or harmful in humans, we will be unable to generate revenues from them, and we will have to cease operations.***

Testing of our replacement therapy technology has to date been undertaken solely in animals. Those studies have proven our genetically altered strain of *S. mutans* to be effective in preventing tooth decay. It is possible that our strain of *S. mutans* will be shown to be less effective in preventing tooth decay in humans in clinical trials. If our replacement therapy technology is shown to be ineffective in preventing tooth decay in humans, we will be unable to commercialize and generate revenues from this technology. Testing of our antibiotic substance, *mutacin* 1140, has to date been undertaken solely in the laboratory. We have not yet conducted animal or human studies of *mutacin* 1140. It is possible that when we conduct these studies, they will show that *mutacin* 1140 is ineffective or harmful. If *mutacin* 1140 is shown to be ineffective or harmful, we will be unable to commercialize it and generate revenues from sales of *mutacin* 1140. If we are unable to generate revenues from either technology, we may have to cease operations.

***8. It is possible we will be unable to find a method to produce mutacin 1140 in commercial quantities. If we cannot, we will be unable to undertake the pre-clinical and clinical trials which are required in order to obtain FDA permission to sell it, and we will be unable to generate revenues from it, and we may have to cease operations.***

Our antibiotic technology, *mutacin* 1140, is a substance produced by our genetically altered strain of *S. mutans*. To date, it has been produced only in laboratory cultures. In order for us to conduct the pre-clinical and Phase I clinical studies which 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 at economical rates. We have not yet been able to find 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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***9. We must spend at least \$600,000 in 2003 and \$1 million annually following 2003 on development of our technologies under our license agreements with the University of Florida Research Foundation, Inc. We may be unable to raise the financing necessary to do so. We must also comply with certain other conditions of our licenses. If we do not, our licenses to our technologies may be terminated, and we may have to cease operations.***

We hold our replacement therapy and *mutacin* 1140 technologies under licenses from the University of Florida Research Foundation, Inc. Under the licenses, we must spend at least \$600,000 in 2003 and \$1 million in each calendar year following 2003 on development of those technologies before the first commercial sale of products derived from those technologies. If we do not, our licenses may be terminated. Until commercial sales of such products take place, we will not be earning revenues from the sale of products. We 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. We can offer you no assurance we will be able to raise the financing necessary to meet our obligations under our licenses. If we are not, we will lose our licenses to our technologies, and may 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. We can offer you no assurance that we will be able to comply with these conditions. If we are not, and if our license is terminated, our investment in development of our replacement therapy technology will become valueless, and you will lose all or a portion of your investment.

***10. 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 have to cease operations.***

The commercial success of our replacement therapy and *mutacin* 1140 licensed technologies, which have been developed through biotechnology, will depend in part on government and public acceptance of their production, distribution and use. Biotechnology has enjoyed and continues to enjoy substantial support from the scientific community, regulatory agencies and many governmental officials around the world (including in the United States). Future scientific developments, media coverage and political events may diminish such support. Public attitudes may be influenced by claims that health products produced with biotechnology are unsafe for consumption or pose unknown risks to the environment or to traditional social or economic practices. Securing governmental approvals for, and consumer confidence in, such products poses numerous challenges, particularly outside the United States. The market success of technologies developed through biotechnology, such as ours, could be delayed or impaired in certain geographical areas because of such factors. Products based on our technologies may compete with a number of traditional dental therapies and drugs manufactured and marketed by major pharmaceutical companies and other biotechnology companies. Market acceptance of products based on our technologies will depend on a number of factors, including potential advantage over alternative treatment methods. We can offer you no assurance that dentists, physicians, patients or the medical and dental communities in general will accept and utilize products developed from our technologies. If they do not, we will be unable to generate sufficient revenues from our technologies, which may cause us to have to cease operations.

***11. We may be exposed to product liability claims if products based on our technologies are marketed and sold. Because we have limited liability insurance coverage, 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, and upon the performance of your investment. Although we carry \$1,000,000 in general liability insurance, such insurance may not be sufficient to cover any potential liability. We could be sued for a large sum of money and held liable in excess of our liability coverage. If we cannot pay the judgment we may have to cease operations.

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

We intend to sublicense our licensed, patented technologies to pharmaceutical companies after completion of Phase I clinical studies. If we are successful in doing so, our sublicensees will pay the costs of Phase II and III clinical trials, and manufacture and market 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 can offer no assurance we would be able to obtain the necessary financing. If we are not, we may have to cease operations.

***13. There is uncertainty relating to favorable third-party reimbursement in the United States. If we can't obtain third party reimbursement for products based on our technologies, we may have to cease operations.***

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

***14. Although Dr. Jeffrey Hillman is our Chief Scientific Officer, he will devote only approximately 75% of his working time to the affairs of our company and he has agreed to assign to our company only those inventions that he may conceive or discover which relate to our existing proprietary intellectual rights. If he should conceive of or discover further inventions which do not relate to our existing intellectual property rights, we will not get the economic benefit of those inventions. If Dr. Hillman conceives of or discovers inventions which do not relate to our intellectual property rights which compete with our technologies, we may earn less revenue from our technologies.***

Dr. Jeffrey Hillman is responsible for having discovered our only two technologies and is, therefore, considered to be a key participant in our future research and development program relating to those technologies. Dr. Hillman will, however, be devoting only 75% of his working time to the affairs of our company. Dr. Hillman has agreed that only those new inventions that he discovers or conceives and which relate to our existing intellectual property rights will become our property. This means that Dr. Hillman is not required to transfer any new inventions that he discovers or conceives which do not relate to our existing intellectual property rights. If he should conceive of or discover further inventions which do not relate to our existing intellectual property rights, we will not get the economic benefit of those inventions. If Dr. Hillman conceives of or discovers inventions which do not relate to our intellectual property rights which compete with our technologies, we may earn less revenue from our technologies. As Dr. Hillman may be conducting research and development activities for the benefit of others, his personal interests and obligations to others may conflict with his obligations to act in the best interests of our company. If such a conflict arises, we may be exposed to liability to others and our ability to achieve our business objectives may be impaired.

***15. Because there is no public trading market for our common stock, you may not be able to resell your stock.***

There is currently no public trading market for our common stock. Therefore there is no central place, such as stock exchange or electronic trading system, to resell the shares comprised in the units and which may be obtained upon exercise of the Series A and B warrants. If you do want to resell your shares, you will have to locate a buyer and negotiate your own sale. The TSX Venture Exchange has conditionally approved the listing of our common stock. Listing will be subject to us fulfilling all of the requirements of the TSX Venture Exchange, including distribution of these securities to a minimum number of public securityholders. The Series A and B warrants are not transferable and will not be listed on any stock exchange.

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***16. Sales of shares of our common stock which are presently owned by our directors and officers and subject to escrow and other resale restrictions could reduce the market price of our common stock when the resale restrictions expire.***

On completion of this offering, the majority of our common stock will be owned by our directors and officers. The stock they own will be subject to escrow and other restrictions on resale. These restrictions will fall away as time passes. Once the restrictions fall away, our directors and officers may resell their shares in the market. If our controlling shareholders sell substantial amounts of shares upon release from escrow, this may reduce the market price of our common stock. The interests of our current management may conflict with your interests.

**17. Special Note Regarding Forward-Looking Statements** . This prospectus contains forward-looking statements that reflect our current views with respect to future events and financial performance. In some cases, you can identify forward-looking statements by words like "believe," "expect," "estimate," "anticipate," "intend," "project," "plan," "may," "should," "potential" and "continue." These statements are only predictions, and apply only as of the date of this prospectus. You should not consider that they are made with certainty. These statements are subject to risks and uncertainties, including those set out above and others, that could cause actual results to differ materially from historical results or our predictions. Although we believe that the expectations referred to in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We are under no duty to update forward-looking statements to conform them to actual results after the date of this prospectus.

**You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. This prospectus may only be used where it is legal to sell these securities. The information contained in this prospectus may only be accurate on the date of this prospectus.**

#### USE OF FUNDS AVAILABLE

Our offering is being made in the Canadian provinces of British Columbia and Alberta through our underwriter, Haywood Securities Inc. We have agreed to pay Haywood a commission of 7.5% of the gross proceeds of the sale of the units, and to reimburse Haywood for its reasonable expenses in connection with the offering. We have also agreed to issue shares and warrants to Haywood, as described under "Plan of Distribution." In addition to Haywood's commission, we anticipate incurring further expenses in connection with the offering of \$350,000. Our estimated working capital deficit at April 30, 2003 is \$(284,000). Our estimated working capital deficit together with the net proceeds of our offering yields the funds available to us.

The table below sets forth the calculation of the amount of our available funds.

Gross Proceeds	\$	3,000,000
Commission		225,000
Offering Expenses		350,000
		<hr/>
Net Proceeds		2,425,000
+Working Capital Deficit at <u>April 30, 2003</u>		(284,000)
		<hr/>
=Funds Available to us	\$	2,141,000
		<hr/>

We will use our available funds as follows:

Our available funds will be used to pay the commission and offering expenses, to fund the costs of certain of the pre-clinical and clinical trials of our technologies we must undertake before we can obtain FDA approval to sell products based on our technologies, and for working capital.

The amounts we will pay from our available funds for expenses of the offering are: \$885.50 for SEC filing fees; \$1,500 (estimated) for Alberta and British Columbia Securities Commission filing fees; \$8,500 (estimated) for TSX Venture Exchange listing fees; \$50,000 for Haywood's expenses, \$225,000 (estimated) for United States and Canadian legal fees; \$4,000 for printing our prospectus; \$50,000 for accounting fees; \$2,000 for our transfer agent and warrant agent fees; and \$8,114.50 for miscellaneous unforeseen expenses relating to the offering.

We will use our available funds as follows:

\$100,000 to the University of Florida for patent expenses; \$75,000 for regulatory consulting firm fees; \$50,000 for peptide production research and \$126,000 for 14 months salary (including payroll taxes and benefits) of a scientist we intend to hire to help us develop a method of producing *mutacin* 1140 in commercial quantities; \$140,000 for pre-clinical studies relating to our replacement therapy technology ( this sum includes additional pre-clinical animal studies estimated to cost approximately \$40,000 which the FDA will require us to perform in order to lift the clinical hold on

our new investigational drug application) and \$250,000 for pre-clinical studies relating to our *mutacin* 1140 technology; \$370,000 for the costs of Phase I clinical trials for our replacement therapy technology; and \$20,000 for the costs of the investigational new drug application we intend to make for our *mutacin* 1140 technology.

The table below sets forth the use of our available funds:

Patent expenses paid to University of Florida		\$	100,000	
Regulatory:				
Consulting Fees	\$	75,000		75,000
<i>Mutacin</i> 1140 production research:				
peptide production research		50,000		
Salary (including related taxes and benefits):		126,000		
production scientist (14 months)				176,000
Pre clinical research:				
replacement therapy		140,000		
<i>mutacin</i> 1140		250,000		
				390,000 [1]
Clinical trials for replacement therapy:				
Phase I trials		370,000		
				370,000 [1]
<i>Mutacin</i> 1140 investigational new drug application				20,000
General and administration costs for one and one-half years:				
Salaries		573,000	[2]	
Legal and accounting fees		210,000		
Rent and utilities		54,000		
Insurance		42,000		
Other costs		56,000		
				935,000
Working capital reserve				75,000
				2,141,000
Payment of costs incurred causing working capital deficit[3]				284,000
Net Proceeds			\$	2,425,000

[1] These sums together include salary of \$120,000 payable to Dr. Jeffrey Hillman

[2] Includes salary of \$180,000 payable to Mento A. Soponis and \$100,000 payable to Paul A. Hassie

[3]

Principal and interest on \$100,000 principal amount note dated Feb. 14, 2003 payable to Cornet Capital Corp. payable on the earlier of demand and one year from date of note with interest at 10% per year, and \$75,000 principal amount note dated April 29, 2003 payable to Cornet Capital Corp. one year from the date of note with interest of 10% per year, (see Liquidity and Capital Resources on page 40). \$ 192,500

Deferred compensation to officers as follows: 91,500 (of \$143,000)

Mento A. Sponis	\$	68,500
Jeffrey Hillman		20,000
Paul Hassie		<u>3,000</u>
		91,500
	\$	<u>                    </u>

(see Limited Operating History: Need for Additional Capital on page 36.

\$ 284,000

On March 19, 2003, we submitted a new investigational new drug application in respect of a strain of our licensed, patented strain of *S. mutans* we have modified to address FDA concerns with our previous investigational new drug application in respect of our replacement therapy technology. The FDA has put our new investigational drug application on clinical hold, pending redesign of certain experimental protocols, completion of the final animal study, and completion of new pre-clinical animal toxicity studies and studies demonstrating complete eradication of our new strain of *S. mutans* from test animals. We will have to amend our new investigational drug application to describe the new protocols and the results of these studies. If upon review of the amendment to our new investigational drug application, the FDA has further objections to the commencement of human clinical trials, we will undertake additional animal studies in order to meet their objections. We will continue with the present development program for *mutacin* 1140.

If the FDA ultimately denies us permission to conduct human clinical trials for our replacement therapy technology, we will aggressively pursue the in-licensing of one or more new technologies from the University of Florida and other Universities. We will re-direct any remainder of the funds presently devoted to the salary of the clinical trials manager, and to clinical trials for replacement therapy, toward expenses in connection with pursuing such in-licensing.

#### **DETERMINATION OF OFFERING PRICE**

Before this offering, there has been no public market for our common stock. The price of the units we are offering was determined by negotiation between ourselves and Haywood in order for us to raise \$3,000,000 in this offering. The offering price bears no relationship whatsoever to our assets, earnings, book value or other criteria of value, and we cannot assure you will be able to resell the shares of common stock comprised in the units, or any shares of common stock you may obtain upon exercise of the Series A or B warrants, above the offering price of the units or at all. Among the factors considered were:

- \* our lack of operating history
- \* the proceeds to be raised by the offering
- \* the amount of capital to be contributed by purchasers in this offering in proportion to the amount of stock to be retained by our existing shareholders, and
- \* our relative cash requirements.

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#### **RESALE OF OUTSTANDING COMMON STOCK, DIVIDEND POLICY AND NUMBER OF SHAREHOLDERS**

No issued and outstanding shares of our common stock are subject to options to purchase or warrants and none of our outstanding securities are convertible into shares of common stock with the exception of 315,000 options to acquire 315,000 shares of common stock at an exercise price of \$1.25 per share. The options expire on September 19, 2007

9,425,704 of our outstanding shares of common stock could be sold pursuant to Rule 144 of the Securities Act of 1933. We have agreed to register 625,000 shares of our common stock under the Securities Act of 1933 upon the occurrence of certain events which have yet to take place. These events are referred to under "Recent Sales of Unregistered Securities." We have also agreed to register the 599,940 shares we issued to the University of Florida Research Foundation, Inc. upon its request, if we determine to register any other of our shares under the United States Securities Act of 1933. The University of Florida Research Foundation, Inc. has waived those rights with respect to this offering. See "Description of Securities: Registration Rights."

We are not offering or proposing to offer publicly any shares of our common stock other than those comprised in the units and which may be obtained upon exercise of the warrants which are being sold under this registration statement.

We have not declared any cash dividends, nor do we intend to at this time. We are not subject to any legal restrictions respecting the payment of dividends, except that we may not pay dividends if the payment would render us insolvent. Our future dividend policy will be based on our cash resources and needs. We do not anticipate declaring dividends for the foreseeable future, as we anticipate that all our available cash will be needed for our operations.

There are presently 15 holders of record of our common stock.

### CAPITALIZATION

Our authorized capital is 100,000,000 shares of common stock with par value of \$.001 per share, and 20,000,000 shares of preferred stock without par value, of which 9,425,704 shares of common stock and no shares of preferred stock are outstanding at April 30, 2003.

The following table sets forth our capitalization at December 31, 2002 on a historical basis and as adjusted to reflect the sale of the shares comprised in the units and the issuance of 100,000 shares of common stock to Haywood.

This table should be read in conjunction with the section entitled, Management's Discussion and Analysis of Financial Condition and Plan of Operations, our Financial Statements and Notes, and other financial and operating data included elsewhere in this prospectus.

	12/31/2002	As Adjusted After Offering
<b>Stockholder's Equity (Deficit):</b>		
Common Stock: 100,000,000 shares authorized par value \$0.001		
9,425,704 issued and outstanding	\$ 9,426	
11,925,704 issued and outstanding		\$ 11,926
Additional Paid-in Capital	628,234	3,050,734
Accumulated Deficit	(721,142)	(721,142)
<b>TOTAL STOCKHOLDERS' EQUITY (DEFICIT)</b>	<b>\$ (83,482)</b>	<b>\$ 2,341,518</b>

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### DILUTION OF THE PRICE YOU PAY FOR YOUR SHARES

Dilution represents the difference between the offering price and the net tangible book value per share immediately after completion of this offering. Net tangible book value is the amount that results from subtracting total liabilities and intangible assets from total assets. Dilution arises mainly as a result of our arbitrary determination of the offering price of the units. Dilution of the value of the shares comprised in the units you purchase is also a result of the lower book value of the shares held by our existing stockholders.

As of December 31, 2002, the net tangible book value of our shares of common stock was \$(83,482) or approximately \$(0.01) per share based upon 9,425,704 shares outstanding.

Upon completion of this offering, the net tangible book value of the 11,925,704 shares which will be outstanding will be \$2,341,518, or approximately \$0.20 per share. The amount of dilution you will incur will be \$1.05 per share. The net tangible book value of the shares held by our existing stockholders will be increased by \$0.21 per share without any additional investment on their part. You will incur an immediate dilution from \$1.25 per share to \$0.20 per share.

After completion of this offering, you will own approximately 20.1% of the total number of shares then outstanding, shares for which you will have made a cash investment of \$3,000,000, or \$1.25 per share. This will represent 78.5% of the total investment in our company. Our existing stockholders will own approximately 79.0% of the total number of shares then outstanding, for which they have made contributions of cash, services and other assets totaling \$822,860 or approximately \$0.09 per share. This will represent 21.5% of the total investment in our company.

The foregoing figures assume that none of the Series A and B warrants comprised in the units, or any of Haywood's warrants, will be exercised, and that none of our existing stock options will be exercised.

The following table compares the differences of your investment in our shares with the investment of our existing stockholders.

**Existing Stockholders:**

Price per unit	\$	1.25
Net tangible book value per share before offering	\$	(0.01)
Gain to existing shareholders	\$	0.21
Net tangible book value per share after offering	\$	0.2
Increase to present stockholders in net tangible book value per share after offering	\$	0.21
Capital contributions	\$	-0-
Number of shares outstanding before the offering		9,425,704
Number of shares after offering held by existing stockholders		9,425,704
Percentage of ownership after offering		79.0% [1]

[1] Does not include 100,000 shares of common stock we will issue to Haywood as part of its compensation.

**Purchasers of Units in this Offering:**

Price per unit	\$	1.25
Dilution per share	\$	1.05
Capital contributions	\$	3,000,000
Number of shares after offering held by public investors		2,400,000
Percentage of ownership after offering		20.1%

**PLAN OF DISTRIBUTION: TERMS OF THE OFFERING**

We are offering through our underwriter, Haywood Securities Inc., 2.4 million units, at a price of \$1.25 per unit. Our offering will be made only in the Canadian provinces of British Columbia and Alberta. Each unit consists of one share of common stock of our company, one half of one non-transferable Series A warrant and one half of one non-transferable Series B warrant. One whole Series A warrant may be exercised for 6 months from the date of closing of the offering to acquire a further share of common stock at a price of \$2.00 per share. One whole Series B warrant may be exercised for 9 months from the closing date to acquire a further share of common stock at \$3.00 per share. Whole warrants only may be exercised. We will not allow the issuance of fractional shares of common stock. For so long as our United States registration statement remains effective, this prospectus qualifies the issue of shares of our common stock upon exercise of the Series A and B Warrants in the United States.

We have entered into an agency agreement dated March 28, 2003 with Haywood. Haywood has agreed to offer our units for sale to the public in British Columbia and Alberta. Our offering is a "best efforts" offering, on an "all or none" basis. Although Haywood has agreed to use its reasonable commercial efforts to sell the units, it is not obliged to purchase any units which are not sold. We will pay Haywood a sales commission equal to 7.5% of the selling price for each unit sold to an investor under our offering. We will issue to Haywood 500,000 warrants, each exercisable for two years from the closing date to purchase one share of our common stock, at a price of \$1.25 per share. We will also issue 100,000 shares of our common stock to Haywood under the agency agreement. We have agreed to reimburse Haywood for its reasonable expenses in connection with our offering, regardless of whether it is completed. If the offering is not completed, we will not pay Haywood any compensation. In that event, we do not know how we will reimburse Haywood's expenses. For so long as our United States registration statement remains effective, this prospectus qualifies the resale of the shares we will issue to Haywood, and the shares which may be acquired on exercise of the warrants we will issue to Haywood, by Haywood in the United States.

Haywood's warrants, the underlying shares of common stock and the 100,000 shares of common stock we will issue to Haywood are included in this registration statement, and we have promised to cause this or another registration statement to remain effective until the earlier of the time all of such securities are sold and 18 months from the date of closing of our offering. Haywood will only sell its 100,000 shares of common stock and the shares of common stock underlying its warrants pursuant to its prospectus delivery requirements.



Haywood may form a selling group of Canadian registered investment dealers to assist with sales of the units as subagents. No selling group members will be members of the National Association of Securities Dealers in the United States. Haywood will pay selling group members 6% of the 7.5% cash commission payable in respect of sales by selling group members, and 72% of the warrants issuable to Haywood in connection with such sales. All compensation paid to members of the selling group will be paid from Haywood's compensation. No additional compensation will be payable by us to members of the selling group. The offering will commence on the effective date of this registration statement, which will occur concurrently with or after the date of issue of a Mutual Reliance Review System Decision Document evidencing the issue of receipts for the Canadian prospectus in Alberta and British Columbia by the British Columbia Securities Commission, and will continue for a period of 90 days from the date of issue of an MRRS Decision Document. We expect those dates to occur at approximately the same time. We expect that the offering will be closed on or about \_\_\_\_\_, 2003. The offering must be completed within 90 days from date of issuance of an Mutual Reliance Review System decision document for the Canadian prospectus, unless such time period is extended by the British Columbia Securities Commission. Completion of our offering is subject to obtaining subscriptions for all of the units. Those who wish to participate in our offering must open accounts with Haywood or members of its selling group, and deposit the purchase price of the units they wish to purchase into their accounts. Subscription funds will not be held in escrow; rather, they will be withdrawn from client accounts on the day of closing. If subscriptions are not obtained for all the units, no funds will be withdrawn from client accounts and amounts deposited will continue to show as credits to the account until otherwise utilized or withdrawn.

Haywood may terminate its obligations under the agency agreement, and Haywood may withdraw all subscriptions on behalf of investors, at its discretion, on the basis of Haywood's assessment of the state of the financial markets or upon the occurrence of the following: if any order to cease or suspend trading in our securities, or prohibiting or materially restricting the distribution of any of the securities which are the subject of this offering, is issued or announced or commenced by any competent regulatory authority not based solely on activities or alleged activities of Haywood which is not rescinded, revoked or withdrawn; if any inquiry, investigation (formal or informal) or other proceeding in relation to us or any of our directors or senior officers is

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announced or commenced by any securities regulatory authority or stock exchange which, in Haywood's discretion, materially adversely effects the trading or distribution of the securities which are the subject of our offering; if there is any adverse material change, financial or otherwise, in our assets, liabilities, business, condition, capital or prospects (financial or otherwise), as determined by Haywood in its discretion; if, in Haywood's opinion, it would be impracticable or unprofitable to continue to offer the securities which are the subject of our offering for sale; if any financial occurrence or event of national or international consequence or governmental action, law, or regulation or other occurrence of any nature whatsoever which, in Haywood's opinion, would seriously or adversely affect the market for the securities which are the subject of this offering or our business should develop or occur; or if we are in breach or non-compliance in any material respect with any representation, warranty, term or condition of our agency agreement with Haywood.

Pursuant to the agency agreement, we have agreed to indemnify Haywood in respect of all losses, claims, damages or liabilities which Haywood may become subject under the United States *Securities Act* of 1933, the United States *Securities Exchange Act* of 1934, or the British Columbia and Alberta *Securities Acts*, if they arise out of or are based upon our breach of any representation or warranty of ours contained in the agency agreement or the Series A and B warrant indenture, or our failure to comply with any of our obligations under those agreements, or any untrue statement or alleged untrue statement of a material fact contained in this registration statement or the Canadian prospectus, or in any amendment or supplement to those documents, or our omission or alleged omission to state in those documents a material fact required to be stated in them, or which is necessary to make the statements contained in them not misleading.

Haywood has informed us that it does not expect to confirm sales of units offered under this prospectus to any accounts over which it exercises discretionary authority.

Applicable United States securities laws require that we register the shares which you may acquire upon exercise of your Series A and B warrants and the shares which Haywood may acquire on exercise of the warrants we will issue to it, or use an available exemption in order to legally issue them. We have promised in our agency agreement with Haywood to keep this registration statement effective for the term of such warrants; however, we can offer you no assurance that we will be able to do so. If we are not able to do so, you may be unable to exercise your warrants. If you

are not able to exercise your warrants, you will lose a portion of your investment.

The TSX Venture Exchange has conditionally approved the listing of our common stock. Listing will be subject to us fulfilling all of the requirements of the TSX Venture Exchange, including distribution of these securities to a minimum number of public securityholders. We do not intend to list our common stock on any exchange or quotation system in the United States. **Our Series A and B warrants are non-transferable and will not be listed on any stock exchange or quotation service.**

Haywood Securities (USA) Inc. is a wholly-owned subsidiary of Haywood, and is a member of the National Association of Securities Dealers. Neither Haywood Securities (USA) Inc. nor any other member of the National Association of Securities Dealers is participating in this offering.

### **Section 15(g) of the Exchange Act**

Our shares of common stock are covered by the "penny stock" rules under Section 15(g) of the Securities Exchange Act of 1934, as amended, and the related rules of the SEC. They impose additional sales practice requirements on United States broker/dealers who sell our securities. These rules require, among other things, that a broker engaging in a transaction in our securities provide its customers with:

- \* a standardized risk disclosure document;
- \* current quotations or similar price information;
- \* disclosure of the amount of compensation or other remuneration received by the broker and its sales persons as a result of the penny stock transactions; and
- \* monthly account statements.

The broker must provide the bid and offer quotations and compensation information before effecting the transaction. This information must be contained in the customer's confirmation.

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

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

## **BUSINESS**

### **Corporate**

Oragenics, Inc. was incorporated under the laws of Florida on November 6, 1996. We commenced operations in 1999. Our registered office is located at 4730 S.W. 103rd Way, Gainesville, Florida 36208, and our head office is located at 12085 Research Drive, Alachua, Florida 32615.

We amended our articles of incorporation on May 8, 2002, in order to change our name from Oragen, Inc. to Oragenics, Inc. and to increase our authorized capital from 100,000 shares of common stock to 100,000,000 shares of common stock and 20,000,000 shares of preferred stock.

### **General**

We are a biotechnology research and development company created and operating to attempt to commercialize two new technologies. Our licensed, patented replacement therapy technology may prove to be a new treatment for human tooth decay. Before products incorporating our licensed, patented technologies may be produced or sold in the United States, we must obtain FDA approval. If we are successful in obtaining regulatory approval, for one or both of our licensed, patented technologies, we will attempt to license other technologies, from the University of Florida or elsewhere, to which we believe members of our team such as Dr. Hillman can add value.

### **Federal Food and Drug Administration 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 any products we may develop.

### **General**

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

1. pre-clinical laboratory and animal tests
2. investigational new drug application
3. clinical trials (Phases I, II and III)
4. pharmaceutical development
5. new drug application (review and approval)
6. 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.

### **Pre-Clinical Trials and Investigational New Drug Application**

Pre-clinical 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 pre-clinical 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. Submissions of an investigational new drug application may not result in FDA approval to commence clinical trials. See "Regulatory Status" below.

### **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 I trials generally involve 20-40 people at an estimated cost of \$10,000 per patient, taking six months to one year to complete.

## **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 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 pre-clinical and human clinical trials 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.

### **Our Business Strategy**

For our business to become profitable and competitive, our technologies must be approved for production and sale by the FDA. Our present strategy for financing the clinical trials which will be necessary as part of the FDA approval process involves conducting the research and development work in respect of our technologies through Phase I clinical trials. Assuming we complete Phase I clinical trials successfully, we intend to sub-license our licensed, patented technologies to pharmaceutical companies, which would be responsible for completing Phase II and III clinical trials and for undertaking the new drug applications. We anticipate that such sub-licenses would provide for payment of fees to us, a portion of which would be payable upon execution and the balance of which would be payable upon achievement of product development milestones, and for payment to us of royalties from sales. This strategy would serve to avoid the high costs of Phase II and III trials we would otherwise have to pay, and generate revenues from our technologies sooner than if we conducted those trials ourselves. There can be no assurance that we will be able to enter into such sub-licenses on terms favorable to us, or at all.

If we are successful in sublicensing one or both of our technologies, we intend to seek to license promising new technologies in our fields of expertise. We hope to be able to obtain licenses of other technologies firstly from the University of Florida, with which a number of our directors and officers have a strong relationship, and secondly from other universities.

### **Our Technologies**

#### **Replacement Therapy**

##### ***Background***

Our licensed, patented replacement therapy technology is the fruit of 25 years of research by our founder and chief scientific officer, Dr. Jeffrey Hillman. In the course of his research at Forsyth Dental Center and the University of Florida, Dr. Hillman isolated a strain of a species of bacteria naturally resident on teeth with the ability to out compete and displace other strains of that species. The strains of that species typically found on teeth produce lactic acid, which causes tooth decay. Dr. Hillman, through recombinant DNA technology, succeeded in replacing a gene in the strain of bacteria with the ability to out-compete. That gene is responsible for producing lactic acid. Dr. Hillman replaced it with a gene that causes that strain to produce other harmless, non-decay-causing substances. The University of Florida has obtained a patent in respect of that genetically altered strain, and we have obtained an exclusive license of that patent from the University of Florida. Our replacement therapy technology may prove to be a new treatment for human tooth decay.

In 2000, we entered into a sponsored research agreement with respect to our replacement therapy technology. Under that agreement, we were paid \$357,787 in respect of research and development costs. The agreement allowed our sponsor the exclusive option to negotiate a sublicense of our replacement therapy technology. Our sponsor did not exercise the option, and it has expired. We have had no further discussions or negotiations with the sponsor since the agreement expired.

### **Market Opportunity**

The dental care market in the United States is \$58 billion annually. Of this sum, a considerable portion is related to tooth decay. Since the introduction of fluoride, no significant technology has been introduced to prevent tooth decay. Our licensed, patented replacement therapy technology may prove to be the first new treatment for human tooth decay in many years.

## Technical Background

Many different types of bacteria reside in everyone's mouth. *Streptococcus mutans* (*S. mutans*) is a bacteria that resides on nearly everyone's teeth. This bacteria converts sugar that we eat into lactic acid. Lactic acid erodes the tooth's enamel and causes the great majority of tooth decay. Our replacement therapy technology consists of a genetically modified strain of *S. mutans* that does not produce lactic acid. Our strain of *S. mutans* produces tiny quantities of a substance known as *mutacin* 1140, which allows our strain to out-compete the strain of *S. mutans* which is naturally resident on a person's teeth. Our strain eliminates the resident strain of *S. mutans* and replaces it in the mouth. It will be administered as a pharmaceutical composition by dentists in office visits. Because our strain out-competes resident strains on teeth, one treatment may last for a long time. Preliminary studies conducted by our Chief Scientific Officer, Dr. Jeffrey Hillman have shown our Replacement Therapy technology to be effective and non toxic in animals.[5] We hope that further testing will confirm these results. We have not yet conducted human clinical trials.

## Animal Studies

Dr. Jeffrey Hillman, Our Chief Scientific Officer, and others have conducted animal studies of the effectiveness of our replacement therapy technology in rats at the Forsyth Institute, the University of Florida and our company from 1976 to 2002.[6] In the most recent of these studies, our strain of *S. mutans* and wild-type strains of *S. mutans* were grown in culture in the presence of sugar. After careful analysis of the culture, it was found that the wild strain made lactic acid almost exclusively from the metabolism of sugar. It also made very small amounts of other acids and the non-acidic compounds, ethanol and acetoin. By contrast, our strain made mostly the non-acidic compounds, ethanol and acetoin, from metabolism of the sugar. Our strain produced absolutely no detectable lactic acid. We then infected 2 identical groups of conventional rats with either the wild strain or our strain. A third identical group of rats was not infected and served as a control group. After feeding the rats a diet containing sugar for 8 weeks, the teeth of the rats were carefully inspected to determine their incidence and severity of tooth decay. It was found that animals infected with our strain had no more tooth decay than did the control group animals. Both the group infected with our strain and the control group had only half the tooth decay experienced by the wild strain.

Dr. Hillman and others also conducted a 6 month toxicity study in rats. They infected a group of rats with our licensed, patented strain of *S. mutans*. No gross or histological side effects were found during colonization of the rats over this prolonged period.

These studies provide scientific evidence of the effectiveness of our licensed, patented strain of *S. mutans* in preventing tooth decay, and of its non-toxicity, in animals.

## Manufacturing

The manufacturing methods for producing our strain of *S. mutans* to be used in our replacement therapy technology will be standard fermentation methods. These involve culturing bacteria in large vessels, and harvesting them when mature by centrifuge or filtration. The cells will then be suspended in a pharmaceutical medium appropriate for application in the human mouth. These methods are commonplace and readily available within the pharmaceutical industry. We intend to sub-license our replacement therapy technology to a pharmaceutical company after completion of Phase I clinical studies. If we are successful in doing so, the sub-licensee company will manufacture and market our replacement therapy technology.

## Method of Administration

We expect, if we are successful in obtaining the necessary regulatory approvals, that the product based on our replacement therapy technology will be a liquid rinse which will be applied to a patient's teeth by a dentist. We expect that it will be available by prescription only.

[5] Hillman et al, Construction and Characterization of an Effector Strain of *Streptococcus mutans* for Replacement Therapy of Dental Caries, *Infection and Immunity* (2000) Vol.68, No. 2.

[6] Hillman et al, Construction and Characterization of an Effector Strain of *Streptococcus mutans* for Replacement Therapy of Dental Caries, *Infection and Immunity* (2000) Vol.68, No. 2

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## Competition

We do not know of any direct competitors with our licensed, patented replacement therapy technology. We understand that certain companies have been researching vaccines to inhibit the growth of *S. mutans*. However, every vaccine has drawbacks, including induced-heart-reactive antibodies in animals. Major studies would be required to establish that elimination of naturally occurring bacteria such as *S. mutans* from the mouth will not create serious, unintended consequences. 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. Many of our potential competitors in these areas 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 tooth sealants and fluoride treatments administered by dentists, and fluoride based toothpastes. Some of our competitors will include Colgate, Procter & Gamble, Unilever, GlaxoSmithKline and Dentsply. All of these companies are much larger and have far greater technical and financial resources than us. It is our intention to compete in the market for dental care products by obtaining a strategic partner with a dedicated sales force in the dental office market. There can be no assurance we will be able to obtain any such partner. If we are unable to secure such a strategic partner, we will seek to enter into a contract manufacturing arrangement with a pharmaceutical manufacturing company, and to enter into distribution agreements with dental product distributing companies. There can be no assurance we will be able to enter into any such arrangement.

### **License**

We hold our patented replacement therapy technology under license from the University of Florida Research Foundation Inc. The license is dated August 4, 1998. It was amended on September 15, 2000, July 10, 2002, September 25, 2002 and March 2003. It provides us with an exclusive world wide license to make, use and sell products and processes covered by patent no. 5,607,672. This patent covers the genetically altered strain of *S. 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 we make to the products and processes covered by the patent. Our license is for the period of the patent, subject to the performance of terms and conditions contained therein. The patent is dated March 4, 1997, and will expire on March 3, 2014.

Under the license, we have entered into an Equity Agreement with the University of Florida Research Foundation, Inc. under which we have issued as partial consideration for our license 599,940 shares of our common stock which is 6.4% of our total outstanding shares as of December 31, 2002. We are obligated to pay 5% of the selling price of our products to the University of Florida Research Foundation, Inc. If we sublicense the license, we are obligated to pay 20% of all amounts we receive from the sublicensee to the University of Florida Research Foundation, Inc. On December 31, 2005 and each year thereafter we are obligated to make a minimum royalty payment of \$50,000. We are obligated to spend or cause to be spent at least an aggregate of \$600,000 in 2003 and an aggregate of \$1,000,000 in each calendar year following 2003 on the research, development and regulatory prosecution of our replacement therapy and *mutacin* 1140 technologies together, 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 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 must pay \$100,000 for the patent expenses when we have received at least \$1,000,000 in external funding. We will make this payment from the proceeds of this offering.

Further, we are required to maintain liability insurance coverage appropriate to the risk involved in marketing the products. We have obtained liability insurance in the amount of \$1,000,000.

### **Intellectual Property Matters**

We do not hold any patents on our replacement therapy technology. Our rights to this technology flow from our license with the University of Florida Research Foundation, Inc.

We received notification from B.C. International Corporation on July 29, 2002 that a gene utilized in our licensed, patented strain of *S. mutans* infringes a patent which it holds under a license. Their notification did not state that they intended to pursue legal remedies. Management of our company does not believe the gene in question infringes that patent. We have sent them correspondence setting out our position. We have heard nothing further from them.

### **Regulatory Status**

We submitted an investigational new drug application for our replacement therapy technology in 1998. The FDA placed our application on clinical hold on December 3, 1998 pending resolution of concerns related to transmission of our genetically modified strain of *S. mutans* by those treated with it to others who have not been treated with it, possible mutation of our strain to an acid-producing strain, and the possibility of genetic transmission of the ability to produce *mutacin* 1140 from our strain to other forms of bacteria which occur naturally in human beings. The clinical hold order was issued because the FDA believed our application did not contain sufficient information to allow it to assess the risks to the subjects in our proposed human clinical studies. We may not commence Phase I human clinical studies of our replacement therapy technology until the clinical hold is lifted. We have amended our first investigational new drug application three times to respond to the FDA's concerns. We filed a new investigational new drug application in March of 2003. This investigational new drug application has also been placed on hold until we satisfy the FDA's safety concerns. As a result of the research and development work we have done to respond to the FDA's concerns, we have gained valuable knowledge about the use and administration of our replacement therapy technology.

On October 23, 2000, we met with representatives of the FDA's Center for Biological Evaluation and Research to discuss their concerns. At that meeting, we and the Center's representatives discussed design of the pre-clinical experiments which the FDA would require in response to the clinical hold. We agreed with the FDA to perform such experiments, and that the Center will review the results from the experiments in a timely manner. We agreed with the FDA that when we again amended our investigational new drug application to submit the results from those experiments to the Center, it would consider that a complete response to the clinical hold. If the results of the experiments are positive, the Center will have our proposed clinical studies reviewed by the Vaccines and Related Biological Product Committee, an advisory committee for safety. If the Center and the Committee conclude our proposed clinical studies are safe, our application will be granted and we will commence Phase I trials of our replacement therapy technology.

In order to address the FDA's concerns, we developed a modification of our licensed, patented strain of *S. mutans*. The modified strain has a nutritional requirement for a substance known as D-alanine. If D-alanine is withdrawn from its diet, it will die. Conceptually, because of the nutritional requirement of our modified strain, if it is transmitted to those who have not been treated with it, it will die, unless D-alanine is administered regularly. D-alanine will be supplied to the trial subjects with mouth rinse. D-alanine is not normally found in the human diet, which is why it has been selected for our study as a potential recall mechanism. The maintenance system will be by regular mouth rinse, the amount and frequency of which will be determined in the clinical trials. We designed pre-clinical animal experiments with the modified strain to those not treated with it were demonstrated to be very low. Transfer of DNA from our strain to other strains were shown to be statistically extremely low because of the genetic modification made to prevent any DNA transfer. In the rat animal model used, total eradication was not achieved even when D alanine was removed from the diet. This occurred because the rats were able to feed our strain with D-alanine obtained through cross-feeding from bacteria in their feces, which the rats consumed, and reviewed them with our regulatory consultant. We commenced these studies in 2001. The results of the studies can be summarized as follows. The modifications to produce D-alanine dependence had no effect on the modified strain's production of lactic acid or *mutacin* 1140, which suggests that the modified strain compares identically to our original strain with respect to its ability to out compete natural strains and non-production of tooth decay. No adverse side effects were observed in laboratory rats infected with the modified strain, and exposed to D-alanine in their drinking water, for five months. The potential for reversion of the modified strain to lactic acid production and for transmission of the modified strain to those not treated with it were demonstrated to be very low. In the animal model used, total eradication was not achieved.



On March 19, 2003, we submitted a new investigational new drug application to the FDA in respect of our newly modified strain of our licensed, patented strain of *S. mutans*. It incorporates our previous investigational new drug application by reference. Our new investigational drug application refers to the final animal study and indicates that results from that study will be submitted as an amendment when it is complete. On April 18, 2003, the FDA notified us by telephone that it was placing our new investigational new drug application on clinical hold. We spoke again by telephone with the FDA on April 30, 2003. The FDA has indicated that, in order to lift the clinical hold, it wants certain of the experimental protocols for our human clinical trials described in our new investigational new drug application redesigned to include a full physical examination of subjects' spouses, and to include more extensive testing of subjects' spouses. The FDA will also require completion of the final animal toxicity study, and will require additional pre-clinical animal toxicity studies in which our newly modified strain of *S. mutans* and D-alanine are ingested by rats together and separately, and studies demonstrating total eradication of our newly modified strain of *S. mutans* from test animals. The FDA indicated to us that it expects to issue a formal letter outlining its requests within approximately 3 weeks of April 30, 2003, and that it is willing to meet with us to discuss possible animal models for the studies demonstrating total eradication of our newly modified strain that would be satisfactory. The cost of redesign of our experimental protocols will not be material. We estimate that the cost of the additional pre-clinical animal toxicity studies and the studies demonstrating total eradication of our strain will be approximately \$20,000 each. We will require the proceeds of this offering to complete the final studies and amend our investigational new drug application to submit the results from the final animal toxicity study, the redesign of our experimental protocols, and the additional pre-clinical animal studies. We hope to complete the additional studies in January 2004. The FDA's primary safety concern is the theoretical risk of our strain reverting to acid production or of its DNA being transferred to other naturally occurring organisms. Until the FDA is satisfied this theoretical risk is not a safety threat, the FDA will want to see total eradication of the strain from clinical subjects following the first human studies. Before approving our IND, the FDA will submit our application and protocol to the FDA's Vaccines and Related Biological Product Committee or the National Institute of Health's Recombinant DNA Advisory Committee for their recommendations regarding concerns of release of the bacteria into the environment.

If the FDA approves our investigational new drug application, we will be permitted to commence human clinical trials of our licensed, patented replacement therapy technology. The cost per patient is estimated at \$10,000.

Our patient estimate for each phase of the clinical trial process for the replacement therapy technology is:

Phase I	Phase II/III
24-30	3,000

### **Milestones**

- 1 Meet with the FDA to reach agreement on the additional pre-clinical animal studies required to satisfy the issues raised by the FDA's clinical hold of our IND. We hope to do this by the end of June 2003. We expect to pay our regulatory consultants fees of \$75,000 in connection with our discussions and interactions with the FDA.
- 2 Complete the required additional pre-clinical studies. We hope to complete these studies by the end of January 2004, at an estimated cost of \$140,000 for the studies and associated research personnel.
- 3 Complete Phase I clinical trials. We expect to do this within fourteen months of the closing of this offering, and we expect the total cost to be \$370,000.
- 4 Enter into a sub-licensing agreement with one or more major pharmaceutical companies. Assuming favorable results from our Phase I clinical trials, we hope to do this within eighteen months of the closing of this offering.

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## **Mutacin 1140**

### **Background**

Our second licensed, patented technology is *mutacin* 1140, an antibiotic peptide which is produced by our strain of *S. mutans*. It was discovered by Dr. Hillman in the course of his research into our replacement therapy technology. It is a broad spectrum antibiotic which has demonstrated potency, in laboratory studies against all Gram-positive bacteria against which it has been tested.[7] The testing was conducted by our Chief Scientific Officer and director, Dr. Jeffrey Hillman, who is also the majority shareholder of our company, together with others at the University of Florida and at our laboratories in 1998 and 1999.

## Introduction to Antibiotics

Before the development of effective modern antibiotics, serious bacterial infections were as feared as AIDS is today. Since development of antibiotics, they have been less feared. However, society may soon be faced once again with the prospect of bacterial and fungal diseases becoming major causes of death. Resistance to drugs which are effective against bacterial and fungi is increasing, and at a faster pace than development of drugs which are effective against them.

## Market Opportunity

Since the initial discovery and introduction of antibiotics some 50 years ago, doctors and researchers have found that bacteria are efficient at developing or acquiring mechanisms of defence. Until recently, antibiotic resistance appeared to be a relatively minor nuisance. Drug manufacturers were confident they could modify the structure of existing drugs such as penicillins, cephalosporins and tetracyclines faster than bacteria are able to develop drug resistance. Unfortunately, this has not proved to be the case. The numbers of drug resistant bacteria are on the rise, and the development of new treatment options has not kept pace. The single greatest problem in the use of antibiotics today is resistance by the disease causing organisms they are targeted against. The Center for Disease Control estimates that bacteria resistant to known antibiotics cause 44% of hospital infections. Drug resistant bacterial infections affect approximately 9 million people annually in the United States, resulting in some 60,000 deaths. Vancomycin, introduced in 1956, today serves as the last line of defence against certain life-threatening infections. Unfortunately, certain bacteria have developed strains which resist even vancomycin. Many experts caution we may soon see the return of the pre- antibiotic era.

## Technical Background

Preliminary *in vitro* [8] laboratory studies conducted by Dr. Jeffrey Hillman, our Chief Scientific Officer and director have demonstrated *mutacin* 1140's effectiveness against all tested Gram-positive bacteria [9]. Gram-positive bacteria are a class of bacteria that cause a large variety of human infections. We hope further testing will confirm these results. *Mutacin* 1140 belongs to a small class of antibiotics called lantibiotics. Lantibiotics differ from other antibiotics because they contain an unusual amino acid. They are able to kill a wide variety of bacteria by punching holes in their cellular membranes.

Nisin is a lantibiotic that has been widely used for decades as a food preservative. We will study *mutacin* 1140 first for its potential application in the clinical treatment of various infectious diseases. In laboratory studies it has been effective at killing a broad spectrum of bacteria, including the streptococci that cause pharyngitis (strep throat) and pneumonia. It is also effective against Staphylococci, which cause various sorts of infection. [10] At a later time, we may study *mutacin* 1140 for use as a food preservative.

*Mutacin* 1140 has other properties that indicate its potential usefulness and acceptance as an antibiotic. The most striking of these is the observation that these pathogenic bacteria based on testing to date seem to have great difficulty in becoming resistant to it [11]. It is a small, modified peptide that is expected to be absorbed by an oral route of administration. Preliminary animal testing conducted by Dr. Hillman indicates that it does not readily provoke an immune response, indicating that it may not be very allergenic[12].

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- [7] Hillman et al, Construction and Characterization of an Effector Strain of *Streptococcus mutans* for Replacement Therapy of Dental Caries, *Infection and Immunity* (2000) Vol.68, No. 2.
- [8] Studies carried out in isolation from a living organism.
- [9] Wojciehowski, Byers and Hillman, Regulation of Expression of the Structural Gene for *Mutacin* 1140 and Characterization of its Antibacterial Properties (2002), submitted for publication..
- [10] Wojciehowski, Byers and Hillman, Regulation of Expression of the Structural Gene for *Mutacin* 1140 and Characterization of its Antibacterial Properties (2002), submitted for publication..
- [11] Wojciehowski, Byers and Hillman, Regulation of Expression of the Structural Gene for *Mutacin* 1140 and

- Characterization of its Antibacterial Properties (2002), submitted for publication and Hillman et al, Isolation of a *Streptococcus mutans* Strain Producing a Novel Bacterium, *Infection and Immunity* (1984) Vol. 44, No. 1, pp. 141-144.
- [12] Wojciehowski, Byers and Hillman, Regulation of Expression of the Structural Gene for Mutacin 1140 and Characterization of its Antibacterial Properties (2002), submitted for publication and Hillman et al, Isolation of a *Streptococcus mutans* Strain Producing a Novel Bacterium, *Infection and Immunity* (1984) Vol. 44, No. 1, pp. 141-144.

## Laboratory Testing

Dr. Hillman and others have conducted laboratory studies at the Forsyth Institute, the University of Florida and our company to test the efficacy of *mutacin* 1140 as an antibacterial agent from 1984 to the present[13]. To test the ability of *mutacin* 1140 to kill bacteria, standard microbiological testing methods were employed. *Mutacin* 1140 was purified and incorporated into growth medium at different concentrations. This 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 that was observed to inhibit growth of the test bacterium, was recorded.

Purified *mutacin* 1140 was found to have a very broad spectrum of activity. It was found to kill all Gram positive bacteria tested at concentrations comparable to many therapeutically effective antibiotics. The bacteria found to be sensitive included those responsible for human infections such as streptococcal pharyngitis ("strep throat"), the predominant type of human pneumonia, and bacterial endocarditis.

A particularly interesting feature of *mutacin* 1140 is that none of the sensitive species of bacteria tested were able to acquire genetically stable resistance to purified *mutacin* 1140. Acquired resistance to antimicrobial agents by strains of bacteria which cause illness in humans has become a major problem in the recent past.

## Manufacturing

We have not yet identified the production method for *mutacin* 1140.

## Method of Administration

We expect that, if we are successful in identifying a production method for *mutacin* 1140 and obtaining the necessary regulatory approvals, any products based on our *mutacin* 1140 technology will be antibiotic drugs, available only by prescription. We do not yet know the method by which products based on *mutacin* 1140 will be administered to patients. They may be administered orally, topically or by injection.

## Competition

We believe that the current direct competitors with our *mutacin* 1140 technology are antibiotic drugs such as Vancomycin and others. There are strains of bacteria which have developed resistance even to vancomycin. We believe that there is ample room in the marketplace for new antibiotic drugs.

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.

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Many potential competitors of ours are taking approaches quite different from ours to the development of antibiotic drugs. These include traditional natural products screening, genomics to identify new antibiotic 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. The commercial success of our *mutacin* 1140 technology will depend on our ability and the ability of our sublicensees to compete effectively in all these areas. There can be no assurance our competitors will not succeed in developing products which are more effective than *mutacin* 1140, or which would render *mutacin* 1140 obsolete and non competitive.

If we are able to find a suitable method for producing *mutacin* 1140 and to obtain the necessary regulatory approvals, any products based on our *mutacin* 1140 technology will compete against a large number of prescription antibiotics currently on the market, and against new antibiotic products which 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. It is our intention 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 we will be able to obtain any such partner. If we are not, we will be obliged to develop our own channels of distribution for products based on *mutacin* 1140. There can be no assurance we will be able to do so.

[13] Wojciehowski, Byers and Hillman, Regulation of Expression of the Structural Gene for Mutacin 1140 and Characterization of its Antibacterial Properties (2002), submitted for publication and Hillman et al, Isolation of a *Streptococcus mutans* Strain Producing a Novel Bacterium, *Infection and Immunity* (1984) Vol. 44, No. 1, pp. 141-144.

## License

We hold our patented *mutacin* 1140 technology under license from the University of Florida Research Foundation, Inc. dated June 22, 2000. It was amended on September 15, 2000, July 10, 2002, September 25, 2002 and March, 2003. It provides us with an exclusive world wide license to make, use and sell products and processes covered by patents no. 5,932,469 and 6,391,285. These patents together cover *mutacin* 1140, a pharmaceutical preparation containing *mutacin* 1140, and the method of controlling growth of bacteria by use of *mutacin* 1140. Our license is for a period of the patent, subject to the performance of terms and conditions contained therein. 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 we make to the products and processes covered by the patent. Patent No. 5,932,469 is dated August 3, 1999 and expires August 2, 2016, and Patent No. 6,391,285 is dated May 21, 2002 and expires May 20, 2020. Under the terms of the license, we are obligated to pay 5% of the selling price of our products to the University of Florida Research Foundation, Inc. If we sublicense the license, we are obligated to pay 20% of the amounts we receive from the sublicensee to the University of Florida Research Foundation, Inc. In calendar year 2005 and each year thereafter we are obligated to make a minimum royalty payment of \$50,000. We are obligated to spend or cause to be spent at least an aggregate of \$600,000 in 2003 and an aggregate of \$1,000,000 in each calendar year following 2003 on the research, development and regulatory prosecution of our replacement therapy and *mutacin* 1140 technologies together, 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 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. We have obtained liability insurance in the amount of \$1,000,000.

## Intellectual Property Matters

We do not hold any patents on our *mutacin* 1140 technology. Our rights to this technology flow from our license with the University of Florida Research Foundation, Inc.

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We are aware that the University of Laval has obtained a patent in respect of a mutacin antibiotic similar to *mutacin* 1140. It is our view that this patent and our licensed patent do not infringe on each other. The University of Florida Research Foundation, Inc. obtained its patent in respect of *mutacin* 1140 before the University of Laval obtained its patent. Nevertheless, it is possible our licensed patent may infringe the University of Laval's patent. If so, we may have to incur substantial costs related to sublicensing the University's patent, or if we are unable to negotiate a sublicense, we may be exposed to litigation from the University.

## Regulatory Status

We have not yet submitted an investigational new drug application to the FDA for our *mutacin* 1140 technology, because we have not yet found a method to produce it in quantities necessary to undertake such studies. We intend to hire a senior scientist and to engage manufacturing companies and research institutions to assist us in developing such a method with some of the funds which will be available to us on completion of this offering. Refer to "Use of Funds Available." We hope to complete development of such a method within 9 to 12 months of closing of the offering.

Our patient estimate for each phase of the clinical trial process for our *mutacin* 1140 technology is:

Phase I	Phase II/III
24-30	500-1,000

## Milestones

- 1 Hire a senior scientist to lead the development of a production method sufficient to produce commercial quantities of *mutacin* 1140. We expect to do this within one month of the closing of this offering, and we expect employing such a person to cost \$108,000 (including related taxes and benefits) per year.
- 2 Retain one or more manufacturing companies or research institutions to work with us to develop a production method for *mutacin* 1140. We expect to do this within one month of the closing of this offering, and we expect costs during the first year to be \$50,000.
- 3 Develop a suitable production method for *mutacin* 1140. We hope to develop a suitable production method within nine to twelve months of the closing of the offering. We expect that costs associated with finding such a production method will be the costs of hiring a senior scientist and retaining a manufacturing company discussed above.
- 4 Complete pre-clinical studies, including animal toxicity and efficacy, required for an investigational new drug application. We expect to complete this within six months after successful development of a production method. We expect completion of pre-clinical studies to cost \$250,000.
- 5 Submit an investigational new drug application to the FDA. We expect to do this within fifteen months of the closing of this offering, and we expect the costs of preparation and submission of the application to be \$20,000.
- 6 Complete Phase I clinical trials. We expect to do this within twenty-four months of the closing of this offering, and we expect completion to cost \$300,000 - \$350,000.
- 7 Enter into a sub-licensing agreement with one or more major pharmaceutical companies. Assuming favorable results from our Phase I clinical trials, we hope to do this within twenty-six to thirty months of the closing of this offering.

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## Regulatory Consultants

We have engaged ERA Consulting (USA) LLC to provide us with consulting services relating to our regulatory affairs, and strategic and scientific advice related to our projects, under an agreement dated July 16, 2002. The initial term of the agreement is for one year. We have agreed to pay our consultant for these services at the daily and hourly rates charged by those individuals who provide us with services on its behalf. These rates vary between \$63 and \$375 per hour and \$500 and \$3,000 per day. We will also pay our consultant's direct costs of providing services, such as travel, board, lodging, teleconference and courier charges. Either party may terminate the agreement on 30 days written notice.

We have also engaged The Biologics Consulting Group, LLC to provide us with biologics regulatory consulting services relating to our regulatory affairs, under an agreement with a term from December 18, 2002 to December 17, 2003. We have agreed to pay our consultant for these services at the hourly rates charged by those individuals who provide us with services on its behalf. These rates vary between \$165 per hour and \$300 per hour. We will also compensate our consultant for all lodging, travel expenses, business meals and other project-related expenses we agree to in advance. Either party may terminate the agreement at any time by giving written notice.

## Marketing

We presently intend to seek to sublicense our replacement therapy and *mutacin* 1140 technologies to pharmaceutical companies, assuming successful completion of Phase I clinical trials. The sublicensees would be responsible for the costs of Phase II and III trials, and of the new drug applications. Assuming the new drug applications are successful, the sublicensees would be responsible for marketing products derived from our licensed, patented technologies. We intend to select sublicensees on the basis of their experience and financial success. We can offer you no assurances that

we will obtain FDA approval for our technologies or that we will be successful in entering into sublicenses with established multinational companies.

## **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. 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.

### **For 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 and the performance of your investment.

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 Chuck 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**

In our last two fiscal years, we have spent \$457,337 on research and development of our technologies.

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## **If We Do Not Complete Our Offering**

Apart from this offering, we have no plans to raise money. If we are unable to complete this offering we may have to suspend or cease operations.

## **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 our 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.

## **Company's Office**

Our administrative office is located at 12085 Research Drive, Alachua, Florida 32615. This is also our mailing address. Our telephone number is (386) 418-4018. The annual rental is \$24,610 pursuant to the terms of a lease from March 15, 2002 to March 14, 2003. We lease our office space from the University of Florida Research Foundation, Inc. under an office lease dated August 4, 1998, as amended September 15, 2000, July 10, 2002 and September 25, 2002.

## Employees

We are an early-stage biotechnology research and development company and currently have four employees other than our officers and directors. They all work full time. Of our officers and directors who are employed by us, one is full-time, one 75% time and one is part time, to become full time on closing of our offering.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND PLAN OF OPERATIONS

### Overview

We are a biotechnology research and development company created to commercialize two new technologies. The first technology is replacement therapy, which is designed to prevent the principal cause of tooth decay. The second technology is *mutacin* 1140, which is an antibiotic.

### Limited Operating History: Need for Additional Capital

We are a development stage corporation and have generated limited revenues from operations during the last two years. All of our revenues have been from a sponsored research agreement which has expired; none have been from sales.

Our auditors have issued a going concern opinion. This means that our auditors believe there is substantial doubt that we can continue as an on-going business unless we obtain additional capital to pay our bills. This is because we have not generated any revenues from sales and no revenues are anticipated until we are able to enter into sub-licensing agreements with respect to our replacement therapy and *mutacin* 1140 technologies. Accordingly, we must raise cash from sources other than operations. Our only other source for cash at this time is investments by others in us. We must raise cash to finance our operations. If we complete this offering, we do not know how long the money will last, however, we do believe it will last at least twelve months. We are presently unable to finance all of our current cash requirements. We are presently addressing this problem by deferring payment of the salaries of our officers in order to conserve cash. We are presently unable to finance all of our current cash requirements. We are presently addressing this problem by deferring payment of the salaries of our officers in order to conserve cash. As of April 30, 2003, we have deferred approximately \$143,000 of salary payable to Chuck Sponis (\$95,000), Jeffrey Hillman (\$40,500) and Paul Hassie (\$7,500). \$91,500 of this amount

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will be paid from the proceeds of the offering. The balance will be paid from our cash on hand. On February 14, 2003 we borrowed \$100,000 from Cornet Capital Corp. (see "Interest of Management and Others in Material Transactions"), and on April 29, 2003 we borrowed \$75,000 from Cornet Capital Corp., in order to meet our current cash requirements. These borrowings were not made under the loan facility with Cornet Capital Corp. described under "Interest of Management and Others in Material Transactions." No shares were issued to Cornet Capital Corp. in connection with these borrowings. In order to meet our cash requirements prior to the closing of the offering, we may have to draw on our loan facility, or raise cash from other sources, or both. We presently have no plans to raise cash from other sources, and there can be no assurance we will be able to do so if we must.

To meet our need for cash we are attempting to raise money from this offering. We recently raised \$500,000 in consideration of the issuance of 625,000 restricted shares of common stock. We cannot guarantee that we will be able to raise enough money through this offering to stay in business. If we do not raise all of the money we need from this offering to maintain our operations, we will have to find alternative sources, like a second public offering, a private placement of securities, or loans from our officers or others. We have discussed this matter with our officers, however, our officers are unwilling to make any commitment to lend us any money at this time. At the present time, we have not made any arrangements to raise additional cash, other than through this offering and our loan facility with Cornet Capital Corp. see "Interest of Management and Others in Material Transactions." If we need additional cash and can't raise it we will either have to suspend operations until we do raise the cash, or cease operations entirely. If we complete this offering, we believe the cash will last into 2004. Other than as described in this paragraph, we have no other financing plans.

We will complete our public offering within 90 days of the date of issue of a Mutual Reliance Review System Decision Document in respect of our Canadian prospectus by the British Columbia Securities Commission, if subscriptions are received for all the units and the conditions of closing are met. A portion of the funds received from this offering will

be used to maintain our operations until we begin generating revenues.

We do not plan to conduct any research other than continued research relating to our two licensed, patented technologies. Our plan of operation is explained in the business section of this prospectus. We do not plan to buy or sell any plant or significant equipment during the next twelve months.

Our present strategy for financing the clinical trials which will be necessary as part of the FDA approval process involves conducting the research and development work in respect of our technologies through Phase I clinical trials. Assuming we complete Phase I clinical trials successfully, we intend to sub-license our technologies to pharmaceutical companies, which would be responsible for completing Phase II and III clinical trials and for undertaking the new drug application. We will not begin to generate revenues from operations unless and until we complete Phase I clinical trials and enter into a sub-license of one of our technologies. However, we will be spending substantial sums of money on research and development of our technologies. We will not begin generating revenues from sales unless and until a sublicensee obtains approval of a new drug application and begins selling products based on our technologies.

### **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 present strategy involves undertaking the animal studies necessary for approval of an investigational new drug application for each technology. If successful, we will then undertake and complete Phase I human clinical trials. We intend at that point to sub-license each of our technologies to one or more pharmaceutical companies, who will be responsible for funding the completion of the Phase II and III clinical trials for the technologies, the cost of the new drug application (see "Federal Food and Drug Administration Regulations"), and for the manufacture and distribution of products based on our technologies. In order to accomplish these objectives, we must take the following actions:

#### **General**

- 1 Retain a regulatory consulting firm with FDA expertise to assist us in the preparation and filing of FDA regulatory submissions. We have recently engaged two such firms to do so. We expect to pay these firms approximately \$75,000 during the next twelve months.

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### **Replacement Therapy**

- 1 Meet with the FDA to reach agreement on the additional pre-clinical animal studies required to satisfy the issues raised by the FDA's clinical hold of our IND. We hope to do this by the end of June 2003. We expect to pay our regulatory consultants fees of \$75,000 in connection with our discussions and interactions with the FDA.
- 2 Complete the required additional pre-clinical studies. We hope to complete these studies by the end of January 2004, at an estimated cost of \$140,000 for the studies and associated research personnel.
- 3 Complete Phase I clinical trials. We expect to do this within fourteen months of the closing of this offering, and we expect the total cost to be \$370,000.
- 4 Enter into a sub-licensing agreement with one or more major pharmaceutical companies. Assuming favorable results from our Phase I clinical trials, we hope to do this within eighteen months of the closing of this offering.

### **Mutacin 1140**

- 1 Hire a senior scientist to lead the development of a production method sufficient to produce commercial quantities of *mutacin* 1140. We expect to do this within one month of the closing of this offering, and we expect employing such a person to cost \$108,000 per year, including salary and related taxes and benefits.
- 2 Retain one or more manufacturing companies or research institutions to work with us to develop a production method for *mutacin* 1140. We expect to do this within one month of the closing of this offering, and we expect costs during the first year to be \$50,000 to \$75,000.
- 3 Develop a suitable production method for *mutacin* 1140. We hope to develop a suitable production method within nine to twelve months of the closing of the offering.



- 4 Complete pre-clinical studies, including animal toxicity and efficacy, required for an investigational new drug application submission. We expect to complete this within six months after successful development of a production method. We expect completion of pre-clinical studies to cost 250,000.
- 5 Submit an investigational new drug application to the FDA. We expect to do this within fifteen months of the closing of this offering, and we expect the costs of preparation and submission of the application to be \$20,000.
- 6 Complete Phase I clinical trials. We expect to do this within twenty-four months of the closing of this offering, and we expect completion to cost \$300,000 - \$350,000. Funding for completion of these clinical trials is not provided in the proceeds of this offering. In order to fund these trials, we will have to obtain additional funding from other sources. We do not know what these sources will be, and there is no assurance we will be able to identify any sources of additional funding.
7. Enter into a sub-licensing agreement with one or more major pharmaceutical companies. Assuming favorable results from our Phase I clinical trials, we hope to do this within twenty-six to thirty months of the closing of this offering.

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We expect to conduct much of the research and development work through Phase I clinical trials for both technologies within our company. We expect to engage outside companies to work with us on the production of *mutacin* 1140 and to perform toxicity, pharmacokinetic, and spectrum of action studies on the antibiotic.

## **Results of Operations**

### ***Years Ended December 31, 2002 and 2001***

Our revenues decreased to zero in the year ended December 31, 2002 from \$303,912 in 2001. In 2001, our revenues consisted entirely of amounts paid to us under a sponsored research agreement with a major consumer products company. This agreement terminated in late 2001.

Our operating expenses increased 162% to \$709,700 in the year ended December 31, 2002 from \$270,465 in 2001. Research and development expenses increased 110% to \$310,007 in 2002 from \$147,330 in 2001, reflecting the hiring of two full time research staff and a Chief Scientific Officer, increased consumption of laboratory supplies and costs incurred for legal patent protection in 2002. General and administration expenses increased 225% to \$399,693 in 2002 from \$123,135 in 2001, reflecting consulting fees for recruiting, legal and accounting work performed in 2002 and for the amendment to the employment agreement of one of our officers.

Interest income decreased 34% to \$2,169 in 2002 from \$3,297 in 2001, which was a result of the higher average cash balances maintained in 2001 due to the sponsored research agreement. Interest expenses increased 11% to \$8,072 in 2002 from \$7,271 in 2001, reflecting the larger average balance of deferred salaries upon which interest was computed in 2002 over 2001.

We incurred a net loss of \$699,603 in 2002 and had net income of \$13,473 in 2001, reflecting no revenues earned in 2002 and significant increases in operating expenses in 2002 associated with increased research staff, increased consumption of laboratory supplies, the amendment of the employment agreement of one of our officers and costs incurred for recruiting, legal and accounting services.

### ***Years Ended December 31, 2001 and 2000***

We had revenues of \$303,912 and \$53,875 in the years ended December 31, 2001 and 2000, respectively. These revenues consisted principally of amounts paid to us under a sponsored research agreement.

Our operating expenses were \$270,465 and \$69,318 in the years ended December 31, 2001 and 2000, respectively. Research and development expenses increased 443% to \$147,330 in 2001 from \$27,111 in 2000 reflecting research performed on our replacement therapy technology in conjunction with our sponsored research agreement. Specific contributors to the increase in our research and development expenses during 2001 were the hiring of one full time research staff, costs incurred for legal patent protection and payments to research consultants. General and administration expenses increased 192% in 2001 to \$123,135 from \$42,207 in 2000 reflecting the full year of compensation for the chief executive officer and fees for legal and accounting work.

Interest income was \$3,297 in 2001 and zero in 2000, reflecting the higher cash balances maintained in 2001 as a result of revenues received under our sponsored research agreement. Interest expense increased 395% in 2001 to \$7,271 from \$1,469 in 2000 reflecting the higher balances in notes payable to shareholders and deferred salary in 2001.

We had net income of \$13,473 in 2001 and incurred a net loss of \$16,912 in 2000, reflecting primarily the income and expenses associated with our sponsored research agreement.

### **Critical Accounting Policy**

In December 2001, the SEC requested that reporting companies discuss their most "critical accounting policies" in Management's Discussion and Analysis of Financial Condition and Plan of Operations. The SEC indicated that a "critical accounting policy" is one that is important to the portrayal of a company's financial condition and operating results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. While our significant accounting policies are more fully described in Note 1 to our financial statements, we believe the following accounting policy to be critical.

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Our revenue recognition policies are in accordance with the SEC's Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements." We have generated revenue through a sponsored research agreement. The terms of the agreement included non-refundable fees to fund additional research and development to allow the sponsor the ability to assess whether it would exercise a right to license our technology. The agreement also provided for the payment of a non-refundable up-front fee to negotiate an exclusive license for the worldwide manufacturing and marketing rights to our technology.

We recognize revenue relating to the evaluation of our technology ratably over the contracted period that the evaluation and research and development are being performed. We recognize revenue relating to the negotiation of an exclusive license at the termination of the negotiation period. We recognize such revenues only if we are reasonably assured that these amounts will be collected. This assessment involves judgment on our part. If we do not believe that collection of amounts billed, or amounts to be billed to our sponsor, is reasonably assured, then we defer revenue recognition.

### **Liquidity and Capital Resources**

From inception through December 31, 2002, we financed our operations primarily through the issuance of common stock for \$508,616, the issuance of notes payable to shareholders totaling \$85,454 and a sponsored research agreement totaling \$357,787.

We had cash and cash equivalents of \$25,580 at December 31, 2002 that are held in one financial institution and invested overnight in money market funds. During the year ended December 31, 2002, we incurred \$272,000 in fees associated with this offering.

We lease our laboratory and office facilities, as well as certain equipment, under a 12-month cancelable operating lease with annual renewal options. We had no material commitments for the acquisition or lease of any property or equipment. On February 14, 2003, we obtained a loan of \$100,000 from Cornet Capital Corp., and issued an uncollateralized promissory note in the principal amount of \$100,000 that pays interest at 10% per annum to Cornet Capital Corp. as security. Principal and interest are payable on demand and in any event before February 14, 2004. On April 29, 2004, we obtained a further loan of \$75,000 from Cornet Capital Corp., and issued an uncollateralized promissory note in the amount of \$75,000 that pays interest at 10% per annum to Cornet Capital Corp. as security. Principal and interest are payable on April 29, 2003. These borrowings were not made under the loan facility with Cornet Capital Corp. described under "Interest of Management and Others in Material Transactions." No shares were issued to Cornet Capital Corp. in connection with these borrowings.

We expect to incur substantial additional research and development expenses including continued increases in personnel and costs related to research, preclinical testing and clinical trials.

We anticipate that the estimated net proceeds of this offering will be adequate to satisfy our operating expenses and capital requirements as planned into 2004. We will also have available to us, if required, up to \$500,000 which we may borrow from Cornet Capital Corp. under a loan facility. See "Interest of Management and Others in Material Transactions." We will require substantial funds to conduct research and development and preclinical and Phase I

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

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## MANAGEMENT

### Officers and Directors

Each of our directors serves until his or her successor is elected and qualified. Each of our officers is elected by the board of directors to a term of one (1) year and serves until his or her successor is duly elected and qualified, or until he or she is removed from office. Brian McAlister and Robert Zahradnik serve as the compensation committee. Brian McAlister, Robert Zahradnik and Brian Anderson serve as the audit committee. The board of directors has no nominating committee.

The names, addresses, ages and positions of our officers and directors are set forth below:

Name and Address	Age	Position(s)
Mento A. ("Chuck") Sponis 4730 SW 103 Way Gainesville, FL 32608	58	president, chief executive officer and member of the board of directors
Robert Zahradnik 9 Fox Run Lane Batesville, AR 75201	58	member of the board of directors and the audit and compensation committees
Jeffrey D. Hillman 6424 SW 26 <sup>th</sup> Place Gainesville, FL 32608	53	chief scientific officer and chairman of the board of directors
Brian McAlister 7225 Blenheim Street Vancouver, British Columbia Canada V6N 1S2	46	member of the board of directors and the audit and compensation committees
Brian Anderson 6511 South Canyon Ranch Road Salt Lake City, UT 84121	56	member of the board of directors and the audit committee
Paul A. Hassie 5547 SW 37 <sup>th</sup> Drive Gainesville, FL 32608	51	chief financial officer, treasurer and secretary

Dr. Hillman has been a director of our company since inception. Dr. Zahradnik has been a director since 1996. Mr. Sponis has been an officer and director since August 2000. Mr. McAlister has been a director since March 2002 and Mr. Anderson has been a director since August 2002. Mr. Hassie has held his office since June of 2002. All are expected to hold their offices/positions until the next annual meeting of our stockholders.

### Background of Officers and Directors

*Jeffrey D. Hillman - Chief Scientific Officer and Chairman of the Board of Directors*

Dr. Hillman has been our chief scientific officer and chairman of the board of directors since November 1996. From November 1991, Dr. Hillman has been Professor in the College of Dentistry at the University of Florida in Gainesville, Florida. He teaches classes, trains doctoral candidates and conducts research. However, Dr. Hillman has been on leave from the University of Florida, since February 2001, in order to develop our technologies and technologies for iviGene Corporation, Alachua, Florida. iviGene is engaged in the business of developing vaccines and therapeutics, focusing on genes and gene products that are critical factors in the infection state. iviGene does not compete with us. Dr. Hillman received undergraduate training at the University of Chicago (Phi Beta Kappa), and his D.M.D. degree (cum laude) and Ph.D. from Harvard Medical School. He has authored or co-authored more than 100 publications and textbook chapters on subjects related to the etiology and cure of tooth decay and dental disease. He has been conducting research on our licensed, patented replacement therapy technology for more than 25 years. Dr. Hillman's employment contract with us contains non-competition and non-disclosure provisions.

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Dr. Hillman has also entered into an Employee and Proprietary Information and Invention Agreement with us dated January 2, 2002 under which he has assigned to us all of his interest in any inventions he may make which are based on any of our proprietary rights or any of our other intellectual property during his employment by us. Dr. Hillman will devote 75% of his time to our company.

***Mento A. Sponis - President, Chief Executive Officer and a member of the Board of Directors.***

Since August 2000, Mr. Sponis has been our president, chief executive officer and a member of the board of directors. From December 2000 to June 2002, Mr. Sponis was president and chief executive officer of iviGene Corporation, Alachua, Florida. IviGene is engaged in the business of developing vaccines and therapeutics. Mr. Sponis remains as Chairman of the Board of Directors of iviGene Corporation. From January 2000 to May 2000, Mr. Sponis was a consultant for the office of technology licensing at the University of Florida, Gainesville, Florida where he reviewed agreements and negotiated the terms of technology licenses. From December 1995 to December 1999, Mr. Sponis was president and chief executive officer of USBiomaterials Corporation, Alachua, Florida. US Biomaterials developed healthcare products for bone regeneration and for dental care. Mr. Sponis is a graduate of Princeton University and the George Washington University law school. He has served as CEO for a number of early stage biotechnology companies. He has broad experience in strategic positioning and negotiation of corporate partnerships. Mr. Sponis works for us full time. Mr. Sponis' employment contract with us contains non-competition and non-disclosure provisions. Mr. Sponis will devote 100% of his time to our company.

***Robert T. Zahradnik - Member of the Board of Directors***

Since November 1996, Dr. Zahradnik has been a member of our board of directors. Since July 2000 Dr. Zahradnik has been vice president and a director of iviGene Corporation, Alachua, Florida. iviGene is engaged in the business of developing vaccines and therapeutics. Since September 1999, Dr. Zahradnik has been general manager of ProHealth, Inc., Batesville, Arkansas. ProHealth, Inc. is a manufacturer of nutritional supplements and household and skin care products. Since February 1993, Dr. Zahradnik has been a partner and general manager of Professional Dental Technologies and Therapeutics, Batesville, Arkansas, an oral pharmaceutical manufacturer. Since February 1986, Dr. Zahradnik has been the chief executive officer and chairman of the board of directors of Advanced Clinical Technologies, Inc., Medfield, Massachusetts, a medical diagnostic manufacturer and technical consulting firm. Dr. Zahradnik has signed a Proprietary Information Agreement with us dated September 12, 2002 under which he has agreed not to disclose confidential or secret information related to our business which we disclose to him. He has not signed a non-competition agreement with us. Dr. Zahradnik will devote such portion of his time to our company as is necessary to fulfill his responsibilities.

***Brian McAlister - Member of the Board of Directors***

Since March 2002, Mr. McAlister has been a member of our board of directors. From January 1999 to November 2001, Mr. McAlister was president and chairman of the board of directors of LCM Equity. In November 2001, LCM Equity completed a reverse acquisition with Regma Bio Technologies Ltd. of London, England. Regma Bio Technologies is engaged in the development of biotechnology products. Since March 20, 2000, Mr. McAlister has been a Director of Uscribble.com Writing Inc. Uscribble was a subsidiary corporation of LCM Equity until the completion of the reverse acquisition of with Regma Bio Technologies Ltd. Since 1988, Mr. McAlister has been president of Cornet Capital Corp., a corporation owned and controlled by Mr. McAlister which is engaged in the business of assisting start-up

corporations with capital raising, funding and other consulting activities. Mr. McAlister was a director of Response Biomedical Corp. from June to November of 2001. From November 1999 to July 2000, Mr. McAlister was a director of Advanced Interactive, Inc., a Vancouver, British Columbia corporation, engaged in the business of developing interactive television. From February 1992 to October 1997, Mr. McAlister was a member of the Board of Directors of Novadigm, Inc. a corporation whose securities are traded on the NASDAQ small cap system. Mr. McAlister has been President and a member of the Board of Directors of Midway Gold Corporation, a company whose shares are listed on the TSX Venture Exchange, since January of 1997. Mr. McAlister holds a Bachelor of Science degree in Business Administration with a major in finance from the University of Denver. Mr. McAlister has signed a Proprietary Information Agreement with us dated September 6, 2002 under which he has agreed not to disclose confidential or secret information related to our business which we disclose to him. He has not signed a non-competition agreement. Mr. McAlister will devote 15-20% of his time to our company.

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***Brian Anderson - Member of the Board of Directors***

Since August 2002, Mr. Anderson has been a member of our board of directors. Mr. Anderson has been a principal and partner of Montridge, LLC, Ridgefield CT, an investor relations firm, since August 16, 2002. From 1998 to June of 2002, Mr. Anderson was the President and Chief Executive Officer of Cognetix, Inc., Salt Lake City, Utah, a research and therapeutics development company. From 1995 to 1998, Mr. Anderson was Senior Vice President, Marketing and Commercial Development of Interneuron Pharmaceuticals, Inc., Lexington, Massachusetts (now called Indeueus Pharmaceuticals Inc.), a biopharmaceutical company whose shares are listed on the NASDAQ National Market. From 1987 to 1995 Mr. Anderson held a number of executive positions at Bristol-Myers Squibb, including responsibilities in business development, strategic planning and marketing. Mr. Anderson has signed a Proprietary Information Agreement with us dated September 11, 2002 under which he has agreed not to disclose confidential or secret information related to our business which we disclose to him. He has not signed a non-competition agreement. Mr. Anderson will devote such portion of his time to our company as is necessary to fulfill his responsibilities.

***Paul A. Hassie - Chief Financial Officer, Treasurer and Secretary***

Since July 2002, Mr. Hassie has been our chief financial officer. Since February 2000, Mr. Hassie has been president of BioFlorida, a trade organization located in Gainesville, Florida that supports biosciences in Florida. Since November 1999, Mr. Hassie has been engaged in the business of financial consulting to bioscience companies in the Gainesville, Florida area. From June 1997 to November 1999, Mr. Hassie was chief financial officer of USBiomaterials Corporation located in Alachua, Florida. USBiomaterials developed healthcare products for bone regeneration and for dental care. From January 1992 to May 1997, Mr. Hassie was controller for Transkaryotic Therapies, Inc. located in Cambridge, Massachusetts. Transkaryotic Therapies is engaged in the business of research and development of gene therapy products. From January 1984, to September 1991, Mr. Hassie was senior manager in the Boston office of Ernst & Young LLP, Certified Public Accountants. Mr. Hassie received a Bachelor of Science degree in accounting from Bryant College, Smithfield, Rhode Island in 1977; an MBA from Bryant College in 1981; and, a Masters of Science in Taxation from Bryant College in 1996. Mr. Hassie is a member of the American Institute of Certified Public Accountants and is a licensed Certified Public Accountant in the Commonwealth of Massachusetts. Mr. Hassie has signed a non-disclosure agreement with us dated August 15, 2002 under which he has agreed not to disclose or make commercial use of our technical and proprietary information and products. He has not signed a non-competition agreement with us. If our offering is completed, Mr. Hassie will devote 100% of his time to our company.

**Conflicts of Interest**

All of our officers and directors, with the exception of Mr. Saponis, have other outside business activities which represent a conflict of interest in that they do not devote full-time to our business.

**Scientific Advisory Board**

We use scientists and physicians with expertise related to our technologies to advise us on scientific and medical matters. We expect to have an advisory board consisting of three or four members in the near future. Currently, our scientific advisory board members are:

***Howard K. Kuramitsu, Ph.D***

Dr. Kuramitsu is a UB Distinguished Professor at the State University of New York at Buffalo. He is a leading expert in the area of the biology of the oral cavity and studies diseases associated with the oral cavity. Dr. Kuramitsu serves on the Editorial Boards of the *International Journal of Oral Biology*, *Oral Microbiology and Immunology* and *Infection and Immunity*. He also serves on the NIH-NIDCR Advisory Council. Dr. Kuramitsu's work includes more than 170 publications. Dr. Kuramitsu has signed a Proprietary Information Agreement with us dated September 16, 2002 under which he has agreed not to disclose confidential or secret information related to our business which we disclose to him

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### **Steven J. Projan, Ph.D**

Dr. Projan is Director, Antibacterial Research of Wyeth Research. He is an expert in the regulation of virulence in pathogenic bacteria. Dr. Projan serves on the editorial boards of *Antimicrobial Agents and Chemistry*, *Microbial Drug Resistance*, *Infection and Immunity*, and the *Journal of Bacteriology*. He also serves on the ASM Colloquium Committee of the American Society for Microbiology. Dr. Projan's work includes 64 articles and 45 abstracts. Dr. Projan has signed a Proprietary Information Agreement with us dated November 12, 2002 under which he has agreed not to disclose confidential or secret information related to our business which we disclose to him

## **EXECUTIVE COMPENSATION**

The following table sets forth the compensation paid by us from January 1, 2000 to December 31, 2002, for each of our officers and directors. This information includes the dollar value of base salaries, bonus awards and number of stock options granted, and certain other compensation, if any.

### **Summary Compensation Table**

Names Executive Officer and Principal Position	Year Ended	Long-Term Compensation						
		Annual Compensation			Awards	Payouts		
		Salary (US\$)	Bonus (US\$)	Other Annual Compensation (US\$)	Restricted Stock Award(s) (\$)	Securities Underlying Options/SARs (#)	LTIP Payouts (US\$)	Other Annual Compensation (US\$)
Mento A. Sponis President	2002	109,423	0	0	0	0	0	0
	2001	81,291	0	0	0	0	0	6,010
	2000	30,906	0	0	0	756,000	0	0
Robert Zahradnik Director	2002	0	0	0	0	0	0	0
	2001	0	0	0	0	0	0	0
	2000	0	0	0	0	486,000	0	0
Jeffrey D. Hillman Chief Scientific Officer	2002	55,385	0	0	0	0	0	0
	2001	60,000	0	0	0	0	0	0
	2000	0	0	0	0	0	0	0
Paul A. Hassie Chief Financial Officer, Secretary/Treasurer	2002	15,000	0	0	0	0	0	0
	2001	0	0	0	0	0	0	0
	2000	0	0	0	0	0	0	0
Brian McAlister Director	2002	0	0	0	0	0	0	0
	2001	0	0	0	0	0	0	0
	2000	0	0	0	0	0	0	0
Brian Anderson Director	2002	0	0	0	0	0	0	0
	2001	0	0	0	0	0	0	0
	2000	0	0	0	0	0	0	0

[1] Retirement plan contribution

We have employment agreements with Mento A. Sponis and Jeffrey Hillman.

Under the terms of our employment agreement with Mr. Soponis dated May 1, 2002, we are obligated to pay initial compensation of \$90,000 per annum until September 1, 2002 and at the rate of \$180,000 thereafter. The term of the agreement is for a period of three years commencing May 1, 2002 and terminating April 30, 2005. We will reimburse Mr. Soponis for expenses he incurs while employed by us and if he dies during the term of the agreement, we will pay his estate his salary for the month he died and for three additional months thereafter. Mr. Soponis is to devote substantially all his time to our business.

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Under the terms of our employment agreement with Dr. Hillman dated May 1, 2002, as amended October 3, 2002 and December 16, 2002, we are obligated to pay compensation of \$120,000 per annum. The term of the agreement is for a period of three years commencing May 1, 2002 and terminating April 30, 2005. We will reimburse Dr. Hillman for expenses he incurs while employed by us and if he dies during the term of the agreement, we will pay his estate his salary for the month he died and for three additional months thereafter. Dr. Hillman is to devote at least 75% of his time to our business. Dr. Hillman has also signed a Proprietary Information and Invention Agreement with us. Under this agreement, Dr. Hillman has agreed to hold all our proprietary information in the strictest confidence, and assigned to us all of his right, title and interest in any inventions which he makes during the term of his employment with us that incorporate, are based on or relate to any of our proprietary intellectual property rights

Effective August 1, 2002, we employed Mr. Hassie on a part-time basis. Prior to that time, he provided services to us as an independent consultant. We expect to employ Mr. Hassie full time upon completion of this offering. We have no employment agreement with Mr. Hassie. We expect to pay Mr. Hassie a salary of \$100,000 per year following closing.

The compensation discussed herein addresses all compensation awarded to, earned by, or paid to our named executive officers.

There are no other stock option plans, retirement, pension, or profit sharing plans for the benefit of our officers and directors other than as described herein.

#### Individual Option Grants in Last Fiscal Year

Name	Percentage of Securities Underlying Options	Percentage of Total Options Granted to Employees in Fiscal Year	Exercise Price	Expiration Date
Mento A. Soponis	756,000	61%	\$0.00009	Aug. 1, 2010
Robert T. Zahradnik	486,000	39%	\$0.00009	Aug. 1, 2010

#### Aggregated Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values

Name	Number of Shares Acquired on Exercise	Value Realized (\$)	Number of Securities Underlying Unexercised Options Exercisable/Unexercisable	Value of Unexercised In-the-Money Options Exercisable/Unexercisable
Mento A. Soponis	756,000	70.00	0/0	0/0
Robert T. Zahradnik	486,000	45.00	0/0	0/0

#### Long-Term Incentive Plan Awards

We do not have any long-term incentive plans that provide compensation intended to serve as incentive for performance.

#### Options to Purchase Securities

## *Details of the Stock Option Plan*

Our directors have approved the adoption of a stock option plan. The purpose of the stock option plan is to enable our company to attract, retain and motivate qualified directors and employees, to reward directors and employees and key consultants, such as members of our Scientific Advisory Board, for their contribution toward our long term goals, and to enable and encourage such individuals to acquire our shares as long term investments. A brief description of our plan follows.

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1. Only those individuals who are bona fide directors, employees and key consultants of our company may participate in the plan.
2. The plan will be administered by a committee of at least two directors appointed by our board of directors. Where directors, senior officers, 10% beneficial owners of our securities or those committee members are in a position to receive stock options, the board will decide as a whole about the grant of options to them, or appoint two non-employee directors to serve as the committee members with respect to such options.
3. Subject to any antidilution adjustments permitted under the plan, the maximum number of shares that may be issued upon the exercise of stock options granted under the plan may not exceed 1,000,000 shares of common stock.
4. All options we grant under the plan will have a vesting period of at least 18 months from the date they are granted, with either (a) equal release of shares on a quarterly basis; or (b) the release of the majority of the shares later in the vesting period.
5. The exercise price of stock options will be determined by the committee. During the 90 days following closing of the offering, the exercise price may not be less than greater of the offering price of the units and the closing price of our shares on the TSX Venture Exchange on the day prior to the date of grant, less allowable discounts, in accordance with the policies of the TSX Venture Exchange. After 90 days, the minimum exercise price will be the closing price of our shares on the day prior to the date of grant, less allowable discounts.
6. If an option expires and it has not been exercised in full, or if an option is otherwise terminated without having been exercised in full, the number of shares which were subject to the expired or terminated option will again be available for the purposes of the plan.
7. All options which we grant under the stock option plan must expire no more than five years from the date on which the committee grants and we announce the granting of the option.
8. If an option holder ceases to be a director of our company or ceases to be employed by our company (other than by reason of death), then the option granted shall expire no later than the 90<sup>th</sup> day following the date that the option holder ceases to be a director or ceases to be employed by us, subject to the terms and conditions set out in the plan.
9. For so long as we are classified as a Tier 2 company on the TSX Venture Exchange, all the options we grant under the plan will vest as determined by the committee in accordance with the requirements of the TSX Venture Exchange and the plan will be administered in accordance with the requirements of the TSX Venture Exchange.
10. No individual may receive grants of options to purchase more than 5% of our issued and outstanding shares during any one year period.
11. The aggregate number of shares reserved for issuance under options that have been granted to insiders cannot exceed 10% of our outstanding shares, and the aggregate number of shares issued to insiders under the plan cannot exceed 10% of our outstanding shares in any one year period.
12. No options we grant under the stock option plan may be assigned or transferred, other than by will or the laws of descent and distribution or pursuant to a Qualified Domestic Relations Order if it is a non-incentive stock option.

We will not require or seek shareholder approval for the grant of options under the stock option plan, or the exercise of options. We may grant options under the stock option plan to employees of our company regularly employed on a full-time or part-time basis, our directors and officers, and persons who perform services for us on an ongoing basis or who have provided, or are expected to provide, services of value to us.

## **Options Granted**



We have granted the following options to purchase shares of our common stock under our stock option plan:

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<b>Option Holder</b>	<b>Relationship to Us</b>	<b>Shares Subject to Option</b>	<b>Exercise Price</b>	<b>Expiry Date</b>
Brian Anderson	Member of Board of Directors	60,000 [1]	\$1.25	September 19, 2007
Jixiang Mo	Employee	45,000 [1][2]	\$1.25	September 19, 2007
Paul Hassie	Chief Financial Officer, Secretary and Treasurer	30,000 [1]	\$1.25	September 19, 2007
Emily Schuler	Employee	30,000 [1][2]	\$1.25	September 19, 2007
Sandra Allen	Employee	30,000 [1][2]	\$1.25	September 19, 2007
Dr. Howard Kuramitsu	Member of Scientific Advisory Board	60,000 [2][3]	\$1.25	September 19, 2007

[1] One third of these options will vest on the first, second and third anniversaries of the date of grant, September 20, 2002.

[2] Not an officer or director.

[3] One fourth of these options will vest on the first, second, third and fourth anniversaries of the date of grant, September 20, 2002.

### **Compensation of Directors and Members of Scientific Advisory Board**

Messrs. Sponis, Zahradnik, Hillman and McAlister do not receive any compensation for serving as members of the board of directors. In consideration of his agreement to serve as a director, we have granted Mr. Anderson options to purchase 60,000 shares vesting over 3 years under our stock option plan, and to pay him \$2,500 per meeting attended to a maximum of \$10,000 per year. If other "outside" directors agree to serve on our board, we anticipate we will compensate them in a similar manner.

Members of our Scientific Advisory Board receive no compensation other than the grant of options to purchase shares under our stock option plan.

### **Indemnification**

Under our Articles of Incorporation and Bylaws, we may indemnify any officer or director who was or is a party or threatened to be made a party to any threatened, pending or completed proceeding, including a lawsuit, because of his position, if he acted in good faith and in a manner he reasonably believed to be in our best interest. We may advance expenses incurred in defending a proceeding. To the extent that the officer or director is successful on the merits in a proceeding as to which he is to be indemnified, we must indemnify him against all expenses incurred, including attorneys' fees. With respect to a derivative action, indemnity may be made only for expenses actually and reasonably incurred in defending the proceeding, and if the officer or director is judged liable, only by a court order. The indemnification is intended to be to the fullest extent permitted by the laws of the State of Florida.

Regarding indemnification for liabilities arising under the Securities Act of 1933, which may be permitted to directors or officers under Florida law, we are informed that, in the opinion of the Securities and Exchange Commission, indemnification is against public policy, as expressed in the Act and is, therefore, unenforceable.

### **PRINCIPAL SHAREHOLDERS**

The following table sets forth, as of the date of this prospectus, the total number of shares owned beneficially, except as noted below, by each of our directors, officers and key employees, individually and as a group, and the present owners of 5% or more of our total outstanding shares. The table also reflects what their ownership will be upon completion of this offering. Except as noted below, the shareholders listed below have direct ownership of their shares and possess sole voting and dispositive power with respect to the shares.

<b>Name and Address Beneficial Owner</b>	<b>Number of Shares Before the Offering</b>	<b>Percentage of Ownership Before the Offering</b>	<b>Number of Shares After Offering[1]</b>	<b>Percentage of Ownership After the Offering[1]</b>
Mento A. Sponis[2] 4730 SW 103 Way Gainesville, FL 32608	1,244,592[3]	13.2%	1,244,592	10.4%
Robert Zahradnik[2] 161 Stone Ridge Road Franklin, MA 02038	756,000	8.0%	756,000	6.3%
Jeffrey D. Hillman[2] 6424 SW 26 <sup>th</sup> Place Gainesville, FL 32608	5,400,108[4]	57.3%	5,400,108	45.3%
Paul A. Hassie 5547 SW 37 <sup>th</sup> Drive Gainsville, FL 32608	0	0	0	0.00%
Brian McAlister[2][5] 7225 Blenheim Street Vancouver, BC Canada V6N 1S2	800,064	8.5%	800,064	6.7%
Brian Anderson 6511 S. Canyon Ranch Road Salt Lake City, UT 84121	0	0	0	0.00%
<b>All officers and directors as a group (6 persons)</b>	<b>8,200,764</b>	<b>87%</b>	<b>8,200,764</b>	<b>68.8%</b>
University of Florida Research Foundation, Inc.[6]	599,940	6.4%	599,940	5.0%

- [1] Does not take into account any shares which may be issued upon exercise of the Series A and B warrants or the warrants we will issue to Haywood Securities Inc.
- [2] Messrs. Sponis, Zahradnik, Hillman and McAlister, may be deemed to be "promoters" of our company within the meaning of the Securities Acts of British Columbia and Alberta and the Securities Act of 1933, as amended
- [3] Includes shares owned by Justin Sponis and Trevor Sponis, children of Chuck Sponis.
- [4] Includes shares owned by Charles Hillman and Stacia Helfand (children of Dr. Hillman) and the Jeffrey D. Hillman 2002 Trust and the Jeffrey D. Hillman Grantor Retained Annuity Trust (trusts controlled by Dr. Hillman).
- [5] Held directly by Cornet Capital Corp., a corporation wholly owned by Mr. McAlister.
- [6] These shares were issued to the University of Florida Research Foundation, Inc. as partial consideration for the license of our replacement therapy technology.

### Future Sales of Shares

A total of 9,425,704 shares of common stock are issued and outstanding as of December 31, 2002, all of which are restricted securities, as defined in Rule 144 of the Rules and Regulations of the SEC promulgated under the Securities Act. Under Rule 144, the shares can be publicly sold, subject to volume restrictions and restrictions on the manner of

sale, commencing one year after their acquisition.

Rule 144 is an exemption from registration for the resale of restricted securities. Restricted securities are securities acquired in a transaction which did not involve a public offering. In order to comply with the requirements of Rule 144, the following conditions must be met:

- \* there must be adequate current public information regarding us
- \* the restricted securities must have been fully paid for and held by the seller for at least one year from the date he or she acquired them
- \* during the second year from the date of acquisition by the seller, the number of shares which the seller may sell is limited in any three-month period to the greater of 1% of our outstanding shares, or the average weekly trading volume in those shares over the four weeks preceding the potential sale
- \* the securities may only be sold in unsolicited brokers transactions or in transactions directly with a market maker
- \* a Form 144 must be filed with the SEC concurrently with the sale and with any national securities exchange on which the security is traded

Restricted securities that have been held for more than two years by non-affiliates, and persons who are not control persons, may be sold without complying with these conditions. Affiliates, and persons who are control persons, must continue to comply with the foregoing conditions as long as they are affiliates or control persons.

The market price of our shares of common stock could drop as the result of sales of substantial numbers of shares in the public market, or the perception that such sales could occur. This could also make it more difficult for us to raise funds through future sales of shares.

## **DESCRIPTION OF SECURITIES**

### **Common Stock**

We are authorized to issue 100,000,000 shares of common stock, par value \$0.001 per share, of which 9,425,704 are presently issued and outstanding. The holders of our common stock:

- \* have equal ratable rights to dividends from funds legally available if and when declared by our board of directors;
- \* are entitled to share ratably in all of our assets available for distribution to holders of common stock upon liquidation, dissolution or winding up of our affairs;
- \* do not have preemptive, subscription or conversion rights and there are no redemption or sinking fund provisions or rights; and
- \* are entitled to one non-cumulative vote per share on all matters on which stockholders may vote.

All shares of common stock which are the subject of this offering, will be fully paid for and non-assessable when issued. We refer you to our Articles of Incorporation, Bylaws and the applicable statutes of the State of Florida for a more complete description of the rights and liabilities of holders of our securities.

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### **Non-cumulative Voting**

Holders of shares of our common stock do not have cumulative voting rights, which means that the holders of more than 50% of the outstanding shares, voting for the election of directors, can elect all of the directors to be elected, if they so choose, and, in that event, the holders of the remaining shares will not be able to elect any of our directors. After this offering is completed, present stockholders will own approximately 79.0% of our outstanding shares.

### **Cash Dividends**

As of the date of this prospectus, we have not paid any cash dividends to stockholders. The declaration of any future cash dividend will be at the discretion of our board of directors and will depend upon our earnings, if any, our capital requirements and financial position, general economic conditions, and other pertinent conditions. It is our present

intention not to pay any cash dividends in the foreseeable future, but rather to reinvest earnings, if any, in our business operations.

### **Preferred Stock**

We are authorized to issue up to 20,000,000 shares of preferred stock with no par value, in one or more classes or series. The designation and preferences, limitations and relative rights, including dividend rights, dividend rates, conversion rights, conversion rates, voting rights and terms of redemption of the preferred shares will be determined by the board of directors. We have no plans presently to issue any shares of preferred stock.

### **Series A Warrants**

The Series A Warrants will be issued under a warrant indenture between our company and Computershare Trust Company of Canada dated March 28, 2003. Each Series A warrant entitles the holder to purchase one share of common stock at a price of \$2.00 for 6 months from the date of closing of this offering. If the Series A warrants are not exercised by then, they will expire and cannot be exercised thereafter. The warrant indenture will provide, among other things, for appropriate adjustment in the class, number and price of the shares to be issued on exercise of the warrants upon certain events, including any stock split, subdivision, consolidation or reclassification of our common stock or the payment of stock dividends.

### **Series B Warrants**

The Series B warrants will be issued under the warrant indenture referred to above. Each Series B warrant entitles the holder to purchase one share of common stock at a price of \$3.00 for 9 months from the date of closing of this offering. If the Series B warrants are not exercised by then, they will expire and cannot be exercised thereafter.

### **Other Terms of the Series A and B Warrants**

We will pay any transfer tax incurred as a result of the issuance of common stock to the holder upon its exercise.

We will not issue fractional shares upon the exercise of a warrant and you may not exercise one-half of one warrant or any other fraction thereof. The holder of a warrant will not possess any rights as our shareholder until he or she exercises the warrant.

A warrant may be exercised upon surrender of the warrant certificate on or before the expiry date of the warrant at the office of the warrant trustee, with the exercise form found on the back of the warrant certificate, completed and executed as indicated, accompanied by payment of the exercise price (by money order, wire transfer, bank draft or certified cheque payable to the order of Oragenics, Inc.) for the number of shares of common stock with respect to which the warrant is being exercised.

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For a holder to receive shares of common stock which will be "good delivery" in settlement of transactions on the TSX Venture Exchange upon exercise of the warrants, there must be a current registration statement in effect with the SEC and qualification in effect under applicable state securities laws (or applicable exemptions from state qualification requirements) with respect to the issuance of shares of common stock. We have agreed to use our best efforts to cause this or another registration statement with respect to the shares issuable upon exercise of the warrants under the *Securities Act* of 1933 to become and remain effective in anticipation of and before the exercise of the warrants and to take such other actions under the laws of various states as may be required to cause the sale of shares or other securities upon exercise of Series A and B warrants to be lawful.

The foregoing discussion of material terms and provisions of the warrants is qualified in its entirety by reference to the detailed provisions of the warrant indenture, the form of which has been filed as an exhibit to the registration statement of which this prospectus is a part.

For the life of the warrants, the holders thereof have the opportunity to profit from a rise in the market price of the common shares without assuming the risk of ownership of the common shares underlying the warrants. The warrant holders may be expected to exercise their warrants at a time when we would, in all likelihood, be able to obtain any needed capital by an offering of common shares on terms more favorable than those provided for by the warrants.

Furthermore, the terms on which we could obtain additional capital during the life of the warrants may be adversely affected.

### **Redeemable Warrants**

As part of its compensation in connection with the offering, we will issue to our underwriter, Haywood Securities Inc., 500,000 warrants. Each warrant will be exercisable for two years from the date of closing of the offering to purchase one share of common stock at a price of \$1.25 per share. If our shares trade at a price of above \$5.00 per share or more for 20 consecutive trading days on the TSX Venture Exchange or such other exchange as they may be listed on, then we may provide notice to Haywood that it must exercise such warrants within 30 days of the notice, failing which the warrants will expire and may not be exercised thereafter.

### **Reports**

After we complete this offering, we will furnish shareholders with an annual report. We will be required to file reports with the SEC under section 15(d) of the Securities Act. The reports will be filed electronically. The reports we will be required to file are Forms 10-KSB, 10-QSB, and 8-K. You may read copies of any materials we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that will contain copies of the reports we file electronically. The address for the Internet site is [www.sec.gov](http://www.sec.gov). We will be required to send annual and quarterly financial statements to shareholders resident in Alberta and British Columbia, and to file those financial statements with the Alberta and British Columbia Securities Commission.

### **Registrar and Transfer Agent**

We have entered into a Transfer Agent, Registrar and Dividend Agreement between ourselves and Computershare Trust Company of Canada dated January 16, 2003. Upon completion of the offering, Computershare Trust Company of Canada will be the registrar and transfer agent for our securities. Its telephone number is (604) 661-9400.

### **Registration Rights**

Pursuant to our license of our replacement therapy technology from the University of Florida Research Foundation, Inc. described under "Our Technologies," we have entered into an Equity Agreement with the University of Florida Research Foundation, Inc. It provides that if, at any time, we determine to register any shares of our common stock under the United States *Securities Act* of 1933, we will include in such registration the 599,940 shares which we issued to the University of Florida Research Foundation, Inc. as partial consideration for the license, if the University of Florida Research Foundation, Inc. requests us to do so. Under a further agreement with the University of Florida Research Foundation, Inc., dated January 13, 2003, the University of Florida Research Foundation, Inc. has waived its registration rights under the Equity Agreement with respect to this offering.

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## **ESCROWED SECURITIES**

### **National Escrow Policy**

<b>Designation of class</b>	<b>Number of securities held in escrow</b>	<b>Percentage of class [1]</b>
Common Shares	8,200,764	68.8%

[1] This is the percentage of our issued and outstanding shares of common stock which will be escrowed upon completion of the offering.

Under Canadian National Policy 46-201 "Escrow for Initial Public Offerings," those of our shares of common stock which are held by our Principals must be held in escrow.

A "Principal" is:

- (i) a director or senior officer of our company or of a material operating subsidiary of our company;
- (ii) a person or company who has acted as our promoter during the two years before this offering;
- (iii) a person or company who owns or controls more than 10% of our voting securities immediately before and immediately after completion of this offering if that person has elected or appointed or has the right to elect or appoint one of our directors or senior officers or a director or officer of a material operating subsidiary of our company;
- (iv) a person or company who owns or controls more than 20% of our voting securities immediately before and immediately after completion of this offering; and
- (v) associates and affiliates of any of the foregoing persons.

All of our directors and senior officers are Principals.

Under the National Escrow Policy, we have entered into an escrow agreement with Computershare Trust Company of Canada as escrow agent, and our Principals dated March 28, 2003. Under the escrow agreement, our Principals have deposited their common shares in escrow with the escrow agent. The escrow agent will release 10% of our Principals' common shares from escrow on the date our common shares are listed on the TSX Venture Exchange. After that, 15% of our Principals' common shares will be released from escrow every 6 months. The schedule of releases is set out in the following table.

<b>Date</b>	<b>% of escrowed shares to be released</b>
Listing date	10%
6 months from listing date	15%
12 months from listing date	15%
18 months from listing date	15%
24 months from listing date	15%
30 months from listing date	15%
36 months from listing date	15%

We are an "emerging issuer" as defined in the National Escrow Policy. A faster, 18 month release schedule applies to "established issuers" under the policy. If we become an "established issuer" while our Principals' common shares are in escrow, we will "graduate." If we graduate, there will be a catch-up release and an accelerated release of our Principals' common shares which remain in escrow under the 18 month schedule as if we were originally an established issuer. We will "graduate" from being an "emerging" issuer to an "established" issuer if:

- 1 Our shares of common stock are listed on the Toronto Stock Exchange;
- 2 We are classified as a Tier 1 issuer on the TSX Venture Exchange.

Under the National Policy escrow agreement, our Principals' common shares may not be transferred or otherwise dealt with while they are in escrow unless the transfers or dealings are:

- (i) transfers to our directors and senior officers, with approval of our board of directors;
- (ii) transfers to a person or company that before the transfer holds more than 20% of the voting rights attached to our outstanding securities;
- (iii) transfers to a person or company that after the transfer will hold more than 10% of the voting rights attached to our outstanding securities and has the right to elect or appoint one or more of our directors or senior officers;
- (iv) transfers to an RRSP or similar trustee plan provided that the only beneficiaries are the transferor or the transferor's spouse or children;
- (v) transfers upon bankruptcy to the trustee in bankruptcy; pledges to a financial institution as collateral for a good faith loan, and upon a realization; or
- (vi) tenders of escrowed securities to a take-over bid, provided that if the person tendering to the bid is a Principal of the company resulting from completion of the take-over bid, the securities the Principal receives in exchange for tendered escrowed securities will be placed in escrow on the basis of the

resulting company's escrow classification.

Shares must remain in escrow after a permitted transfer.

The number and holders of our common shares which are subject to escrow under the escrow agreement are:

<b>Name of Principal</b>	<b>Number of Escrow Shares Held</b>
Jeffrey Hillman	5,400,108
Mento A. Soponis	1,244,592
Robert Zahradnik	756,000
Cornet Capital Corp. [1]	800,064

[1] Brian McAlister, one of our directors, is the sole shareholder and director of Cornet Capital Corp.

### **TSX Venture Exchange Escrow Policy**

The TSX Venture Exchange applies its own escrow requirements to initial listings. The Exchange's Seed Share Resale Restrictions are hold periods of various lengths which apply where shares are issued to non-Principals prior to an initial public offering. The purchase price of those shares, and the time of their purchase relative to the date of issue of the receipt for preliminary prospectus receipt for an initial public offering determines which Exchange hold period will apply.

The following persons or corporations will be subject to TSX Venture Exchange escrow requirements:

<b>Name of non-Principal Shareholder</b>	<b>Number of Shares Held</b>	<b>Date Acquired</b>
University of Florida Research Foundation, Inc.	599,940 [1]	July 15, 1999

[1] These shares were issued to the University of Florida Research Foundation, Inc. as partial consideration for the license of our replacement therapy technology.

The University of Florida Research Foundation, Inc. will be subject to a Value Security Escrow Agreement dated March 28, 2003. A Value Security Agreement imposes a schedule of escrow release for TSX Venture Exchange Tier 2 Issuers that is identical to that of the National Escrow Policy described above.

### **Pooling Agreement**

Our underwriter, Haywood Securities Inc., has required that certain of our shareholders who are not subject to escrow under the National Escrow Policy or TSX Venture Exchange requirements place their shares in escrow under an escrow agreement between ourselves, Computershare Trust Company, those shareholders and Haywood. The escrow agreement is dated March 28, 2003. The following shares will be subject to that escrow agreement.

<b>Name of non-Principal Shareholder</b>	<b>Number of Shares Held</b>
Cleo Christine Allen	50,000
James Butler	31,250
Quickswood Ltd.	125,000
Ernest Mario	31,250

Amelia Investments Ltd.	262,500
Angel Investment Company Ltd.	125,000

Under this escrow agreement, one sixth of the shares subject to escrow will be released on closing of our offering, and a further one sixth will be released every 3 months following. All of the shares will have been released from escrow 15 months from the closing.

#### INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

On February 22, 2001, Robert T. Zahradnik, a member of the board of directors, loaned us \$57,418 as evidenced by a promissory note of even date therewith which accrues interest at the rate of 7% per annum until paid. The note is payable on demand, or 2 years from its date if demand is not made earlier. At March 31, 2003, the total outstanding balance of the note and accrued interest is \$65,864. Mr. Zahradnik has agreed not to seek repayment of this loan from the proceeds of this offering.

On February 22, 2001, Jeffrey Hillman, our Chief Scientific Officer and chairman of the board of directors, loaned us \$12,186 as evidenced by a promissory note of even date therewith which accrues interest at the rate of 7% per annum until paid. The note is payable on demand, or 2 years from its date if demand is not made earlier. At March 31, 2003, the total outstanding balance of the note was \$14,816. Dr. Hillman has agreed not to seek repayment of this loan from the proceeds of this offering.

On February 28, 1999, Robert T. Zahradnik, a member of the board of directors, loaned us \$15,000 as evidenced by a promissory note of even date therewith which accrues interest at the rate of 7% per annum until paid. The note is payable on demand, or 2 years from its date if demand is not made earlier. At March 31, 2003, the total outstanding balance of the note was \$18,974. Mr. Zahradnik has agreed not to seek repayment of this loan from the proceeds of this offering.

In 2001 we incurred consulting fees of \$60,000 payable to Jeffrey Hillman. The entire amount remains outstanding. We do not intend to pay these fees from the proceeds of this offering. Dr. Hillman has agreed not to seek repayment from the proceeds of this offering.

Under an agreement between ourselves and Cornet Capital Corp., a corporation wholly owned by Brian McAlister, dated March 20, 2002, as amended by an agreement dated December 2, 2002, Cornet Capital has agreed with us to place \$1,000,000 of our common stock with investors and use its best efforts to raise an additional \$2,500,000. In consideration of Cornet's agreement, we issued 800,064 shares of our common stock to Cornet. These shares are held in escrow under an agreement between our company, Cornet and an escrow agent dated as of May, 2002. Under the agreement, the escrow agent will release the shares to Cornet upon receipt of notice from us that Cornet has raised at least \$1,000,000 for us. We have agreed with Mr. McAlister that completion of this offering will constitute fulfillment of the agreement on Mr. McAlister's part, and the shares will be released from escrow on closing of this offering. Neither Cornet nor Mr. McAlister will receive any additional compensation.

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The agreement with Cornet Capital also provides for a loan facility for up to \$500,000 between Cornet and ourselves. Cornet has agreed to enter into a loan agreement with us under which we may draw down funds up to \$500,000 for three years from December 2, 2002 as we need them. Advances under the loan agreement will bear interest at 3% per annum above the U.S. dollar prime rate of the Royal Bank of Canada. We will also issue to Cornet a number of shares of our common stock equal to 20% of the dollar amount of the advance, divided by the discounted market price of our shares on the TSX Venture Exchange.

On February 14, 2003, we issued an uncollateralized promissory note in the principal amount of \$100,000 that pays interest at 10% per annum to Cornet Capital Corp. as security for a loan of \$100,000 cash. Principal and interest is payable on demand and in any event before February 14, 2004. This borrowing was not made under the loan facility with Cornet Capital Corp. No shares were issued to Cornet Capital Corp. in connection with this borrowing. This promissory note will be repaid from the proceeds of this offering.

On April 29, 2003, we issued a further uncollateralized promissory note in the amount of \$75,000 that pays interest at 10% per annum to Cornet Capital Corp. as security for a further loan of \$75,000 cash. Principal and interest are payable on April 29, 2004. This borrowing was not made under the loan facility with Cornet Capital Corp. No shares



were issued to Cornet Capital Corp. in connection with this borrowing. This promissory note will be repaid from the proceeds of this offering.

On May 1, 2002, we entered into an employment agreement with Mento A. Sponis, our president. Under the terms of our employment agreement with Mr. Sponis, we are obligated to pay initial compensation of \$90,000 per annum until September 1, 2002 and at the rate of \$180,000 thereafter. The term of the agreement is for a period of three years commencing May 1, 2002 and terminating April 30, 2005. We will reimburse Mr. Sponis for expenses he incurs while employed by us and if he dies during the term of the agreement, we will pay his estate his salary for the month he died and for three additional months thereafter. We may terminate Mr. Sponis without cause with 90 days notice and the payment of three months' salary beyond the termination date. Mr. Sponis is required to give us 90 days notice in the event of his resignation.

On May 1, 2002, we entered into an employment agreement with Jeffrey D. Hillman, our chief scientific officer. Under the terms of our employment agreement with Dr. Hillman, we are obligated to pay compensation of \$120,000 per annum. The term of the agreement is for a period of three years commencing May 1, 2002 and terminating April 30, 2005. We will reimburse Dr. Hillman for expenses he incurs while employed by us and if he dies during the term of the agreement, we will pay his estate his salary for the month he died and for three additional months thereafter. We may terminate Dr. Hillman without cause with 90 days notice and the payment of three months' salary beyond the termination date. Dr. Hillman is required to give us 90 days notice in the event of his resignation.

We have entered into license and lease agreements with the University of Florida Research Foundation, Inc. The University of Florida Research Foundation, Inc. owns 599,940 shares of our common stock which represents 6.4% of our total outstanding shares prior to this offering and will own 5.0% of our total outstanding shares if the offering is successfully completed. The 5.0% ownership will continue to be evidenced by the 599,940 shares currently owned.

We hold our patented replacement therapy technology under license from the University of Florida Research Foundation Inc.

The license is dated August 4, 1998. It was amended on September 15, 2000, July 10, 2002, September 25, 2002 and March, 2003. It provides us with an exclusive world wide license to make, use and sell products and processes covered by patent no. 5,607,672. This patent covers the genetically altered strain of *S. 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 we make to the products and processes covered by the patent. Our license is for the period of the patent, subject to the performance of terms and conditions contained therein. The patent is dated March 4, 1997, and will expire on March 3, 2014.

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Under the license, we have issued as partial consideration 599,940 shares of our common stock which is 6.4% of our total outstanding shares as of September 30, 2002. We are obligated to pay 5% of the selling price of our products to the University of Florida Research Foundation, Inc. If we sublicense the license, we are obligated to pay 20% of all amounts we receive from the sublicensee to the University of Florida Research Foundation, Inc. On December 31, 2005 and each year thereafter we are obligated to make a minimum royalty payment of \$50,000. We are obligated to spend or cause to be spent at least an aggregate of \$600,000 in 2003 and an aggregate of \$1,000,000 in each calendar year following 2003 on the research, development and regulatory prosecution of our replacement therapy and *mutacin* 1140 technologies together, 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 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 must pay \$100,000 for the patent expenses when we have received at least \$1,000,000 in external funding. We will make this payment from the proceeds of this offering.

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. We have obtained liability insurance in the amount of \$1,000,000.

We hold our patented *mutacin* 1140 technology under license from the University of Florida Research Foundation, Inc. dated June 22, 2000. It was amended on September 15, 2000, July 10, 2002, September 25, 2002 and March, 2003. It provides us with an exclusive world wide license to make, use and sell products and processes covered by patents no. 5,932,469 and 6,391,285. These patents together cover *mutacin* 1140, a pharmaceutical preparation containing *mutacin* 1140, and the method of controlling growth of bacteria by use of *mutacin* 1140. Our license is for a period of the patent, subject to the performance of terms and conditions contained therein. 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 we make to the products and processes covered by the patent. Patent No. 5,932,469 is dated August 3, 1999 and expires August 2, 2016, and Patent No. 6,391,285 is dated May 21, 2002 and expires May 20, 2020. Under the terms of the license, we are obligated to pay 5% of the selling price of our products to the University of Florida Research Foundation, Inc. If we sublicense the license, we are obligated to pay 20% of the amounts we receive from the sublicensee to the University of Florida Research Foundation, Inc. In calendar year 2005 and each year thereafter we are obligated to make a minimum royalty payment of \$50,000. We are obligated to spend or cause to be spent at least an aggregate of \$600,000 in 2003 and an aggregate of \$1,000,000 in each calendar year following 2003 on the research, development and regulatory prosecution of our replacement therapy and *mutacin* 1140 technologies together, 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 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. We have obtained liability insurance in the amount of \$1,000,000.

We also lease our office space at 12085 Research Drive, Alachua, Florida 32615 from the University of Florida. The annual rental is \$24,610 pursuant to the terms of a lease from March 15, 2002 to March 14, 2003.

## **LITIGATION**

We are not a party to any pending litigation and, to the best of our knowledge, no litigation against us is contemplated or threatened.

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## **EXPERTS**

The financial statements of Orogenics, Inc. at December 31, 2002, 2001 and 2000, and for each of the three years in the period ended December 31, 2002, appearing in this prospectus and registration statement have been audited by Ernst & Young LLP, independent certified public accountants, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in Note 11 to the financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

## **LEGAL MATTERS**

Conrad C. Lysiak, Attorney and Counselor at Law, 601 West First Avenue, Suite 503, Spokane, Washington 99201, telephone (509) 624-1475, has passed on the legality of the units and the other securities being registered.

## **FINANCIAL STATEMENTS**

Our fiscal year end is December 31. We will provide audited financial statements to our stockholders on an annual

basis; the statements will be prepared by management and audited by independent certified public accountants.

<b>Report of Independent Certified Public Accountants</b>	F-1
<b>Audited Financial Statements</b>	
Balance Sheets	F-2
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Statements of Changes in Stockholders' Deficit	F-4
Statements of Cash Flows	F-5
<b>Notes to Financial Statements</b>	F-6

## **REPORT OF INDEPENDENT CERTIFIED PUBLIC ACCOUNTANTS**

Board of Directors  
Oragenics, Inc.

We have audited the accompanying balance sheets of Oragenics, Inc. as of December 31, 2002, 2001 and 2000, and the related statements of operations, changes in stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2002. 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 auditing standards generally accepted in the 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 examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as 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, 2002, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As more fully discussed in Note 11 to the financial statements, the Company's deficit working capital and equity position raises substantial doubt about its ability to continue as a going concern. Management's plans as to these matters

are also described in Note 11. 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 might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

February 14, 2003  
Tampa, Florida

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**ORAGENICS, INC.**

**BALANCE SHEETS**

*(In US Dollars)*

	<b>December 31</b>		
	<b>2002</b>	<b>2001</b>	<b>2000</b>
<b>Assets</b>			
Current assets:			
Cash and cash equivalents	\$ 25,580	\$ 200,480	\$ 11,585
Costs associated with initial public offering	271,937	-	-
Prepaid expenses	8,741	-	483
Total current assets	<u>306,258</u>	<u>200,480</u>	<u>12,068</u>
Equipment	4,658	785	2,355
Total assets	<u>\$ 310,916</u>	<u>\$ 201,265</u>	<u>\$ 14,423</u>
<b>Liabilities and stockholders' deficit</b>			
Current liabilities:			
Accounts payable and accrued expenses	\$ 232,811	\$ 70,039	\$ 2,183
Accrued interest	17,462	9,390	2,119
Income tax payable	-	16,000	-
Notes payable to stockholders	85,454	85,454	15,850
Deferred compensation	58,671	34,409	15,762
Deferred revenue	-	-	6,125
Total current liabilities	<u>394,398</u>	<u>215,292</u>	<u>42,039</u>
Stockholders' deficit:			
Preferred stock, no par value; 20,000,000 shares authorized; none issued and outstanding at December 31, 2002, 2001, and 2000	-	-	-
Common stock, \$0.001 par value; 100,000,000 shares authorized; 9,425,704, 7,512,048 and 6,270,048 shares issued			

and outstanding at December 31, 2002, 2001 and 2000, respectively

	<b>9,426</b>	7,512	6,270
Additional paid in capital	<b>628,234</b>	-	-
Accumulated deficit	<b>(721,142)</b>	(21,539)	(33,886)
Total stockholders' deficit	<b>(83,482)</b>	(14,027)	(27,616)
Total liabilities and stockholders' deficit	<b>\$ 310,916</b>	\$ 201,265	\$ 14,423

See accompanying notes.

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**ORAGENICS, INC.**  
**STATEMENTS OF OPERATIONS**  
*(In US Dollars)*

	<b>Year ended December 31</b>		
	<b>2002</b>	<b>2001</b>	<b>2000</b>
Revenue	\$ -	\$ 303,912	\$ 53,875
Operating expenses:			
Research and development	<b>310,007</b>	147,330	27,111
General and administration	<b>399,693</b>	123,135	42,207
Total operating expenses	<b>709,700</b>	270,465	69,318
(Loss) income from operations	<b>(709,700)</b>	33,447	(15,443)
Other income (expense):			
Interest income	<b>2,169</b>	3,297	-
Interest expense	<b>(8,072)</b>	(7,271)	(1,469)
Total other expense, net	<b>(5,903)</b>	(3,974)	(1,469)
(Loss) income before income taxes	<b>(715,603)</b>	29,473	(16,912)
Income tax benefit (expense)	<b>16,000</b>	(16,000)	-
Net (loss) income	<b>\$ (699,603)</b>	\$ 13,473	\$ (16,912)
Basic and diluted net loss per share	<b>\$ (0.08)</b>	\$ -	\$ -

Shares used to compute basic and diluted net loss per share	<b>8,884,239</b>	6,375,533	6,270,048
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See accompanying notes.

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**ORAGENICS, INC.**

**STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT**

*(In US Dollars)*

	<b>Common Stock</b>		<b>Additional</b>	<b>Accumulated</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>Paid In</b>	<b>Deficit</b>	<b>Stockholders'</b>
			<b>Capital</b>		<b>Deficit</b>
Balance at January 1, 2000	6,270,048	\$ 6,270	\$ -	(16,974)	\$ (10,704)
Net loss	-	-	-	(16,912)	(16,912)
Balance at December 31, 2000	6,270,048	6,270	-	(33,886)	(27,616)
Exercise of common stock options for cash	1,242,000	1,242	-	(1,126)	116
Net income	-	-	-	13,473	13,473
Balance at December 31, 2001	7,512,048	7,512	-	(21,539)	(14,027)
Issuance of common stock	<b>1,913,656</b>	<b>1,914</b>	<b>628,234</b>	-	<b>630,148</b>
Net loss	-	-	-	(699,603)	(699,603)
Balance at December 31, 2002	<b>9,425,704</b>	<b>\$ 9,426</b>	<b>\$ 628,234</b>	<b>\$ (721,142)</b>	<b>(83,482)</b>

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See accompanying notes.

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**ORAGENICS, INC.**

**STATEMENTS OF CASH FLOWS**

*(In US Dollars)*

	Year ended December 31		
	2002	2001	2000
<b>Operating activities</b>			
Net (loss) income	\$ (699,603)	\$ 13,473	\$ (16,912)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Depreciation	1,585	1,570	905
Noncash issuance of common stock	122,148	-	-
Changes in operating assets and liabilities:			
Costs associated with initial public offering	(271,937)	-	-
Prepaid expenses	(8,741)	483	(483)
Accounts payable and accrued expenses	162,772	67,856	2,183
Accrued interest	8,072	7,271	1,468
Income tax payable	(16,000)	16,000	-
Deferred compensation	24,262	18,647	15,762
Deferred revenue	-	(6,125)	6,125
Net cash (used in) provided by operating activities	(677,442)	119,175	9,048
<b>Investing activity</b>			
Purchases of equipment	(5,458)	-	(3,260)
Net cash used in investing activity	(5,458)	-	(3,260)
<b>Financing activities</b>			
Proceeds from issuance of notes payable to stockholders	-	69,604	-
Proceeds from issuance of common stock	508,000	-	-
Exercise of common stock options	-	116	-
Net cash provided by financing activities	508,000	69,720	-
Net (decrease) increase in cash and cash equivalents	(174,900)	188,895	5,788
Cash and cash equivalents at beginning of year	200,480	11,585	5,797
Cash and cash equivalents at end of year	\$ 25,580	\$ 200,480	\$ 11,585
<b>Noncash financing activities</b>			
Common stock issued in connection with amendment to officer employment agreement	\$ 122,148	\$ -	-
Common stock issued in connection with investment bank services	\$ 192,016	\$ -	-

See accompanying notes.

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**ORAGENICS, INC.**

**NOTES TO FINANCIAL STATEMENTS**

**DECEMBER 31, 2002**

**1. Organization and Significant Accounting Policies**

Oragenics, Inc. (the Company) (formerly known as Oragen, Inc.) was incorporated in November 1996; however, operating activity did not commence until 1999. The Company is dedicated to the development of genetically engineered *Streptococcus mutans* for oral and other therapeutic applications.

**Basis of Presentation**

The financial statements of the Company, which have been prepared in accordance with accounting principles generally accepted in the United States, conform in all material respects with accounting principles generally accepted in Canada.

**Revenue Recognition**

The Company has earned revenues from a sponsored research agreement. Revenues relating to the evaluation of the Company's technology are recognized ratably over the period that the research is performed and the technology that is being evaluated.

**Concentrations of Credit Risk and Significant Customer**

The Company's cash and cash equivalents are deposited in one financial institution and consist of demand deposits. All revenues earned during 2001 and 2000 were the result of a sponsored research agreement (see Note 3).

**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.

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**ORAGENICS, INC.**

**NOTES TO FINAICIAL STATEMENTS (Continued)**

**1. Organization and Significant Accounting Policies (continued)**

**Cash Equivalents**



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

### Equipment

Equipment is recorded at its acquisition cost. Depreciation is computed utilizing the declining balance and straight-line methods over the estimated useful lives (three years) of the related assets.

### 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

At December 31, 2002, the Company has a stock-based employee compensation plan, which is described more fully in Note 6. 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. No stock-based employee compensation cost is reflected in net income, as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant. The following table illustrates the effect on net loss and earnings 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. For the years ended December 31, 2001 and 2000, the fair value of the Company's employee stock awards was estimated to be zero using a minimum value method; therefore, there is no pro forma effect on net income (loss) for these years.

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## ORAGENICS, INC.

### NOTES TO FINANCIAL STATEMENTS (Continued)

#### 1. Organization and Significant Accounting Policies (continued)

	<b>Year ended December 31, 2002</b>
	<i>(In US Dollars)</i>
Net loss, as reported	\$ (699,603)
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	— (2,925)
Pro forma net loss	\$ (702,528)
Earnings per share:	
Basic and diluted - as reported	\$ (.08)
Basic and diluted - pro forma	\$ (.08)



Depreciation expense for 2002, 2001, and 2000 was \$1,585, \$1,570, and \$905, respectively.

### **3. Sponsored Research Agreement**

In May 2000, the Company entered into a sponsored research agreement with a major healthcare company (the Sponsor) providing the Sponsor an opportunity to evaluate certain technology owned by the Company. In 2001, the sponsored research agreement was extended for four months by the Sponsor with a payment of \$250,000, which also allowed the Sponsor the exclusive opportunity to continue its evaluation and to negotiate rights to the technology. No agreement was negotiated in 2001 and the sponsored research agreement ended prior to December 31, 2001. As of December 31, 2001, all amounts received subject to the agreement have been recognized as revenue.

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## **ORAGENICS, INC.**

### **NOTES TO FINANCIAL STATEMENTS (Continued)**

#### **4. Notes Payable 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 are payable upon demand and accrue interest at 7% per year. No principal or interest payments have been made on these obligations.

#### **5. Deferred Compensation**

During 2000, the Company entered into a two-year employment agreement with an officer and shareholder. The agreement provides for the deferral of compensation until a certain level of investment funding is received and requires 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. At December 31, 2002, 2001, and 2000, deferred compensation plus accrued interest totaled \$39,130, \$36,600, and \$16,035, respectively. Compensation expense and interest expense relating to the employment agreement for the years ended December 31, 2002, 2001, and 2000 was \$0, \$18,647, and \$15,762 and \$2,530, \$1,918, and \$273, respectively.

In December 2002, compensation payments totaling \$24,300 to two officers and directors of the Company were deferred due to limited cash flow of the Company. There is no provision to pay interest on these deferred payments.

#### **6. Stock Options**

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, 2002, the Company had not awarded stock appreciation rights or restricted stock under the Plan. The Company has reserved an aggregate of 1,000,000 shares common stock for grants under the Plan, of which 685,000 shares are available for future grants as of December 31, 2002. The exercise price of each option shall be determined by the Board and an option's maximum term is five years.

A summary of the status of the Company's outstanding stock options, including employee stock options discussed above, as of December 31, 2002, 2001, and 2000 and changes during the periods ending on those dates is presented below:

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**ORAGENICS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

**6. Stock Options (continued)**

	<b>Options</b>	<b>Weighted Average Exercise Price</b>
	_____	_____
Outstanding at January 1, 2000	- \$	-
Granted	1,242,000	.01
	_____	_____
Outstanding at December 31, 2000	1,242,000	.01
Exercised	(1,242,000)	.01
	_____	_____
Outstanding at December 31, 2001	-	-
Granted	315,000	1.25
	_____	_____
Outstanding at December 31, 2002	315,000 \$	1.25
	_____	_____
Exercisable at end of year	- \$	-
	_____	_____

The weighted-average per option fair value of options granted during the year is \$.12 and the remaining contractual life of those options is four years. Options vest over a period of three to four years from respective grant dates. The fair value of these options was estimated at the date of grant using a minimum value option pricing model with the following weighted-average assumptions: weighted average risk-free interest rate of 2.49%; dividend yields of 0%; weighted-average volatility factors of the expected market price of the Company's common stock of 0; and a weighted average expected life of the option of four years.

**7. Retirement Plan**

During 2001, the Company established a defined contribution plan that covers substantially all of the employees of the Company. The plan generally allows for employer contributions up to 15% of each employee's salary, limited to \$30,000 per year. Employees may also contribute up to \$2,000 to the plan annually. Employees are fully vested in all contributions made to the plan. The total expense related to the plan for 2002 and 2001 was \$0 and \$8,938, respectively.

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**ORAGENICS, INC.**
**NOTES TO FINANCIAL STATEMENTS (Continued)**
**8. Income Taxes**

The components of income tax expense (benefit) are as follows:

	<b>Year ended December 31</b>		
	<b>2002</b>	<b>2001</b>	<b>2000</b>
	<i>(In US Dollars)</i>		
Current - federal	\$ (14,000)	\$ 14,000	\$ -
Current - state	(2,000)	2,000	-
Total	\$ (16,000)	\$ 16,000	-

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:

	<b>December 31</b>		
	<b>2002</b>	<b>2001</b>	<b>2000</b>
	<i>(In US Dollars)</i>		
Deferred tax assets:			
Net operating loss carryforward	\$ 213,417	-\$	3,750
Deferred compensation	23,855	12,948	5,931
Consulting services	28,223	-	-
Tax credit	16,211	5,154	-
Total deferred tax assets	281,706	18,102	9,681
Less valuation allowance	(281,706)	(18,102)	(9,681)
Total net deferred taxes	\$ -	-\$	-

## ORAGENICS, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

## 8. Income Taxes (continued)

The following is a reconciliation of tax computed at the statutory federal rate to the income tax expense in the statements of operations for the years ended December 31, 2002, 2001 and 2000:

	Year ended December 31		
	2002	2001	2000
	<i>(In US Dollars)</i>		
Income tax expense (benefit) computed at statutory federal rate of 34%	\$ (243,305)	\$ 10,021	\$ (5,750)
State income taxes (benefits), net of federal expense/benefit	(25,947)	1,075	(614)
Change in valuation allowance	263,604	8,421	5,927
Non-deductible expenses	274	44	-
Research and development credit	16,212	-	-
Other	(26,838)	(3,561)	437
Total	\$ (16,000)	\$ 16,000	\$ -

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 \$281,706, \$18,102 and \$9,681 valuation allowance at December 31, 2002, 2001 and 2000, respectively, 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 years ended December 31, 2002, 2001 and 2000 was \$263,604, \$8,421 and \$5,927, respectively. At December 31, 2002, the Company has available net operating loss carryforwards of \$567,145, which expire in the year 2022.

## 9. Lease

The Company leases its office space and certain office equipment under a 12-month cancelable operating lease with annual renewal options. Total rent expense under this lease was \$18,506, \$9,142 and \$9,901 for the years ended December 31, 2002, 2001 and 2000, respectively. The lease agreement ends in March 2003. The minimum lease payments that are due through the formal lease termination date in 2003 are \$6,100.

## ORAGENICS, INC.

## NOTES TO FINANCIAL STATEMENTS (Continued)

## **10. Transactions with Related Parties**

Costs incurred for consulting services provided by a stockholder of the Company during 2002 and 2001 was approximately \$15,000 and \$60,000, respectively. The unpaid balance of \$75,000 is included in accounts payable and accrued expenses at December 31, 2002.

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 million 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. Under the terms of the agreements, the Company or UFRF may terminate the agreements.

## **11. Liquidity**

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. In light of the Company's deficit working capital and equity positions and current projected operating results and cash flow, management believes additional capital in the form of debt or equity financing is required to maintain and expand its operations. There can be no assurance that the Company will be successful in its attempts to obtain the required funding. These financial statements do not give effect to any adjustments which might be necessary should the Company be unable to continue as a going concern and therefore be required to realize its assets and discharge its liabilities in other than the normal course of business and at amounts different from those reflected in the accompanying financial statements.

## **12. Initial Public Offering**

The Company has filed an offering 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 consists 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 allows the holder to purchase a share of the Company's stock at \$2.00 per share for six months subsequent to the closing of the IPO date. One whole Series B warrant allows the holder to purchase a share of the Company's stock at \$3.00 per share for nine months subsequent to the closing of the IPO date. In addition to receiving a cash commission for each share sold, the underwriting agent will receive 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 for two years following the closing of the IPO. The cost of the IPO is estimated to be \$500,000 including the agent's commission, which will result in net proceeds of \$2,500,000 to the Company.

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**ORAGENICS, INC.**

**NOTES TO FINANCIAL STATEMENTS (Continued)**

## **13. Subsequent Event**

On February 14, 2003, the Company obtained a \$100,000 short-term loan from an investment banker and shareholder. Interest on the borrowing accrues at 10% and is payable with principal in one year.

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**Until \_\_\_\_\_, 2003, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.**

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## **PART II. INFORMATION NOT REQUIRED IN PROSPECTUS**

### **ITEM 24. INDEMNIFICATION OF DIRECTORS AND OFFICERS.**

As provided in our bylaws and under Florida law, our directors shall not be personally liable to our company or any other person for monetary damages for breach of duty of care or any other duty owed to our company as a director, unless the breach of or failure to perform those duties constitutes:

- \* a violation of criminal law, unless the director had reasonable cause to believe his conduct was lawful, or had no reasonable cause to believe his conduct was unlawful;
- \* a transaction from which the director received an improper personal benefit, directly or indirectly;
- \* in a proceeding by or in the right of our company or a stockholder, an act or omission which involves a conscious disregard for the best interests of our company or which involves willful misconduct;
- \* in a proceeding by or in the right of someone other than our company or a stockholder, an act of recklessness or an act or omission which was committed in bad faith or with malicious purpose or in a manner exhibiting wanton and willful disregard of human rights, safety, or



- \* property; or  
a distribution made in violation of Florida law.

Our bylaws provide that we are required to indemnify any director, officer, employee or agent made a party to a proceeding because he is or was our director, officer, employee or agent against liability incurred in the proceeding if he acted in good faith and in a manner the director reasonably believed to be in or not opposed to our best interests and, in the case of any criminal proceeding, he had no reasonable cause to believe his conduct was unlawful.

Our bylaws and Florida law also provide that we shall indemnify a director, officer, employee or agent who has been successful on the merits or otherwise in the defense of any proceeding to which he was a party, or in defense of any claim, issue or matter therein, because he is or was a director, officer, employee or agent of our company against expenses actually and reasonably incurred by him in connection with such defense.

#### ITEM 25. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

The estimated expenses of the offering, all of which are to be paid by the registrant, are as follows:

Underwriter's Commission	\$	225,000
Underwriter's Expenses		50,000
SEC Registration Fee		885.5
Alberta and British Columbia Securities Commissions and TSX Venture		10,000
Exchange filing fees		
Printing Expenses		4,000
Accounting Fees and Expenses		50,000
Legal Fees and Expenses		225,000
Transfer Agent Fees		1,000
Warrant Agent Fees		1,000
Miscellaneous Expenses		8,114.5
<b>TOTAL</b>	<b>\$</b>	<b>575,000</b>

#### ITEM 26. RECENT SALES OF UNREGISTERED SECURITIES

During the past three years, we have sold the shares of common stock which were not registered under the Securities Act of 1933, as amended.

Name and Address	Date	Shares		Consideration	
				Aggregate \$	Average Cost per Common Share \$
Mento A. Sponis 4730 SW 103 Way Gainesville, FL 32608	11/30/2001	756,000	[1]	70	[2] .0000925
	03/25/2002	488,592		122,148	..25
Robert Zahradnik 161 Stone Ridge Road Franklin, MA 02038	07/15/1999	270,000	[1]	25	.0000925
	11/30/2001	486,000		45	..0000925
Cornet Capital Corp.[3] 7225 Blenheim Street Vancouver, BC Canada V6N 1S2	03/25/2002	800,064		200,016	[4] .25
Cleo Christine Allen[5]	05/22/2002	50,000		40,000	.80

3504 West 11<sup>th</sup> Street  
Vancouver, BC  
Canada V6R 2K2

James Butler[5] 109 Cutter Court Ponte Vedra Beach, FL 32082	05/14/2002	31,250	25,000	.80
Quickwood Ltd.[5] The Jardine Building Fourth Floor 33-35 Reid Street Hamilton HM LX Bermuda	05/14/2002	125,000	100,000	.80
Ernest Mario[5] 555 Byron Street #401 Palo Alto, CA 94301	05/14/2002	31,250	25,000	.80
Amelia Investments Ltd.[5] #19 Watergardens-6 Gibraltar; via U.K.	05/23/2002	262,500	210,000	.80
Angel Investment Company Ltd.[5] #19 Watergardens-6 Gibraltar; via U.K.	06/06/2002	125,000	100,000	.80

- [1] Acquired on exercise of options.  
[2] Consideration received in the form of services rendered.  
[3] Brian McAlister, one of our directors, is the sole shareholder and director of Cornet Capital Corp.

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- [4] Consideration received in the form of \$8,000 cash and \$192,016 in services rendered.  
[5] These shareholders entered into Registration Rights Agreements with us, at the time of their subscription, under which they were granted rights as follows: (a) 6 months or more after a firm commitment underwritten public underwriting resulting in our common stock being listed on a US national exchange or NASDAQ, at a price per share to the public of \$8.00, with aggregate proceeds to us of at least \$20 million, of our common shares pursuant to a United States Securities Act registration statement is closed, at least 50% of these shareholders may ask us in writing to file a registration statement under the United States Securities Act covering at least that number of securities held by them that would yield an aggregate offering price of at least \$1,000,000 (which may be underwritten if they make that request). If we receive such a request, we have agreed to use our commercially reasonable efforts to effect a registration statement as soon as practicable, unless we determine in good faith that it would be materially detrimental to file such a registration statement. In that case, we may delay filing a registration statement for 120 days. These shareholders may only make this request of us twice; and (b) if, after we have conducted such an offering in the United States, we propose to register the sale of any of our capital stock under the United States Securities Act in connection with the public offering for cash, then we have agreed to notify each of these shareholders of the registration and include their securities in the registration if they make that request.

We also issued options exercisable to purchase 756,000 shares of common stock at \$0.000092 per share to Mento A. Sponis and options to purchase 456,000 shares of common stock at \$0.000092 per share to Robert T. Zahradnik on August 1, 2000. All these options were exercised on November 30, 2001.

We issued the foregoing restricted securities to the foregoing individuals and entities pursuant to Section 4(2) of the

Securities Act of 1933. All of the foregoing are sophisticated investors and were in possession of all material information relating to the company. Further, no commissions were paid to anyone in connection with the sale of the shares and general solicitation was not made to anyone.

## **ITEM 27. EXHIBITS.**

The following exhibits are filed as part of this registration statement, pursuant to Item 601 of Regulation S-B.

<b>Exhibit No.</b>	<b>Document Description</b>
1.1 *	Letter of Intent with Haywood Securities Inc.
1.2 *	Agency Agreement with Haywood Securities Inc.
3.1 *	Articles of Incorporation.
3.2 *	Bylaws
3.3 *	Amended Articles of Incorporation
3.4 *	Amended Articles of Incorporation
4.1 *	Specimen Stock Certificate.
4.2 *	Specimen Series A warrant certificate
4.3 *	Specimen Series B warrant certificate
4.4 *	Specimen underwriter's warrant certificate.
5.1 *	Opinion of Conrad C. Lysiak, Esq. Regarding the legality of the securities being registered.
10.1 *	License Agreement
10.2 *	Amendment to License Agreement
10.3 *	Second Amendment to License Agreement
10.4 *	Third Amendment to License Agreement
10.5 *	License Agreement
10.6 *	Amendment to License Agreement
10.7 *	Second Amendment to License Agreement
10.8 *	Equity Agreement
10.9 *	Employment Agreement with Mento Soponis
10.10 *	Employment Agreement with Jeffrey D. Hillman
10.11 *	First Amendment to Employment Agreement with Jeffrey D. Hillman
10.12 *	Second Amendment to Employment Agreement with Jeffrey D. Hillman
10.13 *	Employee Proprietary Information and Invention Agreement between ourselves and Jeffrey D. Hillman
10.14 *	Incubator License Agreement - Office Lease

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10.15 *	First Amendment to Incubator License Agreement
10.16 *	Second Amendment to Incubator License Agreement
10.17 *	Series A and B Warrant Indenture
10.18 *	Renewal Term for Incubator License Agreement
10.19 *	Escrow Agreement between our principals, ourselves and Computershare Trust Company
10.20 *	Value Escrow Agreement between ourselves, the University of Florida Research Foundation, Inc. and Computershare Trust Company
10.21 *	Pooling Agreement between our non-Principal shareholders and Haywood Securities Inc.
10.22 *	Financing Agreement between ourselves and Cornet Capital Corp.
10.23 *	First Agreement to Financing Agreement between ourselves and Cornet Capital Corp.
10.24 *	Escrow Agreement between ourselves, Brian McAlister and Sutherland, Asbill and Brennan
10.25 *	First Amendment to Escrow Agreement between ourselves, Brian McAlister and Sutherland, Asbill & Brennan.
10.26 *	Stock Option Plan
10.27 *	Transfer Agent, Registrar and Dividend Disbursing Agent Agreement for Common Stock
10.29 *	Registration Rights Agreements between ourselves and Cleo Christine Allan, James Butler, Quickwood Ltd., Ernest Mario, Amelia Investments Ltd. and Angel Investment

	Company Ltd.
10.30 *	Consultancy Agreement between us and ERA Consulting (USA) LLC
10.31 *	Proprietary Information Agreements between ourselves and Brian Anderson, Brian McAlister, Robert Zahradnik, Howard Kuramitsu, and Steven Projan
10.32 *	Confidential Information Agreement between us and Paul Hassie
10.33 *	Agreement Waiving Registration Rights under Equity Agreement
10.34 *	Second Amendment to Financing Agreement between ourselves and Cornet Capital Corp.
10.35 *	Consultancy Agreement between us and The Biologics Consulting Group, LLC
10.36 *	Fourth Amendment to License Agreements
10.37 *	Agreement between Dr. Robert Zahradnik and ourselves under which Dr. Zahradnik has agreed not to seek repayment of certain loans from the proceeds of this offering
10.38 *	Agreement between Dr. Jeffrey Hillman and ourselves under which Dr. Hillman has agreed not to seek repayment of certain loans from the proceeds of this offering.
10.39 *	Promissory Note with principal amount of \$100,000 payable to Cornet Capital Corp.
10.40 *	Second Amendment to Escrow Agreement
10.41 *	Promissory Note with principal amount of \$75,000 payable to Cornet Capital Corp.
23.1 *	Consent of Ernst & Young LLP
23.2 *	Consent of Conrad C. Lysiak, Esq.

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## ITEM 28. UNDERTAKINGS.

The undersigned registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - a. To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
  - b. To reflect in the prospectus any facts or events which, individually or together, represent a fundamental change in the information in the registration statement; and notwithstanding the forgoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) (Section 230.424(b)) if, in the aggregate, the changes in the volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.
  - c. To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any change to such information in the registration statement.
2. That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
3. To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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### SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing of this Form SB-2 Registration Statement and has duly caused this Form SB-2 Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Alachua, Florida, on this 12<sup>th</sup> day of May, 2003.

#### ORAGENICS, INC.

BY: /s/ Mento A. Soponis  
Mento A. Soponis, President and Chief Executive Officer

BY: /s/ Paul A. Hassie  
Paul A. Hassie, Secretary, Treasurer, Principal Accounting Officer and Chief Financial Officer

KNOW ALL MEN BY THESE PRESENT, that each person whose signature appears below constitutes and appoints Mento A. Soponis, as true and lawful attorney-in-fact and agent, with full power of substitution, for his and in his name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to file the same, therewith, with the Securities and Exchange Commission, and to make any and all state securities law or blue sky filings, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite or necessary to be done in about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying the confirming all that said attorney-in-fact and agent, or any substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Form SB-2 Registration Statement has been signed by the following persons in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Mento A. Soponis Mento A. Soponis	President, Principal Executive Officer and a Member of the Board of Directors	May 12, 2003
/s/ Paul A. Hassie Paul A. Hassie	Chief Financial Officer and Principal Accounting Officer	May 12, 2003
_____ Robert Zahradnik	Member of the Board of Directors	May 12, 2003
/s/ Jeffery Hillman Jeffrey Hillman	Member of the Board of Directors	May 12, 2003
/s/ Brian M. Alister	Member of the Board of Directors	May 12, 2003

/s/ Brian McAlister  
Brian McAlister

Member of the Board of Directors

May 12, 2003

/s/ Brian Anderson  
Brian Anderson

Member of the Board of Director

May 12, 2003