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

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2013.

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT**

For the transition period from _____ to _____

Commission File Number: 001-32188

ORAGENICS, INC.
(Exact name of registrant as specified in its charter)

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

4902 Eisenhower Blvd., Suite 125
Tampa, Florida 33634
(Address of principal executive offices)

813-286-7900
(Issuer's telephone number)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer, "accelerated filer," "non-accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☒

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

Indicate the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date:

As of October 25, 2013, there were 30,506,685 shares of Common Stock, $.001 par value, outstanding.

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PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Oragenics, Inc.

Balance Sheets

	September 30, 2013 (Unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 8,267,888	$ 9,925,967
Restricted cash	—	61,763
Accounts receivables, net	58,878	69,795
Inventory, net	223,318	124,178
Prepaid expenses and other current assets	227,008	221,838
Total current assets	8,777,092	10,403,541
Property and equipment, net	38,198	84,591
Total assets	$ 8,815,290	$ 10,488,132
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,364,968	$ 1,157,520
Short-term notes payable	108,220	47,977
Convertible note payable to shareholder	1,956,000	—
Deferred revenue	23,711	50,989
Total current liabilities	4,452,899	1,256,486
Shareholders' equity:		
Preferred stock, no par value; 20,000,000 shares authorized; none issued and outstanding	—	—
Common stock, $0.001 par value; 50,000,000 shares authorized; 30,168,613 and 27,382,830 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	30,169	27,383
Additional paid-in capital	71,408,003	63,290,625
Accumulated deficit	(67,075,781)	(54,086,362)
Total shareholders' equity	4,362,391	9,231,646
Total liabilities and shareholders' equity	$ 8,815,290	$ 10,488,132

See accompanying notes.

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Oragenics, Inc.

Statements of Operations
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenue, net	$ 253,374	$ 264,248	$ 597,449	$ 901,182
Cost of sales	113,384	164,059	263,990	474,526
Gross profit	139,990	100,189	333,459	426,656
Operating expenses:				
Research and development	6,907,250	600,208	8,289,614	7,130,780
Selling, general and administrative	2,558,205	1,596,554	5,180,702	3,740,022
Total operating expenses	9,465,455	2,196,762	13,470,316	10,870,802
Loss from operations	(9,325,465)	(2,096,573)	(13,136,857)	(10,444,146)
Other income (expense):				
Interest income	3,611	5,645	15,098	7,193
Interest expense	(1,546)	(456,237)	(3,339)	(654,611)
Local business tax	(2,024)	(8,776)	(8,824)	(10,056)
Other income	—	—	144,503	—
Total other income (expense), net	41	(459,368)	147,438	(657,474)
Loss before income taxes	(9,325,424)	(2,555,941)	(12,989,419)	(11,101,620)
Income tax benefit	—	—	—	—
Net loss	$ (9,325,424)	$ (2,555,941)	$(12,989,419)	$(11,101,620)
Basic and diluted net loss per share	$ (0.34)	$ (0.11)	$ (0.47)	$ (0.76)
Shares used to compute basic and diluted net loss per share	27,515,372	23,793,309	27,496,676	14,578,448

See accompanying notes.

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Oragenics, Inc.

Statements of Cash Flows

	For the Nine Months Ended September 30,	
	2013	**2012**
Cash flows from operating activities:		
Net loss	$(12,989,419)	$(11,101,620)
Adjustments to reconcile net loss to net cash used in operating activities:		
Technology access fee paid in common stock and convertible note payable to shareholder	6,000,000	5,798,001
Accretion of discount on notes payable to shareholder	—	483,559
Depreciation and amortization	64,042	55,793
Stock-based compensation expense	1,624,165	1,057,218
Write off of expired inventory	(240,005)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	10,917	20,265
Inventory, net	140,865	195,643
Prepaid expenses and other current assets	151,861	11,843
Accounts payable and accrued expenses	(280,353)	(104,556)
Deferred revenue	(27,278)	112,879
Net cash used in operating activities	(5,545,205)	(3,470,975)
Cash flows from investing activities:		
Purchase of property and equipment	(17,649)	—
Net cash used in investing activities	(17,649)	—
Cash flows from financing activities:		
Borrowings under note payable to shareholder	—	2,500,000
Borrowings under convertible secured note payable to shareholder	—	750,000
Payments on short-term notes payable	(96,788)	(99,514)
Payment of income taxes associated with stock based compensation	—	(127,291)
Net proceeds from issuance of common stock	3,939,800	11,913,442
Restricted cash released	61,763	120,374
Net cash provided by financing activities	3,904,775	15,057,011
Net increase (decrease) in cash and cash equivalents	(1,658,079)	11,586,036
Cash and cash equivalents at beginning of period	9,925,967	171,739
Cash and cash equivalents at end of period	$ 8,267,888	$ 11,757,775
Supplemental disclosure of cash flow information:		
Interest paid	$ 3,108	$ 2,936
Non-cash investing and financing activities:		
Borrowings under short term notes payable for prepaid expense	$ 157,031	$ 134,914
Par value of common stock issued for cashless exercise of warrants	$ 106	$ —
Conversion of convertible note payable and accrued interest to common shares and warrants	$ —	$ 11,275,196
Discount on note payable to shareholder for warrants issued	$ —	$ 483,559
Par value of forfeited stock	$ —	$ 5
Fair market value of the 771,169 warrants issued to Griffin Securities, Inc. as a reduction in paid in capital from issuance of common stock	$ —	$ 1,850,806

See accompanying notes.

Oragenics, Inc.

Notes to Financial Statements
(Unaudited)

1. Organization

Oragenics, Inc. (formerly known as Oragen, Inc.) (the "Company" or "we") was incorporated in November 1996; however, operating activity did not commence until 1999. The Company is focused on the discovery, development and commercialization of a variety of technologies associated with broad spectrum antibiotics, oral health, and other general health benefits.

2. Basis of Presentation

The accompanying unaudited interim financial statements as of September 30, 2013 and December 31, 2012 (audited) and for the three and nine months ended September 30, 2013 and 2012 have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the financial condition, results of operations and cash flows for the periods presented. The results of operations for the interim period September 30, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013 or any future period.

These financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2012, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 26, 2013. The Company has incurred recurring losses and negative cash flows from operations since inception. To date the Company has not generated significant revenues from operations. The Company generated revenues of $597,449, incurred a net loss of $12,989,419, and used cash of $5,545,205 in its operating activities during the nine months ended September 30, 2013. As of September 30, 2013, the Company had an accumulated deficit of $(67,075,781).

During 2012 and 2011, a significant source of debt and equity funding was provided to the Company by its largest shareholder, the Koski Family Limited Partnership (the "KFLP"). In 2012 the Company raised $13,000,000 in gross proceeds through the private placement sale of its common stock. In 2013 the company raised $3,900,000 in gross proceeds through the private placement of its common stock. The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes the working capital at September 30, 2013 will be sufficient to meet the business objectives as presently structured through December 2014.

The Company's ability to continue operations after its current cash resources are exhausted depends on its ability to obtain additional financing or achieve profitable operations, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in the Company's focus and direction of its research and development programs, competitive and technical advances, or other developments. Additional financing will be required to continue operations after the Company exhausts its current cash resources and to continue its long-term plans for clinical trials and new product development. There can be no assurance that any such financing can be realized by the Company, or if realized, what the terms thereof may be, or that any amount that the Company is able to raise will be adequate to support the Company's working capital requirements until it achieves profitable operations.

The Company intends to seek additional funding through sublicensing arrangements, joint venturing or partnering, sales of rights to technology, government grants and public or private financings. The Company's future success depends on its ability to raise capital and ultimately generate revenue and attain profitability. The Company cannot be certain that additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to it or, if available, will be on terms acceptable to the Company. If the Company issues additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of its common stock, and the Company's current shareholders may experience dilution. If the Company is unable to obtain funds when needed or on acceptable terms, the Company may be required to curtail their current development programs, cut operating costs and forego future development and other opportunities.

3. Significant Accounting Policies

Recently Issued Accounting Pronouncements

There are no new accounting pronouncements issued or effective during the second quarter of 2013 that have had or are expected to have an impact on the Company's financial statements.

Use of Estimates

The preparation of financial statements in conformity with GAAP 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, as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. The principal areas of estimation reflected in the financial statements are stock-based compensation, valuation of warrants, inventory obsolescence reserve, sales returns and allowances and the allowance for doubtful accounts.

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.

Guaranteed Rights of Return

The Company has granted guaranteed rights of return to two dental distributors. The Company defers recognition of revenue on these accounts until either the distributor provides notification to the Company that the product has been sold to the end consumer or the guaranteed right of return period expires. Once notification has been received and verified, the Company records revenue in that accounting period. The Company had $23,711 and $27,812 of revenue deferred under guaranteed rights of return arrangements included in deferred revenue in the balance sheets as of September 30, 2013 and December 31, 2012, respectively.

Inventory

Inventory is stated at the lower of cost or market. Cost, which includes material, labor and overhead, is determined on a first-in, first-out basis. On a quarterly basis, we analyze our inventory levels and reserve for inventory that is expected to expire prior to being sold, inventory that has a cost basis in excess of its expected net realizable value, inventory in excess of expected sales requirements, or inventory that fails to meet commercial sale specifications. Expired inventory is disposed of and the related costs are written off to the reserve for inventory obsolescence. The inventory reserve was approximately $22,000 and $253,000 as of September 30, 2013 and December 31, 2012, respectively.

Stock-Based Payment Arrangements

Generally, all forms of stock-based payments, including stock option grants, warrants, and restricted stock grants are measured at their fair value on the awards' grant date typically using a Black-Scholes pricing model. Stock-based compensation awards issued to non-employees for services rendered are recorded at the fair value of the stock-based payment. The expense resulting from stock-based payments are recorded in research and development expense or selling, general and administrative expense in the statement of operations, depending on the nature of the services provided. Stock-based payment expense is recorded over the requisite service period in which the grantee provides services to us. To the extent the stock option grants, warrants, or restricted stock grants do not vest at the grant date they are subject to forfeiture.

Stock-Based Compensation

GAAP requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values as of the grant date. Stock-based compensation expense is recorded over the requisite service period in which the grantee provides services to us, to the extent the options do not vest at the grant date and are subject to forfeiture. For performance-based awards that do not include market-based conditions, we record share-based compensation expense only when the performance-based milestone is deemed probable of achievement. We utilize both quantitative and qualitative criteria to judge whether milestones are probable of achievement. For awards with market-based performance conditions, we recognize the grant-date fair value of the award over the derived service period regardless of whether the underlying performance condition is met.

Warrants

The Company used the Black Scholes Option Pricing Model in calculating the relative fair value of any warrants that have been issued.

Net Loss Per Share

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

Revenue Recognition

The Company recognizes revenues from the sales of product when title and risk of loss pass to the customer, which is generally when the product is shipped. Grant revenues are recognized as the reimbursable expenses are incurred over the life of the related grant. Grant revenues are deferred when reimbursable expenses have not been incurred.

The Company records allowances for discounts and product returns at the time of sale as a reduction of revenues as such allowances can be reliably estimated based on historical experience or known trends. The Company maintains a return policy that allows customers to return product within a specified period of time prior to and subsequent to the expiration date of the product. The estimate of the provision for returns is analyzed quarterly and is based upon many factors, including industry data of product return rates, historical experience of actual returns, analysis of the level of inventory in the distribution channel, if any, and reorder rates. If the history or product returns changes, the reserve will be adjusted. While the Company believes that the reserves it has established are reasonable and appropriate based upon current facts and circumstances, applying different judgments to the same facts and circumstances would result in the estimated amounts for sales returns and chargebacks to vary. Because the ProBiora3 products are still relatively new to the market, the Company could experience different circumstances in the future and these differences could be material.

Concentrations

The Company is dependent on key suppliers to provide probiotics, blending, warehousing and packaging of its EvoraPlus, EvoraKids, EvoraPro, and Teddy’s Pride products. The Company had four key suppliers during the three and nine months ended September 30, 2013 and 2012. The majority of the Company’s cost of sales are from these key suppliers during the three and nine months ended September 30, 2013 and 2012. Accounts payable and accrued expenses for these vendors totaled approximately $-0- and $99,000 as of September 30, 2013 and December 31, 2012, respectively. As of September 30, 2013, the Company had a prepaid balance of approximately $27,000 with one of these vendors.

4. Stock-based Compensation

The Company recognized stock-based compensation on all employee and non-employee awards as follows:

	Three Months Ended September 30, 2013	Three Months Ended September 30, 2012	Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012
Research and development	$ 183,168	$ 105,858	$ 158,575	$ 116,726
Selling, general and administrative	1,355,175	693,533	1,465,590	940,492
Total Stock based compensation	$ 1,538,343	$ 799,391	$ 1,624,165	$ 1,057,218

The Company granted -0- and 35,000 stock options, with a weighted-average grant date fair value of -0- and $3.41 per share, during the three and nine months ended September 30, 2013, respectively. The Company granted -0- and 100,000 stock options, with a weighted-average grant date fair value of $0 and $1.03 per share, during the three and nine months ended September 30, 2012, respectively. During the nine months ended September 30, 2013, 50,533 stock options previously granted have vested, 56,050 stock options were forfeited and 31,533 included in outstanding stock options were exercised.

Included in the results for the September 30, 2013 quarter is a liability and expense in the amount of $1,487,801 relating to probable awards under the Company's 2012 Equity Incentive Plan ("2012 Plan") pursuant to the Company's long term performance based incentive programs for certain members of management and independent directors that were triggered by the Probiotic ECC. The liability and expense amount represents the grant date fair value of the 422,359 shares expected to be awarded under the 2012 Plan. See Note 8 – Subsequent Events.

5. Warrants

A summary of warrant activity for the year ended December 31, 2012 and the nine months ended September 30, 2013 is as follows:

	Warrants	Weighted Average Price
Balance – December 31, 2011	306,388	$ 19.14
Granted	2,942,094	1.87
Exercised	—	—
Expired	(12,500)	(6.00)
Balance – December 31, 2012	3,235,982	3.53
Granted	—	—
Exercised	(200,000)	1.50
Expired	(288,888)	(19.87)
Balance – September 30, 2013	2,747,094	$ 1.91

On January 31, 2013 Griffin Securities Inc. exercised 200,000 of their previously issued warrants resulting in the issuance of 106,250 shares of our common stock.

The warrants outstanding as of September 30, 2013 are as follows:

Exercise Price	Warrants Outstanding	Expiration Dates
$ 1.50	571,169	7/30/17
$ 2.00	2,170,925	3/23/15
$ 10.00	5,000	4/15/14
	2,747,094	

6. Short-term Notes Payable

As of September 30, 2013 and December 31, 2012, the Company had $108,220 and $47,977 respectively, in short-term notes payable for the financing of various insurance policies. On March 8, 2013, the Company entered into a short-term note payable for $50,037 bearing interest at 6.57% to finance the product liability insurance. Principal and interest payments on this note began April 10, 2013 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on January 10, 2014. On June 20, 2013, we entered into a short-term note payable for $106,994 bearing interest at 4.64% to finance a portion of the directors' and officers' liability insurance and employment practices liability insurance premiums. Principal and interest payments on this note began August 24, 2013 and are made evenly based on a straight line amortization over an 11-month period with the final payment due on June 24, 2014.

7. Convertible Note Payable To Shareholder

On September 30, 2013, the Company entered into an unsecured short-term Convertible Promissory Note in the principal amount of $1,956,000 bearing interest at 3.00% as partial consideration for the Technology Access Fees associated with the Probiotic ECC (discussed below) entered into with Intrexon Corporation. The Convertible Promissory Note is payable, at the Company's option, in cash or shares of the Company's common stock. Principal and accrued interest are due on December 31, 2013.

8. Commitments and Contingencies

The University of Florida Research Foundation Licenses

The Company holds exclusive licenses from the University of Florida Research Foundation, Inc. ("UFRF") for its SMaRT Replacement Therapy and MU1140 product candidates.

MU1140 – The Company has exclusively licensed the intellectual property for our MU1140 lantibiotic technology from the UFRF. The original license agreement was dated June 22, 2000 and was subsequently amended on September 15, 2000, July 10, 2002, September 25, 2002, March 17, 2003 and April 19, 2013. The amended license agreement provides the Company with an exclusive worldwide license to make, use and sell products and processes covered by Patent No. 5,932,469 entitled "Antimicrobial Polypeptide, Nucleic Acid and Methods of Use" and includes U.S. patent numbers 6,964,760; 7,067,125; 6,391,285; 6,475,771 and foreign patents. The Company's license is for the period of the patents, which expire from 2017 through 2019, subject to the performance of terms and conditions contained therein.

SMaRT Replacement Therapy – The Company has exclusively licensed the intellectual property for its replacement therapy technology from the UFRF. The original license agreement was dated August 4, 1998 and was subsequently amended on September 15, 2000, July 10, 2002, September 25, 2002, March 17, 2003 and April 19, 2013. The amended license agreement provides the Company with an exclusive worldwide license to make, use and sell products and processes covered by Patent No. 5,607,672, entitled "Replacement Therapy for Dental Caries", which was filed in the U.S. PTO on June 7, 1995 and made effective on March 4, 1997. The patent will expire on June 7, 2015. The Company's license is for the period of the patent, subject to the performance of terms and conditions contained therein.

Additional Terms of UFRF License Agreements – In the amended license agreements for SMaRT Replacement Therapy and MU1140, the Company is obligated to pay 5% of the selling price of any products developed from the licensed technologies that the Company may sell as royalty to the UFRF. In addition, if the Company sublicenses any rights granted by the amended license agreements, the Company is obligated to pay the UFRF 22% of all revenues received from the sublicenses, excluding monies received solely for development costs. The Company is also obligated to make the following payments to UFRF as follows: a one-time commercialization fee, post-commercialization minimum royalty payments, and a one-time cumulative royalty payment. The one-time commercialization fee would be due on the first anniversary of first commercial sale and is calculated at $5,000 per month between May 1, 2013 and the month of the first anniversary of a commercial sale. The post-commercialization minimum royalty payments of $50,000 annually would be due following payment of a commercialization fee. The one-time additional royalty payment would be due when total cumulative royalties paid to UFRF exceed $2.0 million, upon which we would be obligated to make a one-time additional payment to UFRF of 10% of the total royalties due to UFRF in the calendar year in which cumulative royalties exceeded $2.0 million.

The Company is required to make minimum annual maintenance payments to the UFRF for the term of the amended license agreements in the amount of $10,000 for each license agreement and $20,000 in aggregate. The aggregate minimum annual payments are required to be paid in advance on a quarterly basis (i.e. $5,000 per quarter) for both licenses. The Company must also pay all patent costs and expenses incurred by the UFRF for the preparation, filing, prosecution, issuance and maintenance of the patents.

The Exclusive Channel Collaboration ("ECC") Agreements with Intrexon Corporation ("Intrexon")

On September 30, 2013, the Company entered into an ECC Agreement (the "Probiotics ECC") with Intrexon that governs a "channel collaboration" arrangement in which the Company will use Intrexon's proprietary technology relating to the identification, design and production of genetically modified cells, DNA vectors and in vivo control of expression (the "Technology") for the development and commercialization of probiotics, specifically the direct administration to humans of genetically modified probiotics for the treatment of diseases of the oral cavity, throat, sinus and esophagus, including, but not limited to, aphthous stomatitis and Behcet's disease (collectively, the "Probiotics Program"). The Probiotics ECC establishes committees comprised of Company and Intrexon representatives that will govern activities related to the Probiotics Program in the areas of project establishment, chemistry, manufacturing and controls matters, clinical and regulatory matters, commercialization efforts and intellectual property matters.

The Probiotics ECC grants the Company an exclusive worldwide license to utilize Intrexon's Technology to develop and commercialize probiotics, specifically the direct administration to humans of genetically modified probiotics for the treatment of diseases of the oral cavity, throat, sinus and esophagus ("Company Products"). Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of Company Products, and otherwise is non-exclusive. Subject to limited exceptions, the Company may not sublicense the rights described without Intrexon's written consent.

Under the Probiotics ECC, and subject to certain exceptions, the Company is responsible for, among other things, funding the further anticipated development of probiotics toward the goal of commercialization, conducting preclinical and clinical development of candidate probiotics, as well as for other aspects of manufacturing and the commercialization of the product(s). Among other things, Intrexon is responsible for technology discovery efforts, cell-engineering development, and certain aspects of the manufacturing process.

The Company will pay Intrexon 10% of the net sales derived from the sale of products developed from the exclusive channel collaboration relating to the Probiotics Program. The Company has likewise agreed to pay Intrexon a percentage of revenue obtained from a sublicensee in the event of a sublicensing arrangement. The percentage of the revenue to be paid will be determined at the time that a sublicense agreement is negotiated.

The Company may voluntarily terminate the Probiotics ECC upon 90 days written notice to Intrexon. Intrexon may also terminate the Probiotics ECC if the Company breaches the Probiotics ECC and fails to cure the breach within 60 days or the Company does not pursue development of the Superior Therapy under the probiotics identified by Intrexon that is a "Superior Therapy" as defined in the Probiotics ECC.

Upon termination of the Probiotics ECC, the Company may continue to develop and commercialize any Company Product that, at the time of termination, satisfies at least one of the following criteria:

- commercialized by the Company;
- approved by regulatory authorities;
- a subject of an application for regulatory approval that is pending before the applicable regulatory authority; or
- the subject of at least an ongoing Phase 1, Phase 2 or Phase 3 clinical trial in the field of the Probiotics Program.

In addition, in partial consideration for each party's execution and delivery of the Probiotics ECC, on September 30, 2013 the Company entered into a Stock Purchase and Issuance Agreement and a First Amendment to the Stock Purchase and Issuance Agreement (collectively the "SPIA") with Intrexon. Pursuant to the SPIA, the Company paid Intrexon an up-front technology access fee of $6,000,000 (the "Technology Access Fee") in consideration for the execution of the Probiotics ECC. The Technology Access Fee was paid to Intrexon by the Company through the (i) issuance of 1,348,000 shares (at $3.00 per share) of the Company's common stock (the "Technology Access Shares"), and (ii) a convertible promissory note in the amount of $1,956,000 which is payable, at the Company's option, in cash or shares of Company common stock (the "Convertible Note"). The Convertible Note matures on December 31, 2013 and requires the Company to obtain shareholder approval prior to conversion of the Convertible Note. The conversion price is equal to the closing price per share of the Company's common stock on the last trading day immediately prior to the date of conversion.

On September 30, 2013 the Company also sold to Intrexon 1,300,000 shares of the Company's common stock at a price per share of $3.00 for gross proceeds of $3,900,000. The Company intends to use the proceeds from this sale of common stock towards development of the Company's key initiatives relating to the Probiotics Program, and general corporate purposes.

Under the SPIA and as part of the Probiotics ECC, the Company has also agreed to make certain payments to Intrexon upon the Company's achievement of designated milestones. The milestone payments are each payable to Intrexon, at the Company's election (subject to an election right of Intrexon if the milestone is achieved by a sublicensee), either in cash or in shares of Company common stock (using the fair market value of the shares to calculate the number of shares to be issued to Intrexon in lieu of cash). The Commercialization Milestone Events and amounts payable are as follows:

- $2,000,000 within thirty (30) days of the dosing of a patient by or on behalf of the Company, or an Affiliate (as that term is defined in the Probiotics ECC) or permitted sublicensee of the Company, in a phase II clinical trial, whether such occurs in the United States of America under the jurisdiction of the United States Food and Drug Administration ("FDA") or elsewhere under the jurisdiction of a foreign regulatory agency, for a Company Product;
- $5,000,000 within thirty (30) days of the first meeting of the primary endpoint by or on behalf of the Company, or an Affiliate or permitted sublicensee of the Company, in a phase III clinical trial, whether such occurs in the United States of America under the jurisdiction of the FDA or elsewhere under the jurisdiction of a foreign regulatory agency, for a Company Product;
- $10,000,000 within thirty (30) days of the first to occur of (a) the First Commercial Sale (as that term is defined in the Probiotics ECC) of a Company Product, or (b) the approval of a New Drug Application (as that term is defined in the Probiotics ECC) for a Company Product by the FDA or equivalent regulatory action in a foreign jurisdiction.

None of the Probiotic ECC milestones had been achieved as of September 30, 2013.

On June 5, 2012, the Company entered into an ECC Agreement (the "Lantibiotic ECC") with Intrexon that governs a "channel collaboration" arrangement in which the Company will use Intrexon's advanced transgene and cell engineering platforms for the development and production of lantibiotics, a class of peptide antibiotics that are naturally produced in Gram-positive bacteria and contain the characteristic polycyclic thioether amino acids lanthionine and methyllanthonine (collectively, the "Lantibiotics Program"). The Lantibiotic ECC establishes committees comprised of Company and Intrexon representatives that will govern activities related to the Lantibiotics Program in the areas of project establishment, chemistry, manufacturing and controls matters, clinical and regulatory matters, commercialization efforts and intellectual property matters.

The Lantibiotic ECC grants the Company an exclusive worldwide license to use patents and other intellectual property of Intrexon in connection with the research, development, use, importing, exporting, manufacture, sale, and offer for sale of drug products involving the direct administration to humans or companion animals of a lantibiotic for the prevention or treatment of infectious disease ("Oragenics Products"). Such license is exclusive with respect

to any clinical development, selling, offering for sale or other commercialization of Oragenics Products, and otherwise is non-exclusive. Subject to limited exceptions, the Company may not sublicense the rights described without Intrexon's written consent.

Under the Lantibiotic ECC, and subject to certain exceptions, the Company is responsible for, among other things, funding the further anticipated development of lantibiotics toward the goal of commercialization, conducting preclinical and clinical development of candidate lantibiotics, as well as for other aspects of manufacturing and the commercialization of the product(s). Among other things, Intrexon is responsible for technology discovery efforts, cell-engineering development, certain aspects of the manufacturing process, and costs of filing, prosecution and maintenance of Intrexon's patents.

Subject to certain expense allocations and other offsets provided in the Lantibiotic ECC, the Company will pay Intrexon on a quarterly basis 25% of gross quarterly profits derived in that quarter from the sale of products developed from the Lantibiotic ECC, calculated on an Oragenics Product-by-Oragenics Product basis. The Company has likewise agreed to pay Intrexon on a quarterly basis 50% of revenue obtained in that quarter from a sublicensor in the event of a sublicensing arrangement.

During the first 18 months of the agreement, neither the Company nor Intrexon may terminate the ECC Agreement, except under limited circumstances, including in the event of a material breach by the other party and Intrexon may terminate the Lantibiotic ECC under certain circumstances if the Company assigns its rights under the Lantibiotic ECC without Intrexon's consent. Following the first 12 months of the agreement, Intrexon may also terminate the Lantibiotic ECC if the Company fails to use diligent efforts to develop and commercialize Oragenics Products or if the Company elects not to pursue the development of a Lantibiotics Program identified by Intrexon that is a "Superior Therapy" as defined in the Lantibiotic ECC. Following the first 18 months of the agreement, the Company may voluntarily terminate the Lantibiotic ECC at any time upon 90 days written notice to Intrexon.

Upon termination of the Lantibiotic ECC, the Company may continue to develop and commercialize any Oragenics Product that has been, at the time of termination:

- commercialized by the Company;
- approved by regulatory authorities;
- a subject of an application for regulatory approval that is pending before the applicable regulatory authority; or
- the subject of at least an ongoing Phase 1, Phase 2 or Phase 3 clinical trial in the Field (in the case of a termination by Intrexon due to an uncured material breach by the Company or a voluntary termination by the Company).

The Company's obligation to pay 25% of gross profits or revenue described above with respect to these "retained" products as well as to use diligent efforts to develop and commercialize these "retained" Oragenics Products will survive termination of the Lantibiotic ECC.

In addition, in partial consideration for each party's execution and delivery of the Lantibiotic ECC, the Company entered into a Stock Issuance Agreement with Intrexon. Pursuant to the Stock Issuance Agreement, the Company issued to Intrexon 4,392,425 shares of the Company's common stock as an initial technology access fee, in consideration for the execution and delivery of the Lantibiotic ECC and granted Intrexon certain equity participation rights and registration rights.

Under the Stock Issuance Agreement and as part of the Lantibiotic ECC, the Company has also agreed to make certain payments to Intrexon upon the Company's achievement of designated milestones in the form of shares of Company common stock or, at the Company's option, make a cash payment to Intrexon (based upon the fair market value of the shares otherwise required to be issued). The milestone events and amounts payable are as follows:

(i) upon filing of the first Investigational New Drug application with the U.S. Food and Drug Administration for an Oragenics Product, that number of shares equal to the number of shares of common stock comprising 1.0% of the Base Shares (as defined below);

(ii) upon the dosing of the first patient in the first Phase 2 clinical study with an Oragenics Product, that number of shares equal to the number of shares of common stock comprising 1.5% of the Base Shares;

(iii) upon the dosing of the first patient in the first Phase 3 clinical study with an Oragenics Product, that number of shares equal to the number of shares of common stock comprising 2% of the Base Shares;

(iv) upon the filing of the first New Drug Application ("NDA") or Biologics License Application ("BLA") with the U.S. Food and Drug Administration for an Oragenics Product, or alternatively the filing of the first equivalent regulatory filing with a foreign regulatory agency, that number of shares equal to the number of shares of Common Stock comprising 2.5% of the Base Shares; and

(v) upon the granting of the first regulatory approval of an Oragenics Product, that number of shares equal to the number of shares of Common Stock comprising 3% of the Base Shares.

Base Shares is defined in the Stock Issuance Agreement to mean (i) the number of shares of Company common stock together with any securities or instruments convertible or exercisable for shares of common stock issued and outstanding at the time of the applicable milestone event, (ii) minus any shares issuable upon conversion of Capital Inducement Securities. Capital Inducement Securities is defined in the Stock Issuance Agreement to mean warrants or other convertible securities of the Company issued to investors in connection with a debt or equity investment in the Company that are issued in addition to the primary investment securities and in an amount not to exceed 10% of the overall number of shares issued in the investment (on an as-converted to common stock basis).

None of the Lantibiotic ECC milestones had been achieved as of September 30, 2013.

9. Subsequent Events

On October 18, 2013, the Compensation Committee of the Board of Directors (the "Board") of the Company met and determined that one of the performance goals established in the Company's Long Term Incentive Programs ("LTIP") as part of executive compensation and non-employee director compensation had been achieved. The performance goal met was the goal related to the broadening of the Intrexon relationship to include a new area outside of lantibiotics. As a result of the Compensation Committee's determination, and pursuant to the LTIP, Dr. John Bonfiglio, the Company's Chief Executive Officer, Michael Sullivan, the Company's Chief Financial Officer, and Dr. Martin Handfield, the Company's Vice President of Research and Development, were entitled to awards of 0.50%, 0.18%, and 0.17% respectively of the Company's common stock outstanding at the time of the Compensation Committee's determination that such goal had been met. Accordingly, Dr. Bonfiglio, Mr. Sullivan, and Dr. Handfield were awarded 150,843, 54,304 and 51,287 shares of Company common stock under the Company's 2012 Equity Incentive Plan (the "2012 Plan"), respectively. Also on October 18, 2013 the Board met and determined that a similar performance goal under the previously established Long Term Incentive Program for the compensation of non-employee directors had been met. As a result, the Board approved the award of 33,185 shares of common stock under the Plan, to each of the Company's directors who were not employed by the Company, including Frederick Telling, Charles Pope, Alan Dunton, Christine Koski and Robert Koski. In addition, the Board determined to amend its non-employee director compensation program. In connection with each annual meeting of shareholders commencing with the 2013 Annual Meeting, each continuing non-employee director will be granted an award of 10,000 fully vested shares of the Company's common stock under the Company's 2012 Plan.

The aggregate shares awarded under the 2012 Plan of 422,359 consisted of a total of 165,925 shares to non-employee directors and 256,434 shares to executive officers. Of the aggregate 422,359 shares awarded under the LTIP, (i) 150,843 shares were awarded to Dr. Bonfiglio of which 50,000 shares were retained by the Company for applicable tax withholding obligations, (ii) 54,304 shares were awarded to Mr. Sullivan of which 19,000 shares were retained by the Company for applicable tax withholding obligation, (iii) 51,287 shares were awarded to Dr. Handfield of which 15,287 shares were retained by the Company for applicable tax withholding obligation, and (iv) 33,185 shares were awarded to each of the five non-employee directors.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

Forward-Looking Statements

This 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements include statements regarding, among other things, (a) our need for and availability of working capital, (b) our financing plans, (c) our strategies, (d) our projected sales and profitability, (e) anticipated trends in our industry. Forward-looking statements, which involve assumptions and describe our future plans, strategies, and expectations, are generally identifiable by use of the words "may," "will," "should," "expect," "anticipate," "estimate," "believe," "intend," or "project" or the negative of these words or other variations on these words or comparable terminology. This information may involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from the future results, performance, or achievements expressed or implied by any forward-looking statements. These statements may be found under "Management's Discussion and Analysis of Financial Condition and Results of Operations as well as in this 10-Q generally. Actual events or results may differ materially from those discussed in forward-looking statements as a result of various factors, including, without limitation, the risks outlined under "Risk Factors" in our Form 10-K and in this 10-Q. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements contained in this filing will in fact occur. In addition to the information expressly required to be included in this filing, we will provide such further material information, if any, as may be necessary to make the required statements, in light of the circumstances under which they are made, not misleading.

Overview

We are a healthcare company focused primarily on developing novel antibiotics and oral health products. Within oral health we are marketing our oral health probiotics blend, ProBiora3, to consumers and to dental professionals. We also maintain a suite of other technologies stemming from several years of our research efforts in the oral health space.

Our Antibiotics

Members of our scientific team discovered that a certain bacterial strain produces MU1140, a molecule belonging to the novel class of antibiotics known as lantibiotics. Lantibiotics, such as MU1140, are highly modified peptide antibiotics made by a small group of Gram positive bacterial species. Approximately 60 lantibiotics have been discovered since 1927 when the first lantibiotic, Nisin, was discovered. Lantibiotics are generally recognized to be potent antibiotic agents.

We have performed preclinical testing on MU1140, which has demonstrated the molecule's novel mechanism of action. MU1140 has proven active preclinically against all Gram positive bacteria against which it has been tested, including those responsible for a number of healthcare associated infections, or HAIs. The most common HAIs are caused by drug-resistant bacteria, including methicillin-resistant *Staphylococcus aureus*, or MRSA, vancomycin-resistant *Enterococcus faecalis*, or VRE; and *Clostridium difficile,* or *C. diff*. We believe the need for novel antibiotics is increasing as a result of the growing resistance of target pathogens to existing Food and Drug Administration ("FDA") approved antibiotics on the market.

The challenge presented by lantibiotics is that they have been difficult to investigate for their clinical usefulness as a therapeutic agent in the treatment of infectious diseases due to a general inability to produce or synthesize sufficient quantities of pure amounts of any of these molecules. Standard fermentation methods are used to make a variety of currently marketed antibiotics. When such fermentation methods are used to make lantibiotics the result is the production of only minute amounts of the lantibiotic.

In order to meet the challenge associated with producing sufficient quantities of MU1140 for our clinical trials and ultimately our commercialization efforts, we are pursuing the following path:

- In June 2012, we entered into a worldwide exclusive collaboration agreement with Intrexon Corporation ("Intrexon") for the development and commercialization of the native strain of MU1140 using Intrexon's advanced transgene and cell engineering platforms (the "Lantibiotic ECC"). We expect to pursue our research and development efforts with Intrexon in accordance with the terms of the ECC on the development of the MU1140 molecule and potential derivatives of the molecule.

We have previously performed preclinical testing on native MU1140 and such testing has demonstrated the molecule's novel mechanism of action. We have begun limited preclinical activities on MU1140 developed under the Lantibiotic ECC with Intrexon, in the second half of 2013. These preclinical activities are expected to include toxicity results, pharmacokinetic studies, and efficacy studies in animals. This work will be done solely by us through the use of outside contractors. Pursuit of clinical trials toward the goal of ultimately obtaining regulatory approval will depend upon further successful advancements in our research collaboration efforts with Intrexon and our efforts to have additional product manufactured. Developments from these efforts will dictate our regulatory path. If our preclinical work is successful, we would expect to file an Investigational New Drug application with the FDA by the first quarter of 2015.

Through our work with Intrexon, we have been able to produce an exponential increase in the fermentation titer of the target compound MU1140 and the discovery of a new purification process for MU1140. We believe these developments represent progress toward our goal of commercial production of sufficient quantities of MU1140 and deliver a step in validating the lantibiotics platform targeting infectious diseases. Previously, the ability to manufacture MU1140 by fermentation was originally thought not to be commercially feasible due to low titers and difficulties in purification. In addition to the optimization of fermentation and purification strategies, we are working to leverage Intrexon's genetic and cell engineering expertise to produce analogs of MU1140 toward the goal of establishing a pipeline of new lantibiotics.

Manufacturing requirements and methods for producing MU1140, or an analog, will primarily be dependent upon the end results of our efforts under the ECC with Intrexon. We are actively seeking a third party manufacturer to produce additional quantities of MU1140, or a designated analog, based upon the developments achieved from our work with Intrexon. The additional quantities of MU1140, or a designated analog, are needed for the consummation and pursuit of our preclinical testing activities.

We also produced a synthetic version of MU1140 known as MU1140-S. We created MU1140-S using our patented, novel organic chemistry synthesis platform known as DPOLT (Differentially Protected Orthogonal Lanthionine Technology). We engaged Bachem Americas, Inc. ("Bachem"), a peptide synthesis manufacturing company to assist us with research on producing greater amounts of MU1140-S. While the work performed by Bachem generated improvements in the yield of components necessary to synthesize MU1140-S, further research was determined to be needed, which was beyond the scope of our initial agreement with Bachem. While we continue to pursue this research internally through the use of existing grant funds, at this time our primary focus is with ongoing research and development efforts with Intrexon.

Our Probiotic Products

We are marketing a variety of probiotic products that we developed. Our probiotic products contain the active ingredient ProBiora3, a patented blend of oral care probiotics that promote fresher breath, whiter teeth and support overall oral health. We have conducted scientific studies on ProBiora3 in order to market our products under self-affirmed Generally Recognized As Safe status ("GRAS"). We sell our ProBiora3 products through multiple distribution channels. We continue to seek improvement in the performance of our oral care probiotics business and consistent with these efforts:

- We are focusing our efforts on our direct-to-consumer channel, including internet, as well as on our Dental channel, which entails distribution to dentists throughout the United States; and
- To better serve our customers, we continue to evaluate new delivery systems, which we believe will enable us to deliver ProBiora3 to new markets and end-users.

In order to better understand and define our customer base, we conducted detailed market research utilizing outside consultants at the end of 2012. The goal of the research was to develop a plan to improve market awareness and sales of our oral probiotic product line. The effort produced strategic marketing and sales plans that we have begun to implement. The initial implementation of our new sales approach commenced at the end of the quarter ended June 30, 2013 and as such, continues to be in a roll-out mode. The results for the September 30, 2013 quarter have not met expectations. While more time is needed for the expected benefits of the marketing plan to materialize, we expect to review the results and efforts undertaken to date toward the goal of making changes to improve our results. Our quarter over quarter sales of our probiotic product lines may fluctuate. We believe that the successful execution of our marketing plans can lead to improved probiotic sales on a year over year sales basis.

We initiated two, double blinded randomized, placebo controlled clinical studies, one at the University of Washington and the other at Loma Linda University in California, that we believe could allow us to enhance the claims we can make about our ProBiora3 products and assist us in registering the product for commercial sale in the European Union. Review of the baseline clinical and microbial data from these studies did not demonstrate support for enhanced claims. We believe the results were attributable to the enrollment of test subjects with better than average oral health, which created a situation where there was little or no room for demonstrating an improvement in clinical indices. We have determined that it is more cost effective to terminate these studies and transition our clinical efforts and resources to a more standardized oral care clinical study design capable of demonstrating a product benefit. We, however, continue supporting a two-year study in children in Scandinavia.

Other Product Candidates and Technologies

We also possess and have developed other product candidates and technologies that originated from the discoveries of our scientific team. These other product candidates and technologies include our SMaRT Replacement Therapy, our weight loss agent, LPT3-04, and DPOLT, which was specifically designed as a methodology for synthesizing lantibiotics using traditional organic chemistry techniques. We continue to consider and evaluate opportunities that could promote the advancement of our other product candidates and technologies. We believe our other product candidates and technologies could provide potential partnership opportunities for us. For our product candidates and technologies, we expect to devote limited financial resources toward continued research and development while exploring the possibilities for outlicensing such product candidates or entering into partnerships or collaborative arrangements for the further development of such product candidates.

Our SMaRT Replacement Therapy. Our SMaRT Replacement Therapy is based on the creation of a genetically modified strain of bacteria that colonizes in the oral cavity and replaces native bacteria that cause tooth decay. Our SMaRT Replacement Therapy product candidate is designed to be a painless, one-time, five-minute topical treatment applied to the teeth that has the potential to offer lifelong protection against dental caries, or tooth decay. While we commenced a Phase 1b clinical trial for SMaRT Replacement Therapy during the first quarter of 2011, the very restrictive study enrollment criteria required by the FDA made the enrollment of candidates meeting the restrictive criteria difficult. Due to the enrollment difficulty we encountered with our initial Phase 1a clinical trial and now with our phase 1b clinical trial, we determined to discontinue pursuit of our Phase 1b clinical trial and instead focus our efforts on possible partnering opportunities that may exist for our SMaRT Replacement Therapy.

Our Weight Loss Agent-LPT3-04. LPT3-04 is a naturally occurring compound that is normally consumed in the human diet in small amounts. In the course of our SMaRT Replacement Therapy research, our scientific team also discovered that consumption of a significant amount of LPT3-04 resulted in dose-dependent weight loss in experimental animal models. We have filed a patent application for use of LPT3-04 for weight regulation with the United States Patent Office. We believe this product candidate is positioned for collaboration, or outlicensing opportunities, which we may pursue.

Recent Developments

The Intrexon Transaction

On September 30, 2013, the Company entered into an ECC Agreement (the "Probiotics ECC") with Intrexon that governs a "channel collaboration" arrangement in which the Company will use Intrexon's proprietary technology relating to the identification, design and production of genetically modified cells, DNA vectors and in vivo control of expression (the "Technology") for the development and commercialization of probiotics, specifically the direct administration to humans of genetically modified probiotics for the treatment of diseases of the oral cavity, throat, sinus and esophagus, including, but not limited to, aphthous stomatitis and Behcet's disease (collectively, the "Probiotics Program"). The Probiotics ECC Agreement establishes committees comprised of Company and Intrexon representatives that will govern activities related to the Probiotics Program in the areas of project establishment, chemistry, manufacturing and controls matters, clinical and regulatory matters, commercialization efforts and intellectual property matters.

The Probiotics ECC grants the Company an exclusive worldwide license to utilize Intrexon's Technology to develop and commercialize probiotics, specifically the direct administration to humans of genetically modified probiotics for the treatment of diseases of the oral cavity, throat, sinus and esophagus ("Company Products"). Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of Company Products, and otherwise is non-exclusive. Subject to limited exceptions, the Company may not sublicense the rights described without Intrexon's written consent.

Under the Probiotics ECC, and subject to certain exceptions, the Company is responsible for, among other things, funding the further anticipated development of probiotics toward the goal of commercialization, conducting preclinical and clinical development of candidate probiotics, as well as for other aspects of manufacturing and the commercialization of the product(s). Among other things, Intrexon is responsible for technology discovery efforts, cell-engineering development, and certain aspects of the manufacturing process.

The Company will pay Intrexon 10% of the net sales derived from the sale of products developed from the exclusive channel collaboration relating to the Probiotics Program. The Company has likewise agreed to pay Intrexon a percentage of revenue obtained from a sublicensee in the event of a sublicensing arrangement. The percentage of the revenue to be paid will be determined at the time that a sublicense agreement is negotiated.

The Company may voluntarily terminate the Probiotics ECC upon 90 days written notice to Intrexon. Intrexon may also terminate the Probiotics ECC if the Company breaches the Probiotics ECC and fails to cure the breach within 60 days or the Company does not pursue development of the Superior Therapy under the probiotics identified by Intrexon that is a "Superior Therapy" as defined in the Probiotics ECC.

Upon termination of the Probiotics ECC, the Company may continue to develop and commercialize any Company Product that, at the time of termination, satisfies at least one of the following criteria:

- commercialized by the Company;
- approved by regulatory authorities;
- a subject of an application for regulatory approval that is pending before the applicable regulatory authority; or
- the subject of at least an ongoing Phase 1, Phase 2 or Phase 3 clinical trial in the field of the Probiotics Program.

In addition, in partial consideration for each party's execution and delivery of the Probiotcs ECC, the Company entered into a Stock Purchase and Issuance Agreement and a First Amendment to the Stock Purchase and Issuance Agreement (collectively the "SPIA") with Intrexon. Pursuant to the SPIA, the Company paid Intrexon an up-front technology access fee of $6,000,000 (the "Technology Access Fee") in consideration for the execution of the Probiotics ECC. The Technology Access Fee was paid to Intrexon by the Company through the (i) issuance of 1,348,000 shares of the Company's common stock (the "Technology Access Shares"), and (ii) a convertible promissory note in the amount of $1,956,000 which is payable, at the Company's option, in cash or shares of Company common stock (the "Convertible Note"). The Convertible Note matures on December 31, 2013 and requires the Company to obtain shareholder approval prior to conversion of the Convertible Note. The conversion price is equal to the closing price per share of the Company's common stock on the last trading day immediately prior to the date of conversion. The Company sold to Intrexon 1,300,000 shares of the Company's common stock at a price per share of $3.00 for gross proceeds of $3,900,000. The Company intends to use the proceeds from this sale of common stock towards development of the Company's key initiatives relating to the Probiotics Program, and general corporate purposes.

Under the SPIA and as part of the Probiotics ECC, the Company has also agreed to make certain payments to Intrexon upon the Company's achievement of designated milestones. The milestone payments are each payable to Intrexon, at the Company's election (subject to an election right of Intrexon if the milestone is achieved by a sublicensee), either in cash or in shares of Company common stock (using the fair market value of the shares to calculate the number of shares to be issued to Intrexon in lieu of cash). The Commercialization Milestone Events and amounts payable are as follows:

- $2,000,000 within thirty (30) days of the dosing of a patient by or on behalf of the Company, or an Affiliate (as that term is defined in the Probiotics ECC) or permitted sublicensee of the Company, in a phase II clinical trial, whether such occurs in the United States of America under the jurisdiction of the United States Food and Drug Administration ("FDA") or elsewhere under the jurisdiction of a foreign regulatory agency, for a Company Product;
- $5,000,000 within thirty (30) days of the first meeting of the primary endpoint by or on behalf of the Company, or an Affiliate or permitted sublicensee of the Company, in a phase III clinical trial, whether such occurs in the United States of America under the jurisdiction of the FDA or elsewhere under the jurisdiction of a foreign regulatory agency, for a Company Product;
- $10,000,000 within thirty (30) days of the first to occur of (a) the First Commercial Sale (as that term is defined in the Probiotics ECC) of a Company Product, or (b) the approval of a New Drug Application (as that term is defined in the Probiotics ECC) for a Company Product by the FDA or equivalent regulatory action in a foreign jurisdiction.

About Us

We were incorporated in November 1996 and commenced operations in 1999. We consummated our initial public offering in June 2003. We have devoted substantially all of our available resources to the commercialization of our ProBiora3 products as well as our discovery efforts comprising research and development, clinical trials for our product candidates, protection of our intellectual property and the general and administrative support of these operations. We have generated limited revenues from grants and ProBiora3 product sales through September 30, 2013, and have principally funded our operations through the sale of debt and equity securities, including the exercise of warrants issued in connection with these financing transactions. Prior to 2008 our revenues were derived solely from research grants. Since 2008, our revenues have also included sales of our ProBiora3 products, which we initiated in late 2008. Our net revenues were $597,449 and $901,182 for the nine months ended September 30, 2013 and 2012, respectively, and $1,331,764 and $1,444,447 for the years ended December 31, 2012 and 2011, respectively.

As of September 30, 2013, we had an accumulated deficit of $(67,075,781) and we have yet to achieve profitability. We incurred net losses of $12,989,419 and $11,101,620 for the nine months ended September 30, 2013 and 2012, respectively, and $13,090,446 and $7,678,868 for the years ended December 31, 2012 and 2011, respectively. We expect to incur significant and increasing operating losses for the foreseeable future as we seek to advance our product candidates through preclinical testing and clinical trials to ultimately obtain regulatory approval and eventual commercialization. We are continuing our efforts to raise additional capital. Adequate additional funding may not be available to us on acceptable terms, or at all. We expect that research and development expenses will increase along with general and administrative costs, as we grow and operate our business. There can be no assurance that additional capital will be available to us on acceptable terms, if at all.

Financial Overview

Net Revenues

Our revenues prior to 2008 consisted exclusively of grant funding from government agencies under the National Science Foundation's, or NSF, and National Institutes of Health's, or NIH, Small Business Innovation Research, or SBIR, grants. Since the initial launch of our ProBiora3 products in late 2008, our net revenues for the year ended December 31, 2008 and thereafter, also included sales of our ProBiora3 products. Sales of our ProBiora3 products were $1,194,878 and $1,229,510 for the years ended December 31, 2012 and 2011, respectively and $574,272 for the nine months ended September 30, 2013. Because of our efforts to increase the distribution of our ProBiora3 products, we continue to expect net revenues to increase in the future. However, our ability to achieve an increase in ProBiora3 product revenues will depend on a number of factors, including primarily the success of marketing efforts related to our ProBiora3 products.

We expect that our revenues will fluctuate from quarter to quarter as a result of the volume of sales of our products and the amount of license fees, research and development reimbursements, milestone and other payments from any license or strategic partnerships we may enter into in the future.

Cost of Goods Sold

Our cost of goods sold includes the production and manufacture of our ProBiora3 products, as well as shipping and processing expenses and scrap expense. Scrap expense represents product rework charges, inventory adjustments, inventory replacement reserves, and damaged inventory. Because our ProBiora3 products contain live organisms they have a limited shelf life. As such, we attempt to manage the amount of production we request of our manufacturers and the amount of inventory we maintain. We expect our cost of goods sold would increase as we are successfully able to expand our distribution and sales efforts for our ProBiora3 products.

Research and Development Expenses

Research and development consists of expenses incurred in connection with the discovery and development of our product candidates. These expenses consist primarily of employee-related expenses, which include salaries and benefits and attending science conferences; expenses incurred under agreements with contract research

organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies; the cost of acquiring and manufacturing clinical trial materials; facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, and depreciation of fixed assets; license fees for and milestone payments related to in-licensed products and technology; stock-based compensation expense; and costs associated with non-clinical activities and regulatory approvals. We expense research and development costs as incurred.

Our research and development expenses can be divided into (i) clinical research, and (ii) preclinical research and development activities. Clinical research costs consist of clinical trials, manufacturing services, regulatory activities and related personnel costs, and other costs such as rent, utilities, depreciation and stock-based compensation. Preclinical research and development costs consist of our research activities, preclinical studies, related personnel costs and laboratory supplies, and other costs such as rent, utilities, depreciation and stock-based compensation and research expenses we incur associated with our ECC agreements with Intrexon. While we are currently focused on advancing our product development programs, our future research and development expenses will depend on the clinical success of our product candidates, as well as ongoing assessments of each product candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans, research expenses and capital requirements.

Our research and development expenses were $8,289,614 and $7,130,780 for the nine months ended September 30, 2013 and 2012, respectively.

Our current strategy is to increase our research and development expenses in the future as we continue the advancement of preclinical product development programs for our MU1140 product candidate and with respect to our probiotic projects. The lengthy process of completing preclinical and clinical trials; seeking regulatory approval for our product candidates; and expanding the claims we are able to make, requires expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenues and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Our current MU1140 product development candidate is not expected to be commercially available until sometime after 2016. For our other product candidates and technologies, our plan is to reduce expenditures in research and development. We expect to seek licensing or partnering opportunities with larger pharmaceutical companies with respect to our other product candidates, and technologies while committing limited research and development expenditures.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, business development, marketing, information technology, legal and human resources functions. Other general and administrative expenses include facility costs not otherwise included in research and development expenses, patent filing, and professional fees for legal, consulting, auditing and tax services.

While our quarter over quarter expenses relating to general and administrative costs will fluctuate, we anticipate that our general and administrative expenses when considered from an annual basis will increase for, among others, the following reasons:

- the costs associated with the advertising and marketing of our ProBiora3 products;
- to support our research and development activities, which, subject to available capital, we expect to expand as we continue the development of our product candidates; and
- the increased payroll, expanded infrastructure and higher consulting, legal, accounting and investor relations costs associated with being a public company.

Other Income and (Expense)

Other income and expense includes local business taxes, as well as interest income and expense. Interest income

consists of interest earned on our cash and cash equivalents. The primary objective of our investment policy is capital preservation. Interest income consists primarily of interest associated with our cash balance and interest expense in the prior comparative period associated with our indebtedness.

Income Taxes

As of December 31, 2012 and 2011, we have net operating loss carryforwards of approximately $48,822,000 and $36,480,000, respectively, to offset future federal and state income taxes. We also have research and development and investment tax credit carryforwards of approximately $881,000 and $551,000 as of December 31, 2012 and 2011, respectively, to offset future federal and state income taxes. Our net operating loss and research and development tax credit carryforwards will expire if not used by 2033 and 2023, respectively. Our ability to utilize our net operating loss and tax credit carryforwards may be limited in the event a change in ownership, as defined in Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, has occurred or may occur in the future. The private placement transaction with the KFLP in June 2009 (the "June 2009 Private Placement") constituted such an event and our historical loss carryforwards were limited. In each period since our inception, we have recorded a 100% valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal tax benefit in our statements of operations.

Results of Operations for the Three Months Ended September 30, 2013 and 2012

Net Revenues. We generated net revenues of $253,374 for the three months ended September 30, 2013 compared to $264,248 for the three months ended September 30, 2012. Our ProBiora3 revenues increased from September 30, 2012 due primarily to increased advertising which was offset by a decline in grant revenues.

Cost of Goods Sold. Cost of goods sold was $113,384 for the three months ended September 30, 2013 compared to $164,059 for the three months ended September 30, 2012, a decrease of $50,675. This decrease was due primarily to a decline in scrap expense and shipping and warehousing costs.

Research and Development. Research and development expenses were $6,907,251 for the three months ended September 30, 2013 compared to $600,208 for the three months ended September 30, 2012, an increase of $6,307,043 or 1051%. This increase in research and development expenses was primarily due to the payment of a $6.0 million technology access fee through the issuance of common stock and a Convertible Note payable to Intrexon Corporation pursuant to the terms of the our new Probiotic ECC during the three months ended September 30, 2013. There was no such payment of a Technology Access Fee to Intrexon Corporation during the three month period ending September 30, 2012. There were also increases in consulting costs, salary related costs, and stock-based compensation costs of $208,120, $18,949, and $77,309 respectively.

Selling, General and Administrative. Selling, general and administrative expenses were $2,558,205 for the three months ended September 30, 2013 compared to $1,596,554 for the three months ended September 30, 2012, an increase of $961,651 or 60.2%. This increase was due to increases in salary and salary related costs, stock-based compensation costs, advertising and marketing costs of $113,401, $661,649, and $296,968, respectively which were partially offset by a decrease in consulting costs of $90,029.

Other Income (Expense). Other income (expense) was $41 for the three months ended September 30, 2013 compared to $(459,368) for the three months ended September 30, 2012, resulting in a net change of $459,409. The net change was primarily attributable to a decrease in interest expense of $454,691 due to the conversion of the note payable with warrants to common stock and the write off of the remaining discount to interest expense.

Results of Operations for the Nine Months Ended September 30, 2013 and 2012

Net Revenues. We generated net revenues of $597,449 for the nine months ended September 30, 2013 compared to $901,182 for the nine months ended September 30, 2012. Our ProBiora3 revenues decreased from September 30, 2012 due primarily to a decline in revenues from sales to our international clients and a decline in grant revenues.

Cost of Goods Sold. Cost of goods sold decreased by $210,536 to $263,990 for the nine months ended September 30, 2013 compared to $474,526 for the nine months ended September 30, 2012. This decrease was primarily attributable to a decline in revenues from sales to our international clients and a decrease in scrap expense.

Research and Development. Research and development expenses were $8,289,614 for the nine months ended September 30, 2013 compared to $7,130,780 for the nine months ended September 30, 2012, an increase of $1,158,834 or 16.2%. This increase in research and development expenses was primarily due to the increased expense associated with the payment of consulting fees to Intrexon pursuant to the terms of Lantibiotic ECC for the Lantibiotics Program during the nine month period ending September 30, 2013 of $919,960 when compared to the nine month period ending September 30, 2012. In addition the Technology Access Fee for the Probiotic ECC for the Probiotics Program increased by $202,000 when compared to the Technology Access Fee for the Lantibiotic ECC for the Lantibiotics Program

Selling, General and Administrative. Selling, general and administrative expenses were $5,180,702 for the nine months ended September 30, 2013 compared to $3,740,022 for the nine months ended September 30, 2012; an increase of $1,440,608 or 38.5%. This increase was due to increases in advertising and marketing, stock-based compensation, salary and salary related costs, Board fees and travel costs of $861,382, $525,590, $43,445, $25,784 and $75,479, respectively.

Other Income (Expense). Other income (expense) was $147,438 for the nine months ended September 30, 2013 compared to $(657,474) for the nine months ended September 30, 2012, resulting in a net change of $804,912. The net change was primarily attributable to a decrease in interest expense of $651,272 and an increase in other income of $146,002 due to the receipt of cash relating to the purchase of our membership interest in our mutual insurer by an unrelated third party.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through the sale of equity securities in our initial public offering, the sale of equity securities and warrants in private placements, debt financing and grants. During the nine months ended September 30, 2013 and 2012, our operating activities used cash of $5,545,205 and $3,470,975 respectively. The use of cash in all periods primarily resulted from our net losses adjusted for non-cash items and changes in operating assets and liabilities. We had a working capital surplus of $4,324,193 and $9,147,055 at September 30, 2013 and December 31, 2012, respectively.

During the nine months ended September 30, 2013 and 2012, our investing activities used cash of $17,649 and $0 respectively.

During the nine months ended September 30, 2013 and 2012, our financing activities provided cash of $3,904,775 and $15,057,011, respectively. The cash provided by financing activities during the three months ended September 30, 2013 was primarily due to the release of restrictions on cash offset by reductions in short term notes payable. The cash provided by financing activities during the nine months ended September 30, 2013 was primarily due to the release of restrictions on cash that was offset by reductions in short term notes payable.

Financing

Additional details of our financing activities for the periods reflected in this report are provided below:

Koski Family Limited Partnership Financing Activities

On July 30, 2010, we entered into an unsecured revolving credit agreement (the “Credit Facility”) with the Koski Family Limited Partnership (“KFLP”) an accredited investor and our largest shareholder. Pursuant to the Credit Facility, we were able to borrow up to $2,000,000 from the KFLP at LIBOR plus 6.0%. The term of the Credit Facility was initially for 12 months commencing August 1, 2010.

On January 24, 2011, we entered into a First Amendment to the Credit Facility (the “First Amendment”) to increase the available borrowing from $2,000,000 to $2,500,000 and simultaneously therewith we drew on the Credit Facility as amended by the First Amendment to borrow the additional $500,000 in available funds and executed another revolving unsecured promissory note (the “January 2011 Promissory Note”) initially due on July 30, 2011.

On February 4, 2011, we entered into a Second Amendment (the "Second Amendment") to the Credit Facility. As a result of the Second Amendment, we are able to borrow up to an additional $2,500,000 from the KFLP. Future draws under the Credit Facility, as amended, were limited to $500,000 per month commencing no earlier than March 2011. Under the Second Amendment, the due date of the amounts then outstanding under the Credit Facility was extended by one year from July 30, 2011 to July 30, 2012. The interest rate remained at LIBOR plus 6.0%. The Second Amendment further provided for the automatic conversion of any amounts borrowed and outstanding under the Credit Facility into securities that we may issue in subsequent securities offerings. Any automatic conversion of amounts outstanding under the Credit Facility would be on the same terms of any such offering. In addition, the Second Amendment provided the KFLP with the right to put any undrawn available amounts under the Credit Facility, as amended, to us and thereby have a note issued to the KFLP.

On each of March 15, 2011, April 5, 2011, May 5, 2011, June 3, 2011, and July 8, 2011 we borrowed an additional $500,000 under the Credit Facility, as amended, and executed a revolving unsecured promissory note in such amounts that each matured on July 30, 2012.

On June 29, 2011, we entered into a Third Amendment (the "Third Amendment") to the Credit Facility. As a result of the Third Amendment, we increased our availability under the Credit Facility by $2,000,000 from $5,000,000 to $7,000,000. Future draws of the $2,000,000 in increased availability provided by the Third Amendment to the Credit Facility were limited to $1,000,000 increments beginning no earlier than August 2011 and October 2011, respectively. All other terms of the Credit Facility remained the same.

On each of August 1, 2011 and October 5, 2011, the Company borrowed an additional $1,000,000 under the Credit Facility, as amended by the Third Amendment, and executed a revolving unsecured promissory note in such amounts that matured on July 30, 2012.

On December 9, 2011, we entered into a Fourth Amendment (the "Fourth Amendment") to the Credit Facility. The Fourth Amendment increased the available borrowing under the Credit Facility by $500,000 from $7,000,000 to $7,500,000. On December 9, 2011, the Company drew down on the Credit Facility, as amended, to borrow $500,000 in the newly available funds. All other terms of the Credit Facility remained the same.

On January 23, 2012, we entered into a Fifth Amendment (the "Fifth Amendment") to the Credit Facility. The Fifth Amendment increased the available borrowing under the Credit Facility by $750,000 from $7,500,000 to $8,250,000. On January 23, 2012, we drew down on the Credit Facility, as amended, to borrow $750,000. All other terms of the Credit Facility remained the same.

On March 23, 2012, we entered into an Exchange of Notes for Equity Agreement (the "Debt Exchange Agreement") with the KFLP. Pursuant to the terms of the Debt Exchange Agreement, we issued 6,285,619 shares of common stock and warrants to acquire 1,571,405 shares of common stock to the KFLP in exchange for the cancellation of an aggregate of $8,737,011 of indebtedness owed to the KFLP under the Credit Facility. The outstanding indebtedness consisted of $8,250,000 in principal owed on twelve separate promissory notes previously issued by us to the KFLP under the Credit Facility and accrued interest through March 23, 2012 (the closing date) of $487,011. The Credit Facility was terminated and the previously issued promissory notes thereunder were cancelled. The warrants are exercisable immediately at a price per share of $2.00 and expire three (3) years from the date of issuance.

On March 23, 2012, we also entered into a new loan agreement (the "Loan Agreement") with the KFLP. It provided us with up to $2.5 million in secured funding in two advances of $1,250,000 each with the first advance occurring on March 23, 2012 and the second advance able to be made within 30 days thereafter, subject to the continued accuracy of representations and warranties made by us and that no material adverse events had occurred in connection with the our business. Borrowings under the Loan Agreement matured in three years with interest at the rate of 5.0% and are secured by select assets of us relating to or connected with the ProBiora3, SMaRT Replacement Therapy, MU1140 and LPT3-04 technologies.

The loan amount was subject to automatic conversion upon a subsequent qualified equity financing by the Company of $5,000,000 (excluding any converted debt amount). Pursuant to the Loan Agreement we also issued a warrant to the KFLP to acquire 599,520 shares of our common stock. The warrants are exercisable immediately at a price per share of $2.00 and expire three (3) years from the date of issuance. The fair value of the warrant using the Black Scholes Model is $599,520. The first funding has a fair value of $1,250,000. Using the relative fair value method, the first funding has an initial value of $766,441 and the warrant had an initial value of $483,559. The value of the warrant was credited to Additional Paid-in Capital. This discount of $483,559 was being charged to interest expense over the life of the Loan Agreement until the loan was terminated as disclosed below.

The July 2012 Private Placement

On July 30, 2012, we entered into a Stock Purchase Agreement (the "Purchase Agreement") with certain accredited investors (the "Purchasers") pursuant to which we: (i) sold to the Purchasers an aggregate of 8,666,665 shares of our Common Stock at a price per share of $1.50 (the "Common Shares") for aggregate gross proceeds of approximately $13,000,000 (the "Offering"). We intend to use the net proceeds from this Offering of approximately $12,046,000 to accelerate development of several of our key initiatives including the ECC with Intrexon relating to our lantibiotics program and sales and marketing of our probiotic product lines and general corporate purposes.

Griffin Securities, Inc. (the "Placement Agent") served as the placement agent for the Offering. In consideration for services rendered as the Placement Agent in the Offering, we agreed to (i) pay to the Placement Agent cash commissions equal to $899,698, or 7.0% of the gross proceeds received in the Offering, less certain excluded proceeds, (ii) issue to the Placement Agent, or its designee, a five-year warrant to purchase up to 771,169 shares of our common stock (representing 9% of the common shares sold in the Offering) with an exercise price of $1.50 per share (the "Agent Warrants"); and (iii) reimburse the Placement Agent for its reasonable actual out-of-pocket expenses, incurred in connection with the Offering, including reasonable legal fees and disbursements up to a maximum aggregate amount of $50,000. The determination of the Placement Agent's fees did not include any shares issued to the KFLP, (in connection with the automatic conversion of its secured debt with us described below) or shares acquired by any officers or directors participating in the Offering. The Agent Warrants were valued at $2.40 per share.

Because the Offering constituted a "qualified financing" under the terms of our Loan Agreement with the KFLP, our secured debt in the principal amount of $2.5 million, together with accrued but unpaid interest thereon, due to the KFLP was automatically converted contemporaneously with the closing of the Offering into 1,692,123 shares of common stock issued to the KFLP at the same price of $1.50 per share paid by the Purchasers in the Offering. As a result of the conversion of the secured indebtedness, the Loan Agreement together with the related Security Agreement was terminated and the unamortized discount was expensed and the full value of the $2.5 million borrowed under the Loan Agreement and accrued interest was converted into common stock.

The September 2013 Private Placement and Convertible Note Payable to Shareholder

On September 30, 2013, the Company entered into a Stock Purchase and Issuance Agreement and a First Amendment to the Stock Purchase and Issuance Agreement (collectively the "SPIA") with Intrexon. Pursuant to the SPIA, the Company sold to Intrexon 1,300,000 shares of the Company's common stock at a price per share of $3.00 for gross proceeds of $3,900,000. The Company intends to use the proceeds from this sale of common stock towards development of the Company's key initiatives relating to the Probiotic program, and general corporate purposes.

On September 30, 2013 as partial consideration for the Technology Access Fee paid to Intrexon pursuant to the Probiotic ECC we issued a convertible promissory note in the amount of $1,956,000 which is payable, at the Company's option, in cash or shares of Company common stock (the "Convertible Note"). The Convertible Note matures on December 31, 2013 and requires the Company to obtain shareholder approval prior to conversion of the Convertible Note. The conversion price is equal to the closing price per share of the Company's common stock on the last trading day immediately prior to the date of conversion.

Other Financings

On March 3, 2011, we entered into a short-term note payable for $48,988 bearing interest at 5.48% per annum to finance product liability insurance. Payments on this note were made evenly based on a straight line amortization over a ten-month period with the final payment due on January 10, 2012.

On July 12, 2011, we entered into a short-term note payable for $77,751 bearing interest at 4.75% per annum to finance a portion of the directors' and officers' liability insurance. Principal and interest payments on this note began August 24, 2011 and were made evenly based on a straight line amortization over an 11-month period with the final payment due on June 24, 2012.

On March 10, 2012, we entered into a short-term note payable for $50,037 bearing interest at 6.17% per annum to finance the product liability insurance. Principal and interest payments on this note began April 10, 2012 and were made evenly based on a straight line amortization over a 10-month period with the final payment due on January 10, 2013.

On March 8, 2013, we entered into a short-term note payable for $50,037 bearing interest at 6.57% per annum to finance the product liability insurance. Principal and interest payments on this note began April 10, 2013 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on January 10, 2014.

On June 20, 2013, we entered into a short-term note payable for $106,994 bearing interest at 4.64% per annum to finance a portion of the directors' and officers' liability insurance and employment practices liability insurance premiums. Principal and interest payments on this note begin August 24, 2013 and are made evenly based on a straight line amortization over an 11-month period with the final payment due on June 24, 2014.

Grants

On June 10, 2010, we were awarded the matching $500,000 grant from the NSF to support an SBIR Phase II grant previously awarded in 2008 for further development of our DPOLT platform. On each of June 17, 2010, February 28, 2011, September 29, 2011 and March 29, 2012, we received $125,000 related to this NSF awarded SBIR II Phase II grant for our DPOLT platform. Proceeds from the financing were allocated to further the development of our DPOLT platform, essential to the production of our lead antibiotic, MU1140, subject to the goals set forth by the NSF SBIR Phase II grant received by us.

Future Capital Requirements

Our capital requirements for the remainder of 2013 will depend on numerous factors, including the success of our commercialization efforts and of our research and development, the resources we devote to develop and support our technologies and our success in pursuing strategic licensing and funded product development relationships with external partners. Subject to our ability to generate revenues and cash flow from our ProBiora3 products and our ability to raise additional capital including through possible joint ventures and/or partnerships, we expect to incur substantial expenditures to further commercialize or develop our technologies including continued increases in costs related to research, preclinical testing and clinical studies, as well as costs associated with our capital raising efforts and being a public company. We will require substantial funds to conduct research and development and preclinical and Phase 1 clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase 2 and 3 clinical testing and manufacture and marketing of any products that are approved for commercial sale. Our plans include seeking both equity and debt financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to ensure continuation of our operations and research and development programs.

Our current available cash and cash equivalents are sufficient to satisfy our liquidity requirements. We believe our existing cash and cash equivalents will allow us to fund our operating plan through December 2014. We will continue to seek additional funding for our operations. The sale of additional equity or debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We also will likely require additional capital beyond our currently forecasted amounts, for example, as we continue to work with Intrexon under the Lantibiotic ECC for the development of

MU1140 and the Probiotic ECC for the development of Probiotics. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned clinical testing, research and development and commercialization activities, which could harm our business.

Because of the numerous risks and uncertainties associated with sales of our ProBiora3 products as well as research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the cash flow generated from our ProBiora3 product sales;
- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical trials including the research and development expenditures we expect to make in connection with our collaboration with Intrexon Corporation;
- the cost of manufacturing our ProBiora3 products and product candidates and any products we successfully commercialize;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities for our ProBiora3 products and, if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- our ability to maintain current research and development licensing agreements and to establish new strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- our ability to achieve our milestones under licensing arrangements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our products and future products, if any.

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our shares or debt and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed.

Critical Accounting Estimates and Policies

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”). The preparation of financial statements in accordance with GAAP requires us to make estimates and assumptions that affect reported amounts and related disclosures. We consider an accounting estimate to be critical if it requires assumptions to be made that were uncertain at the time the estimate was made; and changes in the estimate or different estimates that could have been made could have a material impact on our results of operations or financial condition. The principal areas of estimation reflected in the financial statements are stock-based compensation, valuation of warrants, sales returns and allowances, inventory obsolescence and allowance for doubtful accounts. For a detailed discussion of our critical accounting estimates, see our Annual Report on Form 10-K for the year ended December 31, 2012. There have been no material changes to our critical accounting estimates during the nine months ended September 30, 2013.

Recently Issued Accounting Pronouncements

There are no new accounting pronouncements issued or effective during the nine months ended September 30, 2013 that have had or are expected to have an impact on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Oragenics, Inc. is a smaller reporting company as defined by Rule 12b-2 of the Securities and Exchange Act of 1934 and is not required to provide the information required under this item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Management's evaluation of the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act was performed under the supervision and with the participation of our senior management, including our Chief Executive Officer and Chief Financial Officer. The purpose of disclosure controls and procedures is to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures. Based upon Management's evaluation, Management has concluded that our disclosure controls are effective as of the end of the period covered by this report.

During 2011, we disclosed and identified several material weaknesses in our internal controls. Since that time we have been working on remediation of the identified material weaknesses and have provided updates in our periodic reports. Management believes progress has been made during the year ended December 31, 2012 and thereafter to remediate material weaknesses in the internal control over financial reporting. Although the control environment has significantly improved during the year ended December 31, 2012 and thereafter when compared to prior periods, a material weakness still remains. Nevertheless, based on a number of factors, including the performance of additional procedures by management designed to ensure the reliability of our financial reporting, management believes that the financial statements in our Quarterly Report of Form-10Q for the three month period ended September 30, 2013 fairly present, in all material respects, our financial position, results of operations, and cash flows for the periods presented in conformity with GAAP.

As previously disclosed and referenced above, the matters involving internal controls and procedures that our management identified and considered to be material weaknesses that have not yet been satisfactorily remediated is insufficient personnel to employ segregation of duties. While segregation of duties remains a challenge for the Company, management has taken steps to further reduce this risk by continuing to limit access to the accounting system wherever possible. This risk will remain until such time as the Company expands and hires more staff.

Management's Remediation Initiatives

Although management has not fully remediated the material weakness mentioned above, management believes progress is being made as we continue the engagement with a consulting firm specializing in Sarbanes-Oxley Section 404 compliance to assist us in the implementation of internal controls for financial reporting and disclosure and our remediation efforts. During 2012, the consulting firm completed an analysis to identify the most critical controls in our environment and a design and operating effectiveness evaluation of those controls was performed. Reasonable remediation activities were identified based on cost and reduction of risk. All planned remediation was completed prior to year-end. Management will continue to monitor and evaluate risk factors affecting our internal controls as our resources and available liquidity permit. Management is responsible for and is committed to achieving and maintaining a strong control environment, high ethical standards, and financial reporting integrity. This commitment continues to be communicated to, and reinforced with, our employees.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Because of the inherent limitations of internal control, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Changes in Internal Controls over Financial Reporting

Except as indicated in the preceding paragraphs about management's evaluation of disclosure controls and procedures and internal controls, our management, with the participation of our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), has concluded there were no other significant changes in our internal controls over financial reporting that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

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

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

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not a party to any pending legal proceeding that is not in the ordinary course of business or otherwise material to our financial condition or business.

ITEM 1A. RISK FACTORS

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

We have incurred significant losses since our inception and expect to continue to experience losses for the foreseeable future.

We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of approximately $13.0 million and $11 million for the nine months ended September 30, 2013, and 2012, and approximately $13.1 million and $7.7 million for the years ended December 31, 2012, and 2011, respectively. As of September 30, 2013 our accumulated deficit was approximately $67.1 million. We have devoted a significant amount of our financial resources to research and development, including our preclinical development activities and clinical trials, and currently we only have our ProBiora3 products available for commercial sale which to date has not generated significant revenue. We expect that the costs associated with our exclusive channel partnerships with Intrexon Corporation in the areas of lantibiotics ("Lantibiotics Program") and probiotics ("Probiotics Program") and the development and commercialization of our product candidates under the Lantibiotics Program (which includes MU1140) and Probiotics Program using Intrexon's advanced transgene and cell engineering platforms, as well as our expected increased marketing and sales efforts for our ProBiora3 products will increase the level of our overall expenses significantly going forward. As a result, we expect to continue to incur substantial net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' equity and working capital. Because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to accurately predict the timing or amount of substantial expenses or when, or if, we will be able to achieve or maintain profitability. The size of our future net losses will depend, in part, on the rate of growth of our expenses and the rate of growth of our revenues. If we are unable to develop and commercialize our other product candidates or if sales revenue from ProBiora3 products is insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

We will need to raise additional capital in the future to complete the development and commercialization of our product candidates and operate our business.

Developing and commercializing biopharmaceutical products, including conducting preclinical studies and clinical trials and establishing manufacturing capabilities, is expensive. As a result of the approximately $15.9 million in net proceeds from our private placement of common stock in July 2012 and September 2013, we anticipate that our cash resources as of September 30, 2013 will be sufficient to fund our operations for at least the next 15 months. However, changes may occur that would consume our existing capital prior to that time, including the scope and progress of our efforts to develop and commercialize our product candidates. Because we currently expect to devote a significant portion of our resources to develop and commercialize product candidates under our Lantibiotics Program and our Probiotics Program with Intrexon and for ProBiora3 sales and marketing efforts further progress with the development of our other product candidates may be significantly delayed and may depend on the success of our development efforts involving our antibiotic candidates. Our actual costs, as well as the actual revenues from sales of our ProBiora3 products, may ultimately vary from our current expectations, which could materially impact our use of capital and our forecast of the period of time through which our financial resources will be adequate to support our operations. If our current cash, cash equivalents and short-term investments are not sufficient to fully implement our business strategy and sustain our operations, we will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity

offerings, debt financings or corporate collaboration and licensing arrangements. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development and commercialization of one or more of our product candidates, curtail or forego sales and marketing efforts, and/or forego licensing attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

Our ProBiora3 products are currently our only source of product revenue and have not generated substantial revenues to date.

Currently our sole source of product revenues is from sales of our ProBiora3 products, which began in late 2008 and have generated only modest revenues to date. Sales of our ProBiora3 products were $574,272, $790,166, and $587,557 for the nine months ended September 30, 2013, 2012, and 2011, respectively, and $1,194,878, $1,229,510 and $1,128,895 for the years ended December 31, 2012, 2011 and 2010, respectively. While we plan to continue to increase the amount we spend on sales and marketing efforts for our ProBiora3 products, there can be no assurance that it will result in a significant increase in sales. If we are unable to generate significant revenues from our ProBiora3 products our business, financial condition and results of operations will be materially adversely affected.

Our success will depend on our ability to obtain regulatory approval of our product candidates under our Lantibiotics Program and our Probiotics Program and their successful commercialization.

Our product candidates under our Lantibiotics Program and Probiotics Program have not received regulatory approval in any jurisdiction and they may never receive approval or, if approvals are obtained, may never be commercialized successfully. We have incurred and will continue to incur significant costs relating to the preclinical and clinical development of our antibiotic product candidates including MU1140 or any analogs thereof we may develop. We have performed extensive preclinical testing using native MU1140 and have since entered into an Exclusive Channel Collaboration Agreement with Intrexon Corporation. We expect to begin preclinical activities on native MU1140 in the second half of 2013. Those activities may include toxicity results, pharmacokinetic studies, and efficacy studies in animals. This work will be done solely by us through the use of outside contractors. If our preclinical work is successful, we would expect to file an Investigational New Drug application with the FDA by the second quarter of 2015. Even if we are able to conduct successful clinical trials or the required regulatory approvals are obtained, we may never be able to generate significant revenues from our product candidates. If our product candidates are unsuccessful, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, financial condition and results of operations will be materially adversely affected.

Our exclusive channel partnering arrangements with Intrexon are based on an early stage technology in the fields of lantibiotic and probiotics.

Our exclusive channel collaboration arrangement with Intrexon contemplates the use of Intrexon's advanced transgene and cell engineering platforms for the development and production of lantibiotics and probiotics**.** Such technologies have a limited history of use in the design and development of active pharmaceutical ingredients and drug products involving direct administration and may therefore involve unanticipated risks or delays.

We will incur additional expenses in connection with our exclusive channel collaboration arrangements with Intrexon.

Pursuant to our exclusive channel collaborations with Intrexon under our Lantibiotics Program and Probiotics Program, we are responsible for future research and development expenses of product candidates developed under such collaborations, the effect of which we expect will increase the level of our overall research and development expenses going forward. Although all manufacturing, preclinical studies and human clinical trials are expensive and difficult to design and implement, costs associated with the manufacturing, research and development of biologic product candidates are generally greater in comparison to small molecule product candidates. We expect to add additional personnel to support our Lantibiotics Program and Probiotics Program with Intrexon.

Because our collaborations with Intrexon are in the early stage and we have not yet identified a specific product candidate from the Intrexon collaborations, future development costs associated with this program may be difficult

to anticipate and exceed our expectations. Our actual cash requirements may vary materially from our current expectations for a number of other factors that may include, but are not limited to, unanticipated technical challenges, changes in the focus and direction of our development activities or adjustments necessitated by changes in the competitive landscape in which we operate. If we are unable to continue to financially support such collaborations due to our own working capital constraints, we may be forced to delay our activities. If we are unable to obtain additional financing on terms acceptable to us or at all, we may be forced to seek licensing partners or discontinue development.

We may not be able to retain the exclusive rights licensed to us by Intrexon to develop and commercialize lantibiotic products and probiotic products.

Under our exclusive channel collaboration agreements with Intrexon (the "ECC's"), we are responsible for, among other things, funding the further anticipated development of lantibiotics and probiotics toward the goal of commercialization, conducting preclinical and clinical development of product candidate s, as well as for other aspects of manufacturing and the commercialization of the product(s). During the first 18 months, neither we nor Intrexon may terminate the ECC's, except under limited circumstances. Intrexon may terminate such agreements if we do not perform certain specified requirements, including developing therapies identified to us and considered superior by Intrexon. There can be no assurance that we will be able to successfully perform under the ECC's and if the ECC's are terminated it would prevent us from achieving our business objectives.

Our success will depend on our ability to partner or sub-license our product candidates and their subsequent successful commercialization.

Our MU1140 and other product candidates are in early stage development and will require partners with substantial financial resources to continue the development of each of these products to commercialization. In addition, none of these product candidates have received regulatory approval in any jurisdiction and they may never receive approval or, if approvals are obtained, may never be commercialized successfully. We recently determined to cease pursuit of our second Phase 1 clinical trial. There can be no assurance that a new clinical trial for our SMaRT Replacement Therapy product candidate will be commenced, by us in the future or that we will be able to establish a partner relationship or sublicense our Replacement Therapy technology for future development. In addition, we do not know whether any of our clinical trials will be successful or can be completed within our current expected budget. For our MU1140 and other antibiotic product candidates, we have performed extensive preclinical testing using native MU1140 and expect to continue to pursue the preclinical testing of our MU1140 and other antibiotic product candidates during the remainder of 2013. Even if we are able to partner and conduct successful clinical trials or the required regulatory approvals are obtained, we may never be able to generate significant revenues from our MU1140 or other antibiotic product candidates or other product candidates. If our MU1140 product candidate or our other product candidates under the Lantibiotics Program and Probiotics Program or otherwise are unsuccessful, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, financial condition and results of operations will be materially adversely affected.

Our financial results could vary significantly from quarter to quarter and are difficult to predict.

Our revenues and operating results could vary significantly from quarter to quarter due to a variety of factors, many of which are outside of our control. As a result, comparing our operating results on a period-to-period basis may not be meaningful. In addition, we may not be able to predict our future revenues or results of operations. We base our current and future expense levels on our internal operating plans and sales forecasts, and our operating costs are to a large extent fixed. As a result, we may not be able to reduce our costs sufficiently to compensate for an unexpected shortfall in revenues, and even a modest shortfall in revenues could disproportionately and adversely affect financial results for that quarter. Individual products represent meaningful portions of our revenues in any quarter. We may incur significant or unanticipated expenses associated with our research and development efforts of our product candidates under development. In addition to other risk factors discussed in this section, factors that may contribute to the variability of our quarterly results include:

- the timing of release of new products and services by us and our competitors, particularly those that may represent a significant portion of revenues in any given period;
- the popularity of new products, and products released in prior periods;

- changes in pricing policies by us or our competitors;
- fluctuations in the size and rate of growth of overall consumer and retailer demand for our ProBiora3 products;
- our success in entering new geographic markets;
- decisions by us to incur additional expenses, such as increases in marketing or research and development;
- the level of expenses associated with our clinical trials;
- accounting rules governing recognition of revenues;
- the amount we reserve against returns and allowances; and
- the timing of compensation expense associated with equity compensation grants.

As a result of these and other factors, our quarterly and annual operating results could be materially adversely affected. Moreover, our operating results may not meet announced guidance or the expectations of research analysts or investors, in which case the price of our common stock could decrease significantly.

Current and future economic and market conditions could materially adversely affect our revenues, expense levels and profitability.

The U.S. economy and the global economy are recovering from a severe recession. Factors such as uncertainties in consumer spending, a sustained regional and/or global economic downturn or slow recovery may reduce the demand for our ProBiora3 products. Furthermore, challenging economic conditions also may impair the ability of our customers to pay for our commercial products. Because consumer spending for our ProBiora3 products can generally be considered a discretionary purchase, we may experience a more negative impact on our business due to these conditions than other companies that do not depend on discretionary spending. If demand for our ProBiora3 products declines or our customers are otherwise unable to pay for our products, we may be required to offer extensive discounts or spend more on marketing than budgeted and our revenues, expense levels, and liquidity position will be materially adversely affected.

We are subject to government regulation of the processing, formulation, packaging, labeling and advertising of our consumer products.

Under the Federal Food, Drug, and Cosmetic Act, or FDCA, companies that manufacture and distribute foods, such as our ProBiora3 products, are limited in the claims that they are permitted to make about nutritional support on the product label without FDA approval. Any failure by us to adhere to the labeling requirements could lead to the FDA's requiring that our products be repackaged and relabeled, which would have a material adverse effect on our business. In addition, companies are responsible for the accuracy and truthfulness of, and must have substantiation for, any such statements. These claims must be truthful and not misleading. Statements must not claim to diagnose, mitigate, treat, cure or prevent a specific disease or class of disease. We are able to market our ProBiora3 products in reliance on the self-affirmed Generally Recognized As Safe, or self-affirmed GRAS, status of our active ingredient, ProBiora3. No governmental agency or other third party has made a determination as to whether or not ProBiora3 has achieved GRAS status. We make this determination based on independent scientific opinions that ProBiora3 is not harmful under its intended conditions of use. If the FDA, another regulatory authority or other third party denied our self-affirmed GRAS status for ProBiora3, we could face significant penalties or be required to undergo the regulatory approval process in order to market our probiotic products, and our business, financial condition and results of operations will be adversely affected. We cannot guarantee that in such a situation ProBiora3 would be approved.

The FDA's Good Manufacturing Practices, or GMPs, describe the methods, equipment, facilities, and controls for producing processed food and set the minimum sanitary and processing requirements for producing safe and wholesome food. Those who manufacture, package, or hold human food must comply with the GMPs. If we or our suppliers fail to comply with the GMPs, the FDA may take enforcement action against us or our suppliers.

The processing, formulation, packaging, labeling and advertising of our probiotic products are subject to regulation by one or more federal agencies including the FDA, the Federal Trade Commission and the Environmental Protection Agency. Our activities are also subject to regulation by various agencies of the states and localities in which our probiotic products are sold. Any changes in the current regulatory environment could impose requirements that would limit our ability to market our probiotic products and make bringing new products to market more expensive. In addition, the adoption of new regulations or changes in the interpretation of existing

regulations may result in significant compliance costs or discontinuation of product sales and may adversely affect our business, financial condition and results of operations. While our ProBiora3 products are categorized as foods, it is possible that the FDA or a state regulatory agency could classify these products as a cosmetic or a drug. If the products are classified as cosmetics rather than a food, we would be limited to making claims that the products cleanse and beautify, but we could not make structure or function claims. If our probiotic products are classified as drugs, we would not be able to market the ProBiora3 products without going through the drug approval process. Either of these events would limit our ability to effectively market our products and would adversely affect our financial condition and results of operations. If the FDA or a state regulatory agency viewed the products as cosmetics or drugs, they could claim that the products are misbranded and require that we repackage and relabel the products and impose civil and/or criminal penalties. Either or both of these situations could adversely affect our business and operations.

If we undertake product recalls or incur liability claims with respect to our ProBiora3 products, such recalls or claims could increase our costs and adversely affect our reputation, revenues and operating income.

Our ProBiora3 products are designed for human and animal consumption and we may face product recalls or liability claims if the use of our products is alleged to have resulted in injury or death. ProBiora3 is classified as a food ingredient and is not subject to pre-market regulatory approval in the United States. Our ProBiora3 products contain ingredients that do not have long histories of human or animal consumption. Previously unknown adverse reactions resulting from consumption of these ingredients could occur. We may have to undertake various product recalls or be subject to liability claims, including, among others, that our ProBiora3 products include inadequate instructions for use or inadequate warnings concerning possible side effects and interactions with other substances. A product recall or liability claim against us could result in increased costs and could adversely affect our reputation with our customers, which, in turn, could have a material adverse effect on our business, financial condition and results of operations.

Product liability insurance is expensive, is subject to deductibles and coverage limitations, and may not be available in the future. While we currently maintain product liability insurance coverage, we cannot be sure that such coverage will be adequate to cover any incident or all incidents. In addition, we cannot be sure that we will be able to obtain or maintain insurance coverage at acceptable costs or in a sufficient amount, that our insurer will not disclaim coverage as to a future claim or that a product liability claim would not otherwise adversely affect our business, financial condition and results of operations. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. Uncertainties resulting from the initiation and continuation of product liability litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Product liability litigation and other related proceedings may also require significant management attention.

If we fail to comply with our obligations in the agreements with the University of Florida Research Foundation, Inc., under which we license our rights to MU1140 and to SMaRT Replacement Therapy, our license to these product candidates may be terminated and we will be unable to commercialize these product candidates.

We hold our MU1140 and SMaRT Replacement Therapy product candidates under licenses from the University of Florida Research Foundation, Inc., or UFRF. We are required to make minimum annual maintenance payments to the UFRF for the term of the amended license agreements in the amount of $10,000 for each license agreement and $20,000 in aggregate. The aggregate minimum annual payments are required to be paid in advance on a quarterly basis (i.e. $5,000 per quarter) for both licenses. We are also required to pay all patent costs and expenses incurred by the UFRF for the preparation, filing, prosecution, issuance and maintenance of the patents.

The UFRF may terminate our licenses to MU1140 and to SMaRT Replacement Therapy if we breach our obligations to timely pay these amounts, to submit development reports as required under the license agreements or commit any other breach of any other covenants contained in the license agreements. There is no assurance that we will be able to comply with these conditions in a timely manner or at all. If our license agreements are terminated, we will be unable to commercialize these product candidates.

If we are able to commercialize any product candidates, we are obligated to pay 5% of the selling price of any products developed from the licensed technologies that we may sell as royalty to the UFRF. In addition, if we sublicense any rights granted by the amended license agreements, we are obligated to pay the UFRF 22% of all

revenues received from the sublicenses, excluding monies received solely for development costs. We are also obligated to make the following payments to UFRF as follows: a one-time commercialization fee, post-commercialization minimum royalty payments, and a one-time cumulative royalty payment. The one-time commercialization fee would be due on the first anniversary of first commercial sale and is calculated at $5,000 per month between May 1, 2013 and the month of the first anniversary of a commercial sale. The post-commercialization minimum royalty payments of $50,000 annually would be due following payment of a commercialization fee. The one-time additional royalty payment would be due when total cumulative royalties paid to UFRF exceed $2.0 million, upon which we would be obligated to make a one-time additional payment to UFRF of 10% of the total royalties due to UFRF in the calendar year in which cumulative royalties exceeded $2.0 million.

Until commercial sale of any products developed from these licensed product candidates takes place, we will not earn any revenues from these product candidates and will, therefore, need additional financing to fund our required royalty payments and development expenses, such as through the commercialization and sale of our ProBiora3 products, the sale of our debt or equity securities, or otherwise. There can be no assurance that we will achieve sufficient sales of our ProBiora3 products or be able to raise the capital necessary to meet our obligations under our licenses. If we are unable to meet our obligations under these licenses, we may lose the licenses to these product candidates and our business, financial condition and results of operations will be materially adversely affected.

We depend on third-party manufacturers for our ProBiora3 products. The loss of any manufacturer or any interruptions in the supply of our ProBiora3 products would have a negative impact on our revenues and profitability.

We currently have no manufacturing facilities and are dependent upon establishing relationships with independent manufacturers to supply our product needs. We currently have a one supplier that is able to produce two of the three strains of bacteria needed to produce ProBiora3 and one supplier that is able to produce one of the strains of bacteria needed to produce ProBiora3. These suppliers use proprietary methodologies to produce these three strains of bacteria. We believe our arrangements with our contract manufacturers have the capacity to meet our current and expected future manufacturing needs. Although we have qualified and used at least two contract manufacturers for each step in our manufacturing process, we do not have a long-term supply agreement or commitment with any of our manufacturers. If our manufacturers are unable or unwilling to produce our ProBiora products in sufficient quantities, or at all, at acceptable pricing in accordance with specifications we establish from time to time we would need to find alternative manufacturers that are qualified. If, in such instances, we are unsuccessful in obtaining alternative manufacturers, it could impair our ability to sell our ProBiora3 products and would have a negative impact on our revenues and profitability. In addition, competitors who own their manufacturing facilities may have an advantage over us with respect to pricing, availability of product and in other areas through their control of the manufacturing process.

The risks associated with the numerous factors that could cause interruptions in the supply of our products, including manufacturing capacity limitations, regulatory inspections, changes in our sources for manufacturing, disputes with a manufacturer, our failure to timely locate and obtain replacement manufacturers as needed and conditions affecting the cost and availability of raw materials, are magnified when the suppliers are limited in number. Any interruption in the supply of finished products could hinder our ability to timely distribute our products and satisfy customer demand. If we are unable to obtain adequate product supplies to satisfy our customers' orders, we may lose those orders, our customers may cancel other orders, and they may choose instead to stock and purchase competing products. This could result in a loss of our market share and negatively affect our revenues and operations.

If our manufacturers in general fail to meet our requirements and the requirements of regulatory authorities, our revenues may be materially adversely affected.

We do not have the internal capability to manufacture our ProBiora3 products or our LPT3-04 Weight Loss, SMaRT Replacement Therapy, MU1140, or any other c product candidates under GMPs, as required by the FDA and other regulatory agencies. In order to continue to develop and commercialize our product candidates, apply for regulatory approvals for our product candidates, and continue to commercialize our ProBiora3 products, we will need to contract with third parties that have, or otherwise develop, the necessary manufacturing capabilities.

There are a limited number of manufacturers that operate under GMPs that are capable of manufacturing our ProBiora3 products. Furthermore, manufacturing MU1140 or our other potential product candidates on a commercial scale have not yet been undertaken, so there are additional technical skills needed for the manufacture of MU1140 that will further limit the number of potential manufacturers. As such, if we are unable to enter into supply and processing contracts with any of these manufacturers or processors for our MU1140 and other product candidates, or ProBiora3 products we may incur additional costs and delays in development and commercialization.

Problems with these manufacturing processes such as equipment malfunctions, facility contamination, labor problems, raw material shortages or contamination, natural disasters, power outages, terrorist activities, or disruptions in the operations of our suppliers and even minor deviations from normal procedures, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims and insufficient inventory.

If we are required to find an additional or alternative source of supply, there may be additional costs and delays in the development or commercialization of our product candidates. Additionally, the FDA and other regulatory agencies routinely inspect manufacturing facilities before approving a New Drug Application, or NDA, or Biologic License Application, or BLA, for a drug or biologic manufactured at those sites. If any of our manufacturers or processors fails to satisfy regulatory requirements, the approval and eventual commercialization of our commercial products and product candidates may be delayed.

All of our contract manufacturers must comply with the applicable GMPs, which include quality control and quality assurance requirements as well as the corresponding maintenance of records and documentation. If our contract manufacturers do not comply with the applicable GMPs and other FDA regulatory requirements, we may be subject to product liability claims, the availability of marketed products for sale could be reduced, our product commercialization could be delayed or subject to restrictions, we may be unable to meet demand for our products and may lose potential revenues and we could suffer delays in the progress of preclinical testing and clinical trials for products under development. We do not have control over our third-party manufacturers' compliance with these regulations and standards. Moreover, while we may choose to manufacture our products ourselves in the future, we have no experience in the manufacture of pharmaceutical or biological products for clinical trials or commercial purposes. If we decide to manufacture products, we would be subject to the regulatory requirements described above. In addition, we would require substantial additional capital and would be subject to delays or difficulties encountered in manufacturing pharmaceutical or biological products. Regardless of the manufacturer of our products, we will be subject to continuing obligations regarding the submission of safety reports and other post-market information.

We may be unable to find a method to produce MU1140 in large-scale commercial quantities. If we cannot, we will be unable to generate significant revenues from sales of our MU1140 product candidate.

Our antibiotic product candidate, MU1140, is produced by our strain of *S. mutans*. To date, it has been produced only in laboratory cultures. In March 2005 we successfully developed a methodology for producing MU1140 in quantities sufficient to undertake its preclinical testing. In addition, we developed the DPOLT synthetic chemistry methodology to allow large-scale commercial production of, a synthetic version of MU1140, known as MU1140-S. However, this methodology may not be feasible for cost effective, large scale manufacture. In June of 2012 we entered into an exclusive collaboration agreement with Intrexon Corporation to use its advanced transgene and cell engineering platforms to achieve sufficient production quantities of MU1140. While preliminary results from these efforts have demonstrated progress in the increase in production of MU1140, we will need to contract with a third party manufacturer to produce additional quantities in order to be able to pursue further preclinical testing. If we are not able to utilize either of these methodologies for large-scale manufacture, we will be unable to partner and generate revenues from this product candidate and our business, financial condition and results of operations will be materially adversely affected. The manufacturing of MU1140 or any other possible antibiotic product candidates based on lantibiotics, is a highly exacting and complex process. Manufacturing MU1140 or any other antibiotic candidates derived from lantibiotics on a commercial scale has not yet been achieved so there are additional risks that such efforts will not be successful. The Intrexon technology may not be feasible to efficiently develop methodologies to enable large scale manufacturing of MU1140 or other antibiotic product candidates. Third-party manufacturers must have additional technical skills and must take multiple steps to attempt to control the manufacturing processes. If we are unable to produce MU1140 in large-scale commercial quantities, we will be unable to generate significant revenues from sales of our MU1140 product candidate.

Our ProBiora3 products and our product candidates face various forms of competition from other products in the marketplace.

The pharmaceutical and biotechnology industries are characterized by intense competition, rapid product development and technological change. Most of the competition that our ProBiora3 products and our product candidates face comes from companies that are large, well established and have greater financial, marketing, sales and technological resources than we have. Our ProBiora3 products compete with a range of consumer and nutraceutical products. Our commercial success with product candidates will depend on our ability and the ability of any sub-licensees to compete effectively in marketing and product development areas including, but not limited to, sales and branding, drug safety, efficacy, ease of use, patient or customer compliance, price, marketing and distribution. There can be no assurance that competitors will not succeed in developing and marketing products that are more desirable or effective than our ProBiora3 products or the products developed from our product candidates or that would render our products obsolete and non-competitive. We anticipate that our SMaRT Replacement Therapy technology would compete with other companies attempting to develop technologies in the oral health care market, including vaccines.

We rely on the significant experience and specialized expertise of our senior management and scientific team and we have incurred significant turnover in key positions over the last several years.

Our performance is substantially dependent on the continued services and on the performance of our senior management and scientific team, who have extensive experience and specialized expertise in our business. Our performance also depends on our ability to retain and motivate our other key employees. In May 2011, we hired Dr. John Bonfiglio as Chief Executive Officer and in February 2012, we hired Mr. Michael Sullivan, CPA as our Chief Financial Officer. The loss of the services of these key employees could harm our ability to develop and commercialize our product candidates. We have no key man life insurance policies. We have employment agreements with Dr. Bonfiglio and Mr. Sullivan. The term of each of these employment agreements is for an indefinite period and will end when the employment relationship is terminated by either party for any or no reason.

We need to hire and retain additional qualified scientists and other highly skilled personnel to maintain and grow our business.

Our future success depends on our ability to identify, attract, hire, train, retain and motivate highly skilled technical, managerial and research personnel in all areas within our organization. We plan to continue to grow our business and will need to hire additional personnel to support this growth. We believe that there are only a limited number of individuals with the requisite skills to serve in many of our key positions, and we compete for key personnel with other biotechnology and nutraceutical companies, as well as universities and research institutions. It is often difficult to hire and retain these persons, and we may be unable to replace key persons if they leave or be unable to fill new positions requiring key persons with appropriate experience. If we fail to attract, integrate and retain the necessary personnel, our ability to maintain and grow our business could suffer significantly.

If any of our product candidates are shown to be ineffective or harmful in humans, we will be unable to generate revenues from these product candidates.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through preclinical testing and clinical trials that our products are safe and effective for use in humans. To date the testing of the antibiotic substance MU1140 has been undertaken solely in the laboratory and in animals. We have not yet conducted human studies with any MU1140 or any analog thereof. It is possible that when these studies are conducted, they will show that our antibiotic candidates are ineffective or harmful in humans. If MU1140 or any analogs thereof are shown to be ineffective or harmful in humans, we will be unable to commercialize and generate revenues from sales of this compound. If we are unable to generate revenues from MU1140 or any other product candidates, our business, financial condition and results of operations will be materially adversely affected.

We intend to rely on third parties to pay the majority of the costs associated with obtaining regulatory approval for, and manufacturing and marketing of, our product candidates. If we are unable to obtain agreements with third parties to fund these costs, we will have to fund such costs ourselves or we may be unable to extract any value from these technologies.

As we continue our development of product candidates, we intend to either license these product candidates to, or partner with, one or more major pharmaceutical companies at the earliest possible time in their product development. If we do so, we intend for these licensees or partners to pay the costs associated with any remaining development work, regulatory submissions, clinical trials and the manufacturing and marketing of our product candidates. If we are unable to license our product candidates or otherwise partner with third parties, we will have to fund the costs of our clinical trials ourselves or we will be unable to extract any value from these technologies. We will also have to establish our own manufacturing facilities and find our own distribution channels. This would greatly increase our future capital requirements and we cannot assure you that we would be able to obtain the necessary financing to pay these costs or that we will be generating significant revenues from any of our products, such as ProBiora3, sufficient to cover the associated costs. If we do not generate sufficient revenues to cover the associated costs or we cannot obtain financing on acceptable terms or at all, our business, financial condition and results of operations will be materially adversely affected.

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

We are subject to risks of doing business internationally as we attempt to expand our sales through international distributor relationships.

We have entered into a number of international distributor agreements for our ProBiora3 products. As a result, we expect to increase our revenues from international sales. A number of factors can slow or prevent international sales, or substantially increase the cost of international sales, and we may encounter certain risks of doing business internationally including the following:

- reduced protection and enforcement for our intellectual property rights;
- unexpected changes in, or impositions of, legislative or regulatory requirements that may limit our ability to sell our products and repatriate funds to the United States;
- political and economic instability;
- fluctuations in foreign currency exchange rates;
- difficulties in developing and maintaining distributor relationships in foreign countries;
- difficulties in negotiating acceptable contractual terms and enforcing contractual obligations;
- exposure to liabilities under the U.S. Foreign Corrupt Practices Act;
- potential trade restrictions and exchange controls;
- creditworthiness of foreign distributors, customer uncertainty and difficulty in foreign accounts receivable collection; and
- the burden of complying with foreign laws and
- Potential for fines for claimed violations of foreign laws and regulations.

As we attempt to expand our sales internationally, our exposure to these risks could result in our inability to attain the anticipated benefits and our business could be adversely impacted. Our success will depend, in large part, on our ability to anticipate and effectively manage these and other risks associated with our international operations. However, any of these factors could adversely affect our international operations and, consequently, our operating results.

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

Our product and product candidates are protected by patents and patent applications, including patents exclusively licensed from the University of Florida Research Foundation, Inc., or the UFRF. We are the exclusive worldwide licensee to the patents for SMaRT Replacement Therapy and MU1140, which are owned by the UFRF. Our success depends in part on our ability to obtain patents or rights to patents, protect trade secrets, operate without infringing upon the proprietary rights of others, and prevent others from infringing on our patents, trademarks and other intellectual property rights. We will be able to protect our intellectual property from unauthorized use by third parties only to the extent that it is covered by valid and enforceable patents, trademarks and licenses. Patent protection generally involves complex legal and factual questions and, therefore, enforceability of patent rights cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from others may not provide adequate protection against competitors. In addition, any future patent applications may fail to result in patents being issued. Also, those patents that are issued may not provide us with adequate proprietary protection or competitive advantages against competitors with similar product candidates. Moreover, the laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States.

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

In the event of an infringement or violation, we may face litigation and may be prevented from pursuing product development or commercialization. We may receive in the future, notice of claims of infringement of other parties' proprietary rights. We may not have the financial resources to defend against claims of infringement by other parties. Infringement or other claims could be asserted or prosecuted against us in the future and it is possible that past or future assertions or prosecutions could harm our business.

The FDA instituted numerous clinical holds with respect to our Phase 1 clinical trial program for our SMaRT Replacement Therapy product candidate. Although the clinical holds were lifted with respect to the attenuated version of the SMaRT strain, a clinical hold remains in effect for our IND for the non-attenuated SMaRT strain. If the FDA does not lift the clinical hold on this IND, we will be unable to conduct the clinical trials necessary to obtain marketing approval of our product candidate. The FDA's concerns that resulted in these clinical holds may lead to the imposition of a new clinical hold or holds or the failure of our product candidates to obtain marketing approval.

In December 1998, the FDA imposed a clinical hold on the IND for our SMaRT strain. The FDA expressed concerns about the potential for DNA transfer into or from the SMaRT strain; the possible creation of an organism with increased ability to colonize and produce dental caries; and the potential for the transfer of the strain between humans. We met with the FDA to discuss proposed trials of an attenuated SMaRT strain to address the FDA's concerns, and the FDA informed us that such trials required a separate IND. We submitted an IND for the attenuated strain in March 2003.

The FDA then imposed multiple clinical holds with respect to the Phase 1 clinical trials of the attenuated strain. Specifically, we received clinical hold letters in May 2003, February 2004, June 2007 and August 2007. In connection with the clinical hold letter in May 2003, the FDA requested that we provide preclinical data on eradication of the attenuated version of the SMaRT strain once it had been implanted and a plan for the eradication of the attenuated strain in the trial subjects and their spouse or partners. In an April 2004 meeting, the FDA suggested that we conduct two eradication trials: one in subjects without teeth, and, if successful, another trial in subjects with teeth. We submitted revised protocols in accordance with FDA's suggestions, and in November 2004 the FDA lifted the clinical hold for the attenuated strain.

We initiated our first Phase 1 clinical trial in April 2005, but we found it difficult to find subjects who fit the FDA's highly cautious inclusion and exclusion criteria, particularly with respect to the subjects' lack of dentition. We concluded this trial early after enrolling only two of the 15 planned subjects. The FDA then recommended that we revise the protocol for the evaluation of ten healthy male subjects, ranging from 18 to 30 years old and with normal

dentition, in an institutionalized setting. After we submitted additional information, the FDA issued another clinical hold letter in June 2007 for the proposed trial with the attenuated strain, citing the need for a plan with respect to serious adverse effects; a plan for the eradication of the attenuated strain in trial subjects' offspring; and a required pregnancy test for female partners of subjects. We submitted additional protocols in response to the FDA's concerns. In August 2007, the FDA issued another clinical hold letter with required revisions to the protocol for offspring of subjects. We submitted a response to the clinical hold letter in September 2007, and the FDA removed the clinical hold for our Phase 1 trial in the attenuated strain in October 2007.

While we commenced a Phase 1b clinical trial for SMaRT Replacement Therapy during the first quarter of 2011, the very restrictive study enrollment criteria required by the FDA made the enrollment of candidates meeting the restrictive criteria difficult. Due to the enrollment difficulty we encountered with our initial our Phase 1a clinical trial and now with our phase 1b clinical trial, we determined to discontinue pursuit of our Phase 1b clinical trial and instead focus our efforts on possible partnering opportunities that may exist for our SMaRT Replacement Therapy.

There can be no assurance that future clinical trials for the attenuated strain will be successful, or that the FDA will ever lift the clinical hold on the non-attenuated SMaRT strain. In addition, there can be no assurances that we will be able to locate a partner willing to pursue further development of our SMaRT Replacement Therapy technology. If the FDA does not lift the clinical hold on the non-attenuated SMaRT strain, we or a partner would not be able to conduct the clinical trials necessary to pursue marketing approval of the SMaRT strain.

The FDA may impose additional requirements that may significantly increase the time and expense of obtaining FDA approval. Although the FDA has removed the clinical holds with respect to our Phase 1 trials for the attenuated strain, if the FDA has further concerns regarding the safety or risks associated with our trials, the FDA could implement another clinical hold on our ongoing trial or future trials or raise concerns as a part of a future NDA review process for our SMaRT Replacement Therapy product candidate, which could delay or prevent marketing.

Our product candidates are subject to substantial government regulation, including the regulation of preclinical testing and clinical trials. If we are unable to obtain regulatory approval for our product candidates we will be unable to generate revenues.

The production and marketing of products which may be developed from our MU1140 product candidate, our SMaRT Replacement Therapy product candidate or any other product candidates from our Lantibiotics Program and probiotics program or otherwise and our research and development, preclinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities. Most of the product candidates we are developing must undergo rigorous preclinical testing and clinical trials and an extensive regulatory approval process before they can be marketed in the United States or internationally.

If we fail to obtain regulatory approval for our product candidates, or if the FDA fails to lift the clinical hold on our IND for non-attenuated version of SMaRT, we may have to cease further development. Clinical trials on our product candidates are expected to take several years to fully complete. The commencement or completion of preclinical studies or clinical trials can be delayed or prevented for a number of reasons, including:

- our belief that SMaRT Replacement Therapy is one of the first genetically modified bacterial strains for use in humans, which may cause the FDA to proceed with additional caution;
- difficulties in finding a partner with the resources to support large and expensive clinical development and commercialization costs;
- findings in preclinical studies;
- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;
- difficulties obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;
- challenges recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including the size and nature of patient population, proximity of patients to clinical sites, eligibility criteria for the trial, nature of the trial protocol, the availability of approved effective treatments for the relevant condition and competition from other clinical trial programs for similar indications;

- severe or unexpected drug or biologic-related side effects experienced by patients in a clinical trial; and
- difficulties retaining patients who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the trial, lack of efficacy, side effects, or personal issues, or who are lost to further follow up.

Clinical trials also may be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a trial, or a data safety monitoring board, or DSMB, overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;
- unforeseen safety issues or lack of effectiveness; and
- lack of adequate funding to continue the clinical trial.

We cannot assure you that clinical trials will demonstrate the safety or effectiveness of any of our product candidates, or will otherwise satisfy regulatory requirements. Our preclinical studies or clinical trials may produce negative or inconclusive results, there may be inconsistencies between early clinical trial results and results obtained in later clinical trials, and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain FDA approval for their products. If we are unable to resolve the FDA's concerns, we will not be able to obtain regulatory approval for these product candidates.

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

We may encounter such delays and rejection of our product candidates by the FDA or other regulatory authority may also adversely affect our business. Such delays or rejection may be encountered due to, among other reasons, government or regulatory delays, lack of efficacy during clinical trials, unforeseen safety issues, or changes in regulatory policy during the period of product development. More stringent regulatory approval processes in product clearance and enforcement activities could result in our experiencing longer approval cycles, more uncertainty, greater risk, and higher expenses. Even if regulatory approval of a product is granted, this approval may entail limitations on uses for which the product may be labeled and promoted. It is possible, for example, that we may not receive FDA approval to market products based on our licensed, patented product candidates for different indications or to market updated products that represent extensions of our basic product candidates. In addition, we may not receive FDA approval to export our products based on our licensed, patented product candidates in the future, and countries to which products are to be exported may not approve them for import.

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

We cannot assure you that the market and consumers will accept our products or product candidates. If they do not, we will be unable to generate significant revenues from our products or product candidates and our business, financial condition and results of operations will be materially adversely affected.

The commercial success of our ProBiora3 products our MU1140 antibiotic product candidate, and any of our other product candidates and technologies will depend in part on market acceptance by consumers. Biopharmaceutical companies have received substantial support from the scientific community, regulatory agencies and many governmental officials in the United States and internationally. Future scientific developments, media coverage and political events may diminish such support. Public attitudes may be influenced by claims that health products 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 product candidates developed by biopharmaceutical companies could be delayed or impaired in certain geographical areas as a result. Products based on our product candidates may compete with a number of traditional dental therapies and drugs manufactured and marketed by major pharmaceutical companies and biotechnology companies. Market acceptance of products based on our product candidates 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 product candidates. If they do not, we may be unable to generate significant revenues from our product candidates and our business, financial condition and results of operations will be materially adversely affected.

If our products do not receive favorable third-party reimbursement, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not generate significant revenues.

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our proposed formulations and products and related treatments are obtained by governmental authorities, private health insurers and other organizations, such as Health Maintenance Organizations, or HMOs. Reimbursement from third parties depends greatly on our ability to present data which demonstrate positive outcomes and reduced utilization of other products or services as well as cost data which show that treatment costs using the new product are equal to or less than what is currently covered for other products. If our products do not receive favorable third-party reimbursement and patients are unwilling or unable to pay for our products out-of-pocket, it could limit our revenues and harm our business.

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, recent federal and state government initiatives have been directed at lowering the total cost of health care. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Federal and state legislatures will likely continue to focus on health care reform, controlling the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud which could subject us to regulatory sanctions, harm our business and operating results and cause the trading price of our stock to decline.

Effective internal controls required under Section 404 of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our business, reputation and operating results could be harmed. We have discovered, and may in the future discover, areas of our internal controls that need improvement. We cannot be certain that the measures we have taken or intend to take will ensure that we maintain adequate controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls or difficulties encountered in their implementation could subject us to regulatory sanctions, harm our business and operating results or cause us to fail to meet our reporting obligations. Inferior internal controls could also harm our reputation and cause investors to lose confidence in our reported financial information, which could have a negative impact on the trading price of our stock.

Risks Related to Our Common Stock

KFLP, together with members of the Koski family, have a substantial interest in our outstanding shares of common stock.

As of September 30, 2013, the KFLP, together with members of the Koski family, beneficially own approximately 41.6% of our outstanding shares of common stock, and includes outstanding warrants to acquire 2,170,925 shares of our common stock that were issued in connection with our Debt Exchange Agreement and Loan Agreement.

Christine L. Koski and Robert C. Koski, serve on our Board of Directors and they each share voting and investment powers with two other Koski family members as general partners of the KFLP. As a result, the Koski family will be able to affect the outcome of, or exert significant influence over, all matters requiring shareholder approval, including the election and removal of directors and any change in control. In particular, this concentration of ownership of our common stock could have the effect of delaying or preventing a change of control of us or otherwise discouraging or preventing a potential acquirer from attempting to obtain control of us. This, in turn, could have a negative effect on the market price of our common stock. It could also prevent our shareholders from realizing a premium over the market price for their shares of common stock. Moreover, the interests of this concentration of ownership may not always coincide with our interests or the interests of other shareholders, and, accordingly, the Koski family could cause us to enter into transactions or agreements that we would not otherwise consider.

Certain provisions of our articles of incorporation, bylaws, executive employment agreements and stock option plan may prevent a change of control of our company that a shareholder may consider favorable.

Provisions of our articles of incorporation, bylaws, executive employment agreements and stock option plan may discourage, delay or prevent a change of control of our company that a shareholder may consider favorable. These provisions include:

- authorization of the issuance of "blank check" preferred stock that could be issued by our Board of Directors without shareholder approval and that may be substantially dilutive or contain preferences or rights objectionable to an acquirer;
- the ability of our Board of Directors to amend the bylaws without shareholder approval;
- vacancies on our Board may only be filled by the remaining directors and not our shareholders;
- requirements that only our Board, our President or holders of more than 10% of our shares can call a special meeting of shareholders;
- obligations to make certain payments under executive employment agreements in the event of a change of control and termination of employment; and
- immediate vesting of all outstanding stock options.

As a result, these provisions could discourage bids for our common stock at a premium and limit the price that investors are willing to pay in the future for shares of our common stock. However, in our articles of incorporation we expressly elected not to be governed by Sections 607.0901 and 607.0902 of the Florida Business Corporation Act, which are statutory anti-takeover provisions relating to affiliated transactions and control share acquisitions, respectively. As such, we do not have the protection of these statutes in connection with any unwanted takeover attempts which could have the effect of encouraging an attempted change of control without first negotiating with our Board of Directors.

We cannot assure you that our new listing on the NYSE MKT will increase the liquidity of our common stock or that our shares will continue to be listed on the NYSE MKT.

Our common stock commenced trading on the NYSE MKT (formerly the NYSE Amex and the American Stock Exchange) on April 10, 2013, and we are subject to certain NYSE MKT continued listing requirements and standards. Historically the daily trading volume of our shares is relatively low which has made our common stock significantly less liquid and there can be no assurance that liquidity will increase as a result of being listed on the NYSE MKT. We may also incur costs that we have not previously incurred for expenses for compliance with the rules and requirements of the NYSE MKT. We cannot provide any assurance that we will be able to continue to satisfy the requirements of the NYSE's continued listing standards. A delisting of our common stock could negatively affect the price and liquidity of our common stock and could impair our ability to raise capital in the future.

Our stock price has historically been volatile and the trading volume of our stock has been low.

Since our initial public offering in June 2003 and through September 30, 2013 our stock price has fluctuated from $90.00 to $0.75 per share. The trading price of our common stock has been, and may be, subject to wide fluctuations in response to a number of factors, many of which are beyond our control. These factors include:

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

Historically, the daily trading volume of our common stock has been relatively low and on some days our stock does not trade at all. An order for the purchase or sale of a large number of our shares could significantly affect the price at which the order is executed. We cannot guarantee that an active public market for our common stock will be sustained or that the average trading volume will increase. In addition, the stock market in general has experienced significant price and volume fluctuations. Volatility in the market price for particular companies has often been unrelated or disproportionate to the operating performance of those companies. Broad market factors may seriously harm the market price of our common stock, regardless of our operating performance. In addition, securities class action litigation has often been initiated following periods of volatility in the market price of a company's securities. A securities class action suit against us could result in substantial costs, potential liabilities, and the diversion of management's attention and resources. To the extent our stock price fluctuates or remains low, it could impair our ability to raise capital through the offering of additional equity securities.

The issuance of additional equity securities by us in the future could result in dilution to our existing shareholders.

Our board of directors has authority, without action or vote of our shareholders, to issue all or a part of our authorized but unissued shares, except where shareholder approval is required by law. Any issuance of additional equity securities by us in the future could result in dilution to our existing shareholders. Such issuances could be made at a price that reflects a discount or a premium to the then-current trading price of our common stock. In addition, our business strategy may include expansion through internal growth by acquiring complementary businesses, acquiring or licensing additional products or brands, or establishing strategic relationships with targeted customers and suppliers. In order to do so, or to finance the cost of our other activities, we may issue additional equity securities that could result in further dilution to our existing shareholders. These issuances would dilute your percentage ownership interest, which would have the effect of reducing your influence on matters on which our shareholders vote, and might dilute the book value of our common stock. For example, we have recently issued a significant number of shares of our common stock in connection with financings and establishing strategic relationships and as a result our outstanding shares have increased from 5,894,176 shares as of December 31, 2011 to 30,168,613 shares as of September 30, 2013.

In connection with the Lantibiotics ECC that we entered into on June 20, 2012, we will a be required to issue additional shares of our common stock of up to 4.5% of our then outstanding common stock to Intrexon upon meeting certain commercialization milestones.

In connection with the new Probiotics ECC we entered into on September 30, 2013, we will be required, at our option, to pay up to $17 Million cash to Intrexon or issue up to $17 Million of additional shares of our common stock to Intrexon upon meeting certain commercialization milestones. We also issued a convertible promissory note in the amount of $1,956,000 which is payable, at our option, in cash or shares of our common stock (the "Convertible Note"). The Convertible Note matures on December 31, 2013 and the conversion price is equal to the closing price per share of our common stock on the last trading day immediately prior to the date of conversion.

You may also incur additional dilution if performance awards are made pursuant to our long term incentive programs for executives and non-employee directors or holders of stock options, whether currently outstanding or subsequently granted, exercise their options, or if warrant holders exercise their warrants to purchase shares of our common stock. For example, on October 21, 2013 we issued an aggregate of 389,174 shares of our common stock to our executive officers and non-employee directors pursuant to performance awards under our long term incentive programs.

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

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur. In addition, these factors could make it more difficult for us to raise funds through future offerings of common stock. We have recently issued a significant number of shares of common stock and the number of outstanding shares has increased from 5,894,176 shares as of December 31, 2011 to 27,382,830 as of December 31, 2012 and as of September 30, 2013 has increased to 30,168,613 shares . In June of 2012 we issued to Intrexon 4,392,425 shares of our common stock which are subject to piggy – back registration rights. On July 31, 2012, we issued 8,666,665 shares of Common Stock to investors and Warrants to purchase an additional 771,169 shares of Common Stock to the placement agent and pursuant to a Registration Rights Agreement we are required to register these shares and warrant shares for resale. On August 31, we filed a Registration Statement on Form S-1 to register the resale of these shares by the purchasers. The Registration Statement as amended was declared effective by the SEC on September 26, 2012. Accordingly, these shares may be resold in the open market.

As of September 30, 2013, there were 30,168,613 shares of our common stock outstanding, with another 2,747,094 shares of common stock issuable upon exercise of warrants to investors, 607,840 shares issuable upon exercise of options outstanding and an additional 2,689,711 shares available for option grants under our 2012 Equity Incentive Plan. The issuance of shares of our common stock under our 2012 Equity Incentive Plan is covered by Form S-8 registration statements we filed with the Securities and Exchange Commission, or SEC, and upon exercise of the options, such shares may be resold into the market. We have also issued shares of common stock and warrants in connection with previous private placements. Such shares are available for resale as well as certain of the shares of common stock issuable upon exercise of the warrants. We have also issued shares of our common stock in the private placement and financing transaction, which are deemed to be "restricted securities," as that term is defined in Rule 144 promulgated under the Securities Act of 1933, as amended, or Securities Act, and such shares may be resold pursuant to the provisions of Rule 144. For example, on September 30, 2013 we issued 1,348,000 restricted shares of our common stock to Intrexon as part of the technology access fee for the Probiotic's ECC and on the same date we also sold 1,300,000 restricted shares of our common stock to Intrexon in a private placement, The resale of shares acquired from us in private transactions could cause our stock price to decline significantly.

In addition, from time to time, certain of our shareholders may be eligible to sell all or some of their restricted shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, subject to certain limitations. In general, pursuant to Rule 144, after satisfying a six-month holding period: (i) affiliated shareholders, or shareholders whose shares are aggregated, may, under certain circumstances, sell within any three-month period a number of securities which does not exceed the greater of 1% of the then-outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale and (ii) non-affiliated shareholders may sell without such limitations, in each case provided we are current in our public reporting obligations. Rule 144 also permits the sale of securities by non-affiliates that have satisfied a one-year holding period without any limitation or restriction.

We are unable to estimate the number of shares that may be sold because this will depend on the market price for our common stock, the personal or business circumstances of sellers and other factors.

The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified members for our Board of Directors.

As a public company, we are already subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the Sarbanes-Oxley Act. The requirements of these rules and regulations may increase our legal, accounting and financial compliance costs; may make some activities more difficult, time-consuming and costly; and may also place undue strain on our personnel, systems and resources. Our management and other personnel need to devote a substantial amount of time to comply with these requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors and Board committees or as executive officers.

As a public company we are also required to assess our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act and file periodic reports with the SEC. If we are unable to comply with these requirements in a timely manner, or if material weaknesses or significant deficiencies persist, the market price of our stock could decline and we could be subject to sanctions or regulatory investigations, which could harm our business. We must perform an assessment of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. If we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act or the SEC reporting requirements in a timely manner, or if we continue to note or identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. As a smaller reporting company, we do not have to have our independent registered public accounting firm report on the effectiveness of our internal control over financial reporting. If in the future we no longer meet the requirements of a smaller reporting company, our independent registered public accounting firm will have to report on our internal controls over financial reporting. There can be no assurance that our independent registered public accounting firm will not identify material weaknesses which could have an adverse effect on our stock price.

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ITEM 2. UNREGISTERED SALE OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Incorporated by reference to the Exhibit Index filed after signature page.

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SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 25th day of October, 2013.

ORAGENICS, INC.

BY: /s/ John N. Bonfiglio Ph.D.
John N. Bonfiglio Ph.D., President, Chief Executive Officer and Principal Executive Officer

BY: /s/ Michael Sullivan
Michael Sullivan, Chief Financial Officer and Principal Accounting Officer

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EXHIBIT INDEX

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
10.1	Exclusive License Agreement between the Company and the University of Florida Research Foundation, Inc. effective August 4, 1998 for Replacement Therapy for Dental Caries (the "Replacement Therapy License Agreement")	SB-2	333-100568	10.1	10/16/02	
10.2	First Amendment to Replacement Therapy License Agreement dated September 15, 2000	SB-2	333-100568	10.2	10/16/02	
10.3	Second Amendment to Replacement Therapy License Agreement dated June 2002	SB-2	333-100568	10.3	10/16/02	
10.4	Third Amendment to Replacement Therapy License Agreement dated September 25, 2002	SB-2	333-100568	10.4	10/16/02	
10.5	Fourth Amendment to Replacement Therapy License Agreement dated March 2003	SB-2/A-3	333-100568	10.36	4/9/03	
10.6	Standard Exclusive License Agreement with Sublicensing Terms between the Company and the University of Florida Research Foundation, Inc. effective June 22, 2000 (the "MU1140 License Agreement")	SB-2	333-100568	10.5	10/16/02	
10.7	First Amendment to the MU1140 License Agreement dated September 15, 2000	SB-2	333-100568	10.6	10/16/02	
10.8	Second Amendment to the MU1140 License Agreement dated June 10, 2002	SB-2	333-100568	10.7	10/16/02	
10.9	Third Amendment to the MU1140 License Agreement dated September 25, 2002	SB-2	333-100568	10.4	10/16/02	
10.10	Fourth Amendment to the Antimicrobial Polypeptide License Agreement dated March 2003	SB-2/A-3	333-100568	10.36	4/9/03	
10.11	Fifth Amendment to Replacement Therapy License Agreement dated April 2013	8-K	001-32188	10.2	4/23/13	
10.12	Fifth Amendment to the MU1140 License Agreement dated April 2013	8-K	001-32188	10.1	4/23/13	
10.13	Exclusive Channel Collaboration Agreement by and between Oragenics, Inc. and Intrexon Corporation dated as of September 30, 2013.**	8-K	001-32188	10.1	10/1/13	
10.14	Stock Purchase and Issuance Agreement by and between Oragenics, Inc. and Intrexon Corporation dated as of September 30, 2013.	8-K	001-32188	10.2	10/1/13	
10.15	First Amendment to the Stock Purchase and Issuance Agreement dated September 30, 2013.	8-K	001-32188	10.3	10/1/13	
10.16	Convertible Promissory Note dated September 30, 2013.	8-K	001-32188	10.4	10/1/13	

** Confidential treatment has been requested for the redacted portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).					X
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase					X
101.LAB	XBRL Taxonomy Extension Label Linkbase					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase					X

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, John N. Bonfiglio Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Oragenics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors:

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated this 25th day of October, 2013

By: /s/ John N. Bonfiglio Ph.D.
John N. Bonfiglio Ph.D.
Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Michael Sullivan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Oragenics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors:

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated this 25th day of October, 2013

By: /s/ Michael Sullivan
Michael Sullivan
Chief Financial Officer

Exhibit 32.1

Certification of Chief Executive Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)

In connection with the Quarterly Report on Form 10-Q for the quarter ended September 30, 2013 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, John N. Bonfiglio Ph.D., the Chief Executive Officer of the Registrant, hereby certify, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

/s/ John N. Bonfiglio Ph.D.

Name: John N. Bonfiglio Ph.D.
Date: October 25, 2013

Exhibit 32.2

Certification of Chief Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)

In connection with the Quarterly Report on Form 10-Q for the quarter ended September 30, 2013 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Michael Sullivan, the Chief Financial Officer of the Registrant, hereby certify, to the best of my knowledge, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

/s/ Michael Sullivan

Name: Michael Sullivan
Date: October 25, 2013