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

FORM 10-Q

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

For the quarterly period ended September 30, 2012.

OR

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE 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.)**

3000 Bayport Drive, Suite 685
Tampa, Florida 33607
(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 ☒

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

As of November 1, 2012, there were 27,382,830 shares of Common Stock, $.001 par value, outstanding.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Oragenics, Inc.

Balance Sheets

	September 30, 2012 (Unaudited)	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 11,757,775	$ 171,739
Restricted cash	144,586	264,960
Accounts receivable, net	72,379	92,644
Inventory, net	279,949	475,592
Prepaid expenses and other current assets	236,402	113,331
Total current assets	12,491,091	1,118,266
Property and equipment, net	92,893	148,686
Total assets	$ 12,583,984	$ 1,266,952
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,398,603	$ 1,740,216
Short term notes payable	88,492	53,092
Deferred revenue	265,841	152,962
Convertible secured note payable to shareholder	—	7,500,000
Total current liabilities	1,752,936	9,446,270
Shareholders' equity (deficit):		
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; 27,204,721 and 5,894,176 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively	27,205	5,894
Additional paid-in capital	62,901,379	32,810,704
Accumulated deficit	(52,097,536)	(40,995,916)
Total shareholders' equity (deficit)	10,831,048	(8,179,318)
Total liabilities and shareholders' equity (deficit)	$ 12,583,984	$ 1,266,952

See accompanying notes.

Oragenics, Inc.

Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenues, net	$ 264,248	$ 350,351	$ 901,182	$ 1,047,857
Cost of sales	164,059	134,411	474,526	558,205
Gross profit	100,189	215,940	426,656	489,652
Operating expenses:				
Research and development	600,208	562,723	7,130,780	1,606,987
Selling, general and administrative	1,596,554	1,364,326	3,740,022	4,413,535
Total operating expenses	2,196,762	1,927,049	10,870,802	6,020,522
Loss from operations	(2,096,573)	(1,711,109)	(10,444,146)	(5,530,870)
Other income (expense):				
Interest income	5,645	329	7,193	706
Interest expense	(456,237)	(96,722)	(654,611)	(208,182)
Local business tax	(8,776)	212	(10,056)	(1,200)
Total other income (expense), net	(459,368)	(96,181)	(657,474)	(208,676)
Loss before income taxes	(2,555,941)	(1,807,290)	(11,101,620)	(5,739,546)
Net loss	$ (2,555,941)	$(1,807,290)	$(11,101,620)	$(5,739,546)
Basic and diluted net loss per share	$ (0.11)	$ (0.32)	$ (0.76)	$ (1.01)
Shares used to compute basic and diluted net loss per share	23,793,309	5,683,076	14,578,448	5,671,208

See accompanying notes.

Oragenics, Inc.

Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2012	2011
Cash flows from operating activities:		
Net loss	$(11,101,620)	$(5,739,546)
Adjustments to reconcile net loss to net cash used in operating activities:		
Technology access fee paid in common stock	5,798,001	—
Accretion of discount on note payable to shareholder	483,559	—
Depreciation and amortization	55,793	60,144
Stock-based compensation expense	1,057,218	1,058,327
Changes in operating assets and liabilities:		
Accounts receivable, net	20,265	78,642
Income tax receivable	—	362,218
Inventory, net	195,643	(198,846)
Prepaid expenses and other current assets	11,843	98,358
Accounts payable and accrued expenses	(104,556)	29,004
Deferred revenue	112,879	148,197
Net cash used in operating activities	(3,470,975)	(4,103,502)
Cash flows from financing activities:		
Borrowings under note payable to shareholder	2,500,000	
Borrowings under convertible secured note payable to shareholder	750,000	4,000,000
Payments on short term notes payable	(99,514)	(121,335)
Payment of income taxes associated with stock based compensation	(127,291)	—
Net proceeds from issuance of common stock	11,913,442	—
Restricted cash released, net	120,374	92,734
Net cash provided by financing activities	15,057,011	3,971,399
Net increase (decrease) in cash and cash equivalents	11,586,036	(132,103)
Cash and cash equivalents at beginning of the period	171,739	(132,103)
Cash and cash equivalents at end of the period	$ 11,757,775	$ —
Supplemental disclosure of cash flow information		
Interest paid	$ 2,936	$ 4,296
Non-cash investing and financing activities:		
Borrowing under short term notes payable for prepaid expense	$ 134,914	$ 126,739
Par value of restricted stock granted as stock compensation	$ —	$ 20
Conversion of notes 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 restricted stock forfeited	$ 5	$ —
Fair market value of 771,169 warrants issued to Griffin Securities, Inc. as a reduction of 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 oral health, broad spectrum antibiotics and other general health benefits.

2. Basis of Presentation

The accompanying unaudited interim financial statements as of September 30, 2012 and December 31, 2011 (audited) and for the three and nine months ended September 30, 2012 and 2011 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, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012 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, 2011, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 16, 2012. 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. During the nine months ended September 30, 2012, the Company generated revenues of $901,182, incurred a net loss of $(11,101,620) and used cash of $(3,470,975) in its operating activities. As of September 30, 2012 the Company had an accumulated deficit of $(52,097,536).

During 2011 and through June 30, 2012, the Company's primary source of debt and equity funding was provided by its largest shareholder, the Koski Family Limited Partnership, or KFLP. In July 2012, the Company raised $13,000,000 in gross proceeds through the issuance of 8,666,665 shares of its common stock to a number of new shareholders. The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes the working capital at September 30, 2012 will be sufficient to meet the business objectives as presently structured through at least December 2013.

The Company intends to seek additional funding through sublicensing arrangements, joint venturing or partnering, sales of rights to technology, and public or private financings. The Company's future success depends on its ability to raise capital and increase 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 2012 have had or are expected to have an impact on the Company's financial statements.

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 sales as a reduction of revenues as such allowances can be reliably estimated based on historical experience or known trends. Product returns are limited to specific mass retail customers for expiration of shelf life or unsold product over a period of time. 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 charge backs to vary. Because the ProBiora3 products have only recently been introduced, the Company could experience different circumstances in the future and these differences could be material.

Guaranteed Rights of Return

The Company has granted guaranteed rights of return to one mass retail customer and two dental distributors' customer accounts. The Company defers recognition of revenue on these accounts until the customer provides notification to the Company that the product has been sold to the end consumer. Once notification has been received and verified, the Company records revenue in that period. The Company had approximately $21,500 and $26,000 of revenue deferred under guaranteed rights of return arrangements included in deferred revenue in the balance sheets as of September 30, 2012 and December 31, 2011, respectively. There was approximately $9,200 and $9,000 included in inventory under these agreements as of September 30, 2012 and December 31, 2011.

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.

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 for options and warrants. 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.

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 $61,800 and $65,000 as of September 30, 2012 and December 31, 2011, respectively.

Consigned Inventory

The Company has authorized a consignment inventory arrangement with one mass retail customer. As of September 30, 2012 and December 31, 2011, the Company had approximately $-0- and $20,000, respectively, of inventory on consignment located at the retailers' stores and warehouses, which is included in our inventory reserve. Once consignment inventory has been sold by this customer, the customer notifies the Company of the sale and the Company records revenue in that accounting period. The Company authorizes the replenishment of consignment inventory based on orders placed by the customer. The Company is provided with weekly reports of consignment sales activity and balances.

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 convertible revolving note payable, stock options and warrants are not included because they are antidilutive as of December 31, 2011. Shares associated with stock options and warrants are not included because they are antidilutive as of September 30, 2012. 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.

Concentrations

The Company is dependent on key suppliers to provide probiotics, blending, warehousing and packaging of its EvoraPlus, EvoraPlus Kids, EvoraPro, and Teddy's Pride products. The Company had four key suppliers during the three and nine months ended September 30, 2012 and 2011, respectively. The majority of the Company's cost of sales are from these key suppliers during the three and nine months ended September 30, 2012 and 2011. Accounts payable and accrued expenses for these vendors totaled approximately $23,200 and $108,000 as of September 30, 2012 and December 31, 2011, respectively.

4. Commitments and Contingencies

The University of Florida Research Foundation Licenses

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

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 and March 17, 2003. 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. The patent covers the genetically altered strain of *S. mutans* which does not produce lactic acid, a pharmaceutical composition for administering the genetically altered strain and the method of preventing tooth decay by administering the strain. The Company issued 599,940 shares of our common stock to the UFRF as partial consideration for the initial license.

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 and March 17, 2003. 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." 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 UFRF has reserved the right to use and sell products and services for research purposes only. The amended license agreements also provide the UFRF with a license, for research purposes only, to any improvements that we make to the products and processes covered by the patents.

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 20% of all revenues received from the sublicenses, excluding monies received solely for development costs.

The Company is also obligated to make minimum annual royalty payments to the UFRF for the term of the amended license agreement in the amount of $50,000 by the end of each year for each license agreement. The minimum royalty payments are required to be paid in advance on a quarterly basis. For the SMaRT Replacement Therapy and MU1140 minimum royalty payments, the Company must pay the UFRF an aggregate of $100,000 which is required to be paid in equal quarterly installments of $25,000.

Under the terms of the amended license agreements, in each calendar year and in addition to the royalty payment obligations, the Company is obligated to spend, or cause to be spent, an aggregate of $1,000,000 on the research, development, and regulatory prosecution of our SMaRT Replacement Therapy and MU1140 technologies combined, until a product which is covered wholly or partially by the claims of the patent, or is manufactured using a process which is covered wholly or partially by the claims of the patent, is sold commercially. If the Company fails to make these minimum research and development expenditures, the UFRF may terminate our license agreement.

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 Agreement with Intrexon Corporation ("Intrexon")

On June 5, 2012, the Company entered into an Exclusive Channel Collaboration Agreement (the "Channel Agreement") with Intrexon that governs a "channel partnering" 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 Channel Agreement 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 Channel Agreement grants the Company an exclusive worldwide license to use patents and other intellectual property of Intrexon in connection with the research, development, use, importing, manufacture, sale, and offer for sale of drug products involving the direct administration to humans or companies of lantibiotics for the purpose of 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 Channel Agreement, 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 Channel Agreement, 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 Channel Agreement, 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 Channel Agreement other than in the event of a material breach by the other party and Intrexon may terminate the Channel Agreement under certain circumstances if the Company assigns its rights under the Channel Agreement without Intrexon's consent. Following the first 18 months of the agreement, Intrexon may also terminate the Channel Agreement 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 Channel Agreement. Following the first 18 months of the Agreement, the Company may voluntarily terminate the Channel Agreement at any time upon 90 days written notice to Intrexon.

Upon termination of the Channel Agreement, the Company may continue to develop and commercialize any Oragenics Product that, at the time of termination:

- is being commercialized by the Company;
- has received regulatory approval;
- is a subject of an application for regulatory approval that is pending before the applicable regulatory authority; or
- is the subject of at least an ongoing Phase I, Phase A, Phase II or Phase III clinical trial (in the case of a termination by Intrexon due to a Oragenics uncured breach or a voluntary termination by the Company), or an ongoing Phase I clinical trial in the Field (in the case of a termination by the Company due to an Intrexon uncured breach or a termination by Intrexon following an unconsented assignment by the Company or the Company's election not to pursue development of a Superior Therapy).

The Company's obligation to pay 25% of gross profits or revenue described above with respect to these "retained" products will survive termination of the Channel Agreement.

In addition, in partial consideration for each party's execution and delivery of the Channel Agreement, 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 common stock as an initial technology access fee, in consideration for the execution and delivery of the Channel Agreement and granted Intrexon certain equity participation rights and registration rights. See Note 7 — Common Stock.

Under the Stock Issuance Agreement and as part of the Channel Agreement, 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 issues). The milestone events and amounts payable are as follows:

(i) filing of the first Investigational New Drug application with the U.S. Food and Drug Administration that number of shares of common stock equal to the number of shares of Common Stock comprising 1.0% of the Base Shares ;

(ii) upon the dosing of the first patient in the first Phase 2 clinical study, that number of shares of common stock 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, that number of shares of common stock 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 Company Product, or alternatively the filing of the first equivalent regulatory filing with a foreign regulatory agency, that number of shares of common stock 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 of common stock (the 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 these milestones had been achieved as of September 30, 2012.

5. Stock-Based Payment Arrangements

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

	Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Nine months Ended September 30, 2012	Nine months Ended September 30, 2011
Research and development	$ 105,858	$ 32,590	$ 116,726	$ 107,731
Selling, general and administrative	693,533	179,545	940,492	950,596
Total stock based compensation expense	$ 799,391	$ 212,135	$1,057,218	$1,058,327

The Company granted 100,000 stock options, with a weighted-average grant date fair value of $1.03 per share, during the nine months ended September 30, 2012. No stock options were granted during the three months ended September 30, 2012. The Company granted 195,700 and 496,500 stock options, with a weighted-average grant date fair value of $1.02 and $3.30 per share, during the three and nine months ended September 30, 2011, respectively.

During the nine months ended September 30, 2012, 191,925 stock options previously granted have vested and 164,750 stock options were forfeited.

On August 6, 2012, 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 Company successfully raising $10,000,000 of new capital. As a result of the Compensation Committee’s determination, and pursuant to the LTIP, Dr. John Bonfiglio, the Company’s Chief Executive Officer and Dr. Martin Handfield, the Company’s Vice President of Research and Development, were entitled to awards of 0.70% and 0.23% 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 and Dr. Handfield were awarded 188,482 and 61,929 shares of Company common stock under the Company’s Amended and Restated 2002 Stock Option and Incentive Plan (the “Plan”), respectively. Also on August 6, 2012 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 43,081 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.

The aggregate shares awarded under the Plan of 465,816, consisted of a total of 215,405 shares to non-employee directors and 250,411 shares to executive officers. Of the aggregate 465,816 shares awarded under the LTIPs, (i) 132,000 shares were awarded to Dr. Bonfiglio of which 34,914 shares were retained by the Company for applicable tax withholding obligations, (ii) 43,000 shares were awarded to Dr. Handfield of which 11,373 shares were retained by the Company for applicable tax withholding obligations, and (iii) 30,000 shares were awarded to each of the five non-employee directors, with the balance of the remaining aggregate shares awarded of 140,816 to be issued in the future at such time that an increase in the number of shares available under the Company’s Plan could be approved by the shareholders. See Note 11 — Subsequent Events.

The grant date fair value of the 278,713 shares issued under the LTIP was determined to be $429,218.

6. Warrants

A summary of warrant activities for the nine months ended September 30, 2012 and for the year ended December 31, 2011 is as follows:

	Warrants	Weighted Average Price
Balance - December 31, 2010	306,388	$ 19.14
Granted	—	—
Exercised		—
Expired	—	—
Balance - December 31, 2011	306,388	19.14
Granted	2,942,094	1.87
Exercised	—	—
Expired	(12,500)	6.00
Balance - September 30, 2012	3,235,982	$ 3.53

On March 23, 2012, pursuant to the terms of a Debt Exchange Agreement and a Loan Agreement with the Koski Family Limited Partnership, or KFLP, the Company issued warrants to acquire 1,571,405 and 599,520 shares of common stock, respectively, to the KFLP. The warrants are exercisable immediately at a price per share of $2.00 and expire three years from the date of issuance. See Note 9 — Convertible Revolving Notes Payable to Shareholder.

On July 30, 2012, the Company issued to Griffin Securities, Inc., or its designee, a five-year warrant to purchase up to 771,169 shares of the Company's Common Stock with an exercise price of $1.50 per share. The warrant was issued as partial consideration for Griffin Securities, Inc. acting as the Placement Agent for our July 2012 Private Placement Financing. The warrants were valued at $2.40 per share.

The warrants outstanding as of September 30, 2012 are as follows:

Exercise Price	Warrants Outstanding	Expiration Dates
$1.50	771,169	7/30/17
$2.00	2,170,925	3/23/15
$10.00	5,000	4/15/14
$15.00	161,000	5/30/13
$26.00	127,888	5/30/13
	3,235,982	

On September 27, 2012, the KFLP made a distribution of a portion of its warrants to the underlying partners of the KFLP. As a result of such distribution the KFLP retained warrants to acquire 61,405 and 599,520 respectively and its underlying partners (including certain trusts) were issued warrants to acquire an aggregate of 1,510,000 shares of common stock.

7. Common Stock

On March 23, 2012, pursuant to the terms of the Debt Exchange Agreement, the Company issued 6,285,619 shares of common stock to the KFLP. See Note 9 — Convertible Revolving Notes Payable to Shareholder.

On June 5, 2012, in conjunction with the Company's execution and delivery of the Channel Agreement with Intrexon, the Company entered into a Stock Issuance Agreement which included certain registration rights, with Intrexon. On June 5, 2012, pursuant to that Stock Issuance Agreement, Intrexon was issued 4,392,425 shares of the Company's common stock, which was deemed consideration for the execution and delivery of the Channel Agreement. This resulted in the Company recording a non-cash expense of $5,798,001 during the quarter ended June 30, 2012. Under the terms of the Stock Issuance Agreement, the Company agreed to issue to Intrexon additional shares of its common stock based upon the achievement of certain milestones. See Note 4 — Commitments and Contingencies.

The registration rights granted to Intrexon in the Stock Issuance Agreement by the Company consisted of "piggyback registration" rights which permit Intrexon to participate in any firm commitment underwritten offering of securities by the Company, subject to underwriter cutbacks and lockups. In addition, the Company is precluded from granting registration rights in connection with a private placement unless (i) all shares held by Intrexon are, at the time of such private placement, included on a registration statement, or (ii) the Company agrees, in connection with such private placement, to grant Intrexon the right to include on the registration statement a number of Intrexon's Company shares equal to one half of the number of shares to be registered on behalf of the other holders or prospective holders.

Pursuant to the Stock Issuance Agreement, Intrexon is also entitled, at its election, to participate in future securities offerings of the Company that constitute "qualified financings" and purchase securities equal to 30% of the number of shares of common stock or other securities sold in such offering (exclusive of Intrexon's purchase). For this purpose, a "qualified financing" means a sale of common stock or equity securities convertible into common stock in a public or private offering, raising gross proceeds of at least $1,000,000, where the sale of shares is either registered under the Securities Act of 1933, as amended, at the time of issuance or the Company agrees to register the resale of such shares.

The Company's former chief financial officer resigned on January 27, 2012 and as a result of such resignation, 5,000 shares of restricted common stock previously awarded but not yet vested at the time of his resignation were forfeited back to the Company.

On July 30, 2012, the Company entered into a Stock Purchase Agreement (the "Purchase Agreement") with certain accredited investors (the "Purchasers") pursuant to which the Company: (i) sold to the Purchasers an aggregate of 8,666,665 shares of the Company's Common Stock at a price per share of $1.50 (the "Common Shares") for aggregate gross proceeds of approximately $13,000,000 (the "Offering"). The Company intends to use the net proceeds from this offering to accelerate development of several of the Company's key initiatives including its recently announced Channel Agreement with Intrexon relating to the Company's lantibiotics program, sales and marketing of the Company's 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, the Company 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 the Company's 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 total amount charged to additional paid-in-capital as a result of the Offering was $1,086,558. This amount is comprised of $949,698 for services provided by Griffin Securities, Inc., $130,520 for services provided by the Company's legal counsel and independent accountants, and $6,340 for other services.

In connection with the Offering, the Company also entered into a registration rights agreement with the Purchasers (the "Registration Rights Agreement"). The Registration Rights Agreement required that the Company file a registration statement (the "Initial Registration Statement") with the Securities and Exchange Commission (the "SEC") within forty-five (45) days of the closing date of the Offering (the "Filing Date") for the resale by the Purchasers of all of the Common Shares and all shares of Common Stock issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect thereto (the "Registrable Securities"). The Initial Registration Statement must be declared effective by the SEC within ninety (90) days of the closing date of the Offering (the "Effectiveness Date") subject to certain adjustments. Upon the occurrence of certain events (each an "Event"), including, but not limited to, that the Initial Registration Statement is not filed prior to the Filing Date, the Company will be required to pay liquidated damages to each of the Purchasers equal to 1.5% of the aggregate purchase price paid by such Purchaser for the Registrable Securities upon the date of the Event and then monthly thereafter until the earlier of: (i) the Event is cured, or (ii) the registrable shares are eligible for resale under Rule 144 without manner of sale or volume limitations. In no event shall the aggregate amount of liquidated damages payable to each of the Purchasers exceed in the aggregate 10% of the aggregate purchase price paid by such Purchaser for the Registrable Securities.

On August 31, 2012, the Company filed Form S-1 Registration Statement with the SEC. On September 21, 2012 the Company filed Amendment No. 1 to Form S-1 Registration Statement with the SEC. On September 26, 2012 the Registration Statement was declared effective by the SEC.

In connection with the Offering, the KFLP waived receiving comparable registration rights as the Purchasers in the Offering as well as its piggyback registration rights applicable to the Offering. Intrexon also waived its piggyback registration rights applicable to the Offering and waived its participation rights.

8. Short Term Notes Payable

As of December 31, 2011, the Company had $53,092 in short-term notes payable for the financing of various insurance policies. On March 10, 2012, the Company entered into a short-term note payable for $50,037 bearing interest at 6.17% to finance the product liability insurance. Principal and interest payments on this note begin April 10, 2012 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on January 10, 2013.

On August 24, 2012 the Company entered into a short-term note payable for $84,876 bearing interest at 4.75% to finance the director and officers and employment practices liability insurance premiums. Principal and interest payments on this note began August 24, 2012 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on May 24, 2013.

9. Convertible Revolving Notes Payable to Shareholder

Prior to December 31, 2011 the Company had entered into a number of unsecured revolving credit agreements and amendments (the "Credit Facility") with the Koski Family Limited Partnership ("KFLP"), and accredited investor and the Company's largest shareholder. As of December 31, 2011 the Company had borrowed $7,500,000 under the Credit Facility. On January 23, 2012, the Company 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, the Company 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, the Company 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, the Company issued 6,285,619 shares of common stock and a warrant 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 our previously existing unsecured revolving credit facility (the "Credit Facility) with the KFLP. 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 of $487,011 through March 23, 2012 (the closing date). As a result of the Debt Exchange Agreement, the Credit Facility was terminated and the previously issued promissory notes thereunder were cancelled. The warrant is exercisable immediately at a price per share of $2.00 and expires three years from the date of issuance. The Company valued the common stock and warrant at $8,737,011 which equaled the carrying value of the Credit Facility and related

accrued interest. The market for the Company's stock did not generate enough volume to provide accurate pricing for the block of stock and warrants covered by the Debt Exchange Agreement. A significant discount to the market for the Company's stock would be needed to sell the shares issued and issuable pursuant to the warrant, as such, the value of the existing indebtedness under the Credit Facility of $8,737,011 was determined to be indicative of the combined value of the transaction. As a result, no gain or loss was recognized on this exchange of debt for equity.

On March 23, 2012, the Company also entered into a new loan agreement (the "Loan Agreement") with the KFLP which provided the Company with up to $2.5 million in secured funding in two advances of $1,250,000, the first of which occurred on March 23, 2012 and the second occurred on April 23, 2012. The Loan Agreement provided that borrowings would mature in three years and bear interest at the rate of 5.0% and were secured by select Company assets relating to or connected with the Company's technologies. Pursuant to the Loan Agreement the Company issued an additional warrant to the KFLP to acquire 599,520 shares of our common stock. The warrant is exercisable immediately at a price per share of $2.00 and expires three years from the date of issuance. See Note 6 — Warrants.

Amounts borrowed under the Loan Agreement were subject to automatic conversion upon a subsequent "qualified financing" by the Company of $5,000,000 (excluding any converted debt amount) of its securities to accredited investors.

On July 30, 2012, the Company entered into a Stock Purchase Agreement (the "Purchase Agreement") with certain accredited investors (the "Purchasers") pursuant to which the Company: (i) sold to the Purchasers an aggregate of 8,666,665 shares of the Company's Common Stock at a price per share of $1.50 (the "Common Shares") for aggregate gross proceeds of approximately $13,000,000 (the "Offering").

Because the Offering constituted a "qualified financing" under the terms of the Company's Loan Agreement with the KFLP, the Company's secured debt in the principal amount of $2.5 million, together with accrued but unpaid interest of $38,185 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 and related agreements were terminated. In addition the Company recognized $443,970 in interest expense due to the conversion of the note payable with warrants to common stock and the write off of the remaining discount to interest expense.

10. Related Party Transactions.

The Company's Chairman, Dr. Frederick Telling, participated in the Company's Offering and acquired 98,111 shares. The participation of Dr. Telling was approved by the disinterested directors.

11. Subsequent Events

On October 23, 2012, the shareholders approved the amendment, restatement and renaming of our 2002 Amended and Restated Stock Incentive Plan as our Amended and Restated 2012 Equity Incentive Plan. As a result of that approval, the remaining aggregate shares that were previously awarded of 140,816 and that were earned as a result of the achievement of one of the performance goals established in the Company's Long Term Incentive Programs established as part of executive compensation and non-employee director compensation were issued. A total of 75,411 shares were issued to executive officers and 65,405 shares were issued to non-employee directors.

Of the aggregate 140,816 shares issued under the LTIPs, (i) 56,482 shares were issued to Dr. Bonfiglio of which 14,939 shares were retained by the Company for applicable tax withholding obligations, (ii) 18,929 shares were awarded to Dr. Handfield of which 5,007 shares were retained by the Company for applicable tax withholding obligations.

On October 23, 2012 the Compensation Committee of the Board of Directors approved the award of 83,500 shares of our common stock to Michael Sullivan our Chief Financial Officer. Of the 83,500 shares which were awarded, 26,261 shares were retained by the Company for applicable tax withholding obligations. The award was made in consideration of Mr. Sullivan's services since he joined the Company, including but not limited to, his services regarding the Company's securities filings, the financings by the KFLP, the Intrexon collaboration, the recent substantial capital raise closing and related follow-on registration statement. The fair market value of the shares awarded to Mr. Sullivan was $175,350.

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 or Plan of Operation" and "Business," 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 probiotic blend, ProBiora3 to consumers and to dental professionals.

Our Antibiotics

While conducting research and development on of our technologies, 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 50 lantibiotics have been discovered since 1927 when the first lantibiotic, nisin, was discovered. Lantibiotics are known to be potent antibiotic agents.

We have performed extensive 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.

The challenge presented by lantibiotics is that we have not been able to investigate their clinical usefulness due to our inability so far to produce or synthesize sufficient quantities of pure amounts of any of these molecules as a therapeutic agent for the treatment of infectious diseases. Standard fermentation methods, such as those used to make a variety of other antibiotics, typically result in production of only minute amounts of the lantibiotic. In cases where large amounts of a lantibiotic are made, such as with nisin, the unique chemical structure of lantibiotics has prevented the necessary purification needed for clinical testing.

In order to meet the challenge associated with producing sufficient quantities of MU1140 for our clinical trials and ultimately commercialization efforts, we are currently pursuing parallel paths as follows:

- We recently entered into a worldwide exclusive collaboration agreement ("ECC") with Intrexon Corporation ("Intrexon") for the development and commercialization of the native strain of MU1140 using Intrexon's advanced transgene and cell engineering platforms. Our efforts with Intrexon pursuant to the ECC continue to move forward following the capital raise we recently concluded. We expect to increase our research and development efforts with Intrexon in accordance with the terms of the ECC.

- 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), which we expect to continue to develop internally. We concluded our work with Bachem, a peptide synthesis manufacturing company. While the work performed by Bachem yielded 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. Rather than pursue an expanded agreement with Bachem we determined to proceed internally with continued research and development on increasing the yield associated with MU1140-S using DPOLT, which if successful, could lead to the first-ever synthetic route to commercial-scale production of a lantibiotic.

Our Probiotic Products

We have developed and are commercializing a variety of probiotic products that 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, or 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 received the Frost and Sullivan Award for excellence in Oral Care Probiotics in 2011;
- 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;
- we refocused our channel efforts, successfully limiting exposure to capital-intensive areas such as mass retail and increasing efforts in cost-effective, focused markets such as dental offices;
- we recently announced the successful completion of an independently conducted, randomized, double blind clinical trial on EvoraKids; and
- 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.

We have recently repositioned the Company towards increasing our focus and efforts – both financially and operationally-on our probiotics business and on the development of our antibiotic product candidate. We expect to focus on our oral health probiotic business to improve market awareness and provide for the potential for increased future sales. We expect to devote a substantial portion of our available resources to our oral health probiotic business and continued research and development and clinical trials for our antibiotic product candidate toward the goal of outlicensing such product candidate. For our other technologies and product candidates we expect to devote sufficient resources for their continued development toward the goal of outlicensing such product candidates or entering into partnerships or collaborative arrangements for the further development of such product candidates. In addition, we expect to devote resources to the protection of our intellectual property and the general and administrative support of our operations.

Other Technologies

Our SMaRT Replacement Therapy. 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. 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. We commenced a second Phase 1 clinical trial for SMaRT Replacement Therapy during the first quarter of 2011. Due to the very restrictive study enrollment criteria required by the FDA, enrollment of candidates meeting the restrictive criteria in this trial has been very slow. As a result we plan to meet with the FDA toward the goal of seeking approval for a revised enrollment criteria to make it less restrictive so that the trial can proceed. We continue to evaluate the research and development efforts for our SMaRT Replacement Therapy including the commitment of additional financial resources. The further commitment of funding will depend on a variety of factors, including but not limited to, the outcome of our objective to obtain a revised enrollment criteria with the FDA and the environment for partnering opportunities given the potential benefits we perceive that exist with our Replacement Therapy.

Our Weight Loss Agent-LPT3-04. In the course of our SMaRT Replacement Therapy research, our scientific team also discovered that consumption of a significant amount of LPT3-04, a naturally occurring compound which is normally consumed in the human diet in small amounts, resulted in dose-dependent weight loss in experimental animal models. LPT3-04 consumption in the required amounts has been shown to be safe in humans. Due to the natural sweetness of LPT3-04 and the relatively large amounts of it that need to be consumed on a daily basis to achieve the desired weight loss effect, current product development efforts are focused on incorporating the compound into bars, milkshakes, and other food products. In furtherance of our efforts to date in developing LPT3-04:

- Our LPT3-04 product yielded successful clinical results, paving the way for a potential newly commercialized product and/or partnership; and
- We have submitted a patent application for the use of LPT3-04 for weight regulation with the United States Patent and Trademark Office, or U.S. PTO.

We are positioning our LPT3-04 weight loss agent for licensing following the successful completion of the proof-of-concept human clinical trial.

We also continue to consider and evaluate opportunities and/or partnerships that will promote the advancement of our portfolio of scientific technologies, including DPOLT which was specifically designed as a methodology for synthesizing lantibiotics using traditional organic chemistry techniques. Additionally, we have other non-core technologies that originated from the discoveries of our scientific team, including CMAT, which is a biomarker discovery platform. We believe these other non-core technologies could provide potential opportunities for future research and development for us.

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, 2012, 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. For the nine months ended September 30, 2012 and 2011 and the years ended December 31, 2011 and 2010, respectively our net revenues were $901,182, $1,047,857, $1,444,447 and $1,308,910.

As of September 30, 2012, we had an accumulated deficit of $52,097,536 and we have yet to achieve profitability. We incurred net losses of $11,101,620 and $5,739,546 for the nine months ended September 30, 2012 and 2011, respectively, and $7,678,868 and $7,805,165 for the years ended December 31, 2011 and 2010, 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 expect that research and development expenses will increase along with general and administrative costs, as we grow and operate our business.

Recent Developments

The Intrexon Corporation Transaction:

On June 5, 2012, we entered into a worldwide Exclusive Channel Collaboration Agreement (the "Channel Agreement") with Intrexon Corporation ("Intrexon") through which we intend to develop and commercialize lantibiotics, a novel class of broad spectrum antibiotics, as active pharmaceutical ingredients (API) for the treatment of infectious diseases in humans and companion animals. Contemporaneously with the Channel Agreement, we entered into a Stock Issuance Agreement with Intrexon which authorized the issuance of shares of our common stock as a technology access fee to Intrexon and provided for future stock issuances of our common stock to Intrexon upon the achievement of designated milestones.

The Exclusive Channel Collaboration Agreement with Intrexon

The Channel Agreement with Intrexon governs a "channel partnering" arrangement in which we 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 Channel Agreement establishes committees comprised of our representatives 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 Channel Agreement grants us an exclusive worldwide license to use patents and other intellectual property of Intrexon in connection with the research, development, use, importing, manufacture, sale, and offer for sale of drug products involving the direct administration to humans or companies of lantibiotics for the purpose of 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, we may not sublicense the rights described without Intrexon's written consent.

Under the Channel Agreement, and subject to certain exceptions, we are 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 Channel Agreement, we will pay Intrexon on a quarterly basis 25% of gross quarterly profits derived in that quarter from the sale of products developed from the Channel Agreement, calculated on an Oragenics Product-by-Oragenics Product basis. We have 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 we nor Intrexon may terminate the Channel Agreement other than in the event of a material breach by the other party and Intrexon may terminate the Channel Agreement under certain circumstances if the we assign our rights under the Channel Agreement without Intrexon's consent. Following the first 18 months of the agreement, Intrexon may also terminate the Channel Agreement if we fail to use diligent efforts to develop and commercialize Oragenics Products or if we elect not to pursue the development of a Lantibiotics Program

identified by Intrexon that is a "Superior Therapy" as defined in the Channel Agreement. Following the first 18 months of the Agreement, we may voluntarily terminate the Channel Agreement at any time upon 90 days written notice to Intrexon.

Upon termination of the Channel Agreement, we may continue to develop and commercialize any Oragenics Product that, at the time of termination:

- is being commercialized by us;
- has received regulatory approval;
- is a subject of an application for regulatory approval that is pending before the applicable regulatory authority; or
- is the subject of at least an ongoing Phase I, Phase A, Phase II or Phase III clinical trial (in the case of a termination by Intrexon due to a Oragenics uncured breach or a voluntary termination by the Company), or an ongoing Phase I clinical trial in the Field (in the case of a termination by the Company due to an Intrexon uncured breach or a termination by Intrexon following an unconsented assignment by the Company or the Company's election not to pursue development of a Superior Therapy).

Our obligation to pay 25% of gross profits or revenue described above with respect to these "retained" products will survive termination of the Channel Agreement.

The Stock Issuance Agreement and Certain Registration Rights

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

Under the Stock Issuance Agreement and as part of the Channel Agreement, we have also agreed to make certain payments to Intrexon upon our achievement of designated milestones in the form of shares of our Common Stock or at our option make a cash payment to Intrexon (based upon the fair market value of the shares otherwise required to be issues). The milestone events and amounts payable are as follows:

(i) filing of the first Investigational New Drug application with the U.S. Food and Drug Administration that number of shares of common stock equal to the number of shares of Common Stock comprising 1.0% of the Base Shares ;

(ii) upon the dosing of the first patient in the first Phase 2 clinical study, that number of shares of common stock 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, that number of shares of common stock 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 Company Product, or alternatively the filing of the first equivalent regulatory filing with a foreign regulatory agency, that number of shares of common stock 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 of common stock (the 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 our 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 we may issue to investors in connection with a debt or equity investment in us 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).

The registration rights granted to Intrexon in the Stock Issuance Agreement by the Company consisted of "piggyback registration" rights which permit Intrexon to participate in any firm commitment underwritten offering of securities by the Company, subject to underwriter cutbacks and lockups. In addition, the Company is precluded from granting registration rights in connection with a private placement unless (i) all shares held by Intrexon are, at the time of such private placement, included on a registration statement, or (ii) the Company agrees, in connection with such private placement, to grant Intrexon the right to include on the registration statement a number of Intrexon's Company shares equal to one half of the number of shares to be registered on behalf of the other holders or prospective holders.

Pursuant to the Stock Issuance Agreement, Intrexon is also entitled, at its election, to participate in future securities offerings of the Company that constitute "qualified financings" and purchase securities equal to 30% of the number of shares of common stock or other securities sold in such offering (exclusive of Intrexon's purchase). For this purpose, a "qualified financing" means a sale of common stock or equity securities convertible into common stock in a public or private offering, raising gross proceeds of at least $1,000,000, where the sale of shares is either registered under the Securities Act of 1933, as amended, at the time of issuance or the Company agrees to register the resale of such shares.

The Stock Issuance Agreement contains a standstill provision pursuant to which, among other things, Intrexon has agreed that, for a period of three years, subject to certain exceptions and unless invited in writing by the Company to do so, neither Intrexon nor its affiliates will, directly or indirectly: (i) effect or seek, initiate, offer or propose to effect, or cause or participate in any acquisition of securities or assets of the Company; any tender or exchange offer, merger, consolidation or other business combination involving the Company; any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to the Company; or any "solicitation" of "proxies" or consents to vote any voting securities of the Company, or in any way advise or, assist any other person in doing so; (ii) form, join or in any way participate in a "group" with respect to any securities of the Company; (iii) otherwise act to seek to control or influence the management, Board of Directors or policies of the Company; (iv) take any action reasonably expected to force the Company to make a public announcement regarding any such matters; or (v) enter into any agreements, discussions or arrangements with any third party with respect to any of the foregoing.

The July 2012 Private Placement Financing and Secured Debt Conversion:

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 to accelerate development of several of our key initiatives including the recently announced Channel Agreement with Intrexon relating to the our lantibiotics program, sales and marketing of our probiotic product lines and general corporate purposes.

In connection with the Offering, we also entered into a registration rights agreement with the Purchasers (the "Registration Rights Agreement"). The Registration Rights Agreement requires us to file a registration statement (the "Initial Registration Statement") with the Securities and Exchange Commission (the "SEC") within forty-five (45) days of the closing date of the Offering (the "Filing Date") for the resale by the Purchasers of all of the Common Shares and all shares of Common Stock issuable upon any stock split, dividend or other distribution, recapitalization or similar event with respect thereto (the "Registrable Securities"). The Initial Registration Statement must be declared effective by the SEC within ninety (90) days of the closing date of the Offering (the "Effectiveness Date") subject to certain adjustments. Upon the occurrence of certain events (each an "Event"), including, but not limited to, that the Initial Registration Statement is not filed prior to the Filing Date, the Company will be required to pay liquidated damages to each of the Purchasers equal to 1.5% of the aggregate purchase price paid by such Purchaser for the Registrable Securities upon the date of the Event and then monthly thereafter until the earlier of: (i) the Event is cured, or (ii) the registrable shares are eligible for resale under Rule 144 without manner of sale or volume limitations. In no event shall the aggregate amount of liquidated damages payable to each of the Purchasers exceed in the aggregate 10% of the aggregate purchase price paid by such Purchaser for the Registrable Securities.

On August 31, 2012, we filed Form S-1 Registration Statement with the SEC. On September 21, 2012, we filed Amendment No. 1 to Form S-1 Registration Statement with the SEC. On September 26, 2012, the Registration Statement was declared effective by the SEC.

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 the 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.

Because the Offering constituted a "qualified financing" under the terms of our existing 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. The KFLP waived receiving comparable registration rights as the Purchasers in the Offering as well as its piggyback registration rights applicable to the Offering. Intrexon also waived its piggyback registration rights applicable to the Offering and waived its participation rights. As a result of the conversion of the secured indebtedness, the Loan Agreement together with the related Security Agreement and related agreements have been terminated.

New Trading Symbol

The Company's shares are traded on the OTCBB and are also traded on the OTCQB, an inter-dealer quotation system for publicly traded companies that are current in their SEC required filings. The Company's symbol has also changed to "OGEN".

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 also included sales of our ProBiora3 products. Sales of our ProBiora3 products were $790,166, $899,164, $1,229,510 and $1,128,895 for the nine months ended September 30, 2012 and 2011 and for the years ended December 31, 2011 and 2010, respectively. Because of our efforts to increase the distribution of our ProBiora3 products, we expect net revenues to increase in the near future. However, our success will depend on a number of factors, including our ability to continue to engage in 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 we may receive upon 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. We expect our costs of goods sold to increase as we are 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. While we are currently focused on advancing each of our product development programs, our future research and development expenses will depend on the clinical success of each product candidate, 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 and capital requirements.

We expect our research and development expenses related to the probiotics programs as well as our antibiotic product development program to increase in the future. Costs related to other areas may decrease until we partner or license them. Our research and development expenses were $7,130,780, $1,606,987, $2,449,178 and $2,014,784 for the nine months ended September 30, 2012 and 2011 and for the years ended December 31, 2011 and 2010, respectively. Our research and development expenses may also increase in the future as we seek to continue the advancement of our clinical trials for our SMaRT Replacement Therapy. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires expenditure of substantial resources. Our current product development candidates are not expected to be commercially available before 2016.

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.

We anticipate that our general and administrative expenses will increase for, among others, the following reasons:

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

Other Income (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 expense consists primarily of interest and costs associated with our convertible revolving note payable to shareholder and short term notes payable.

Income Taxes

As of December 31, 2011, we have net operating loss carryforwards of approximately $36,480,000 to offset future federal and state income taxes. We also have research and development and investment tax credit carryforwards of approximately $551,000 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 2022. 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 constituted such an event and our historical loss carryfowards 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, 2012 and 2011

Net Revenues. We generated net revenues of $264,248 for the three months ended September 30, 2012 compared to $350,351 for the three months ended September 30, 2011. Our ProBiora3 revenues decreased from Q3 2011 due primarily to a decline in advertising and promotional expenditures which was primarily attributable to lack of funding to support a high level of marketing, advertising and promotional activities.

Cost of Goods Sold. Cost of goods sold increased by $29,648 to $164,059 for the three months ended September 30, 2012 compared to $134,411 for the three months ended September 30, 2011. This increase was primarily attributable to an increase in scrap expense as certain lots of our inventory began to reach the end of their useful lives.

Research and Development. Research and development expenses were $600,208 for the three months ended September 30, 2012 compared to $562,723 for the three months ended September 30, 2011, an increase of $37,485 or 6.67%. This increase in research and development expenses was primarily due to increases in consulting costs and stock based compensation costs of $211,217 and $73,267 respectively. These increases were offset by decreases in salary and salary related costs, clinical trial costs and patent related costs of $116,967, $77,921, and $56,924 respectively.

Selling, General and Administrative. Selling, general and administrative expenses were $1,596,554 for the three months ended September 30, 2012 compared to $1,364,326 for the three months ended September 30, 2011; an increase of $232,229 or 17.02%. This increase was due to increases in stock based compensation costs and legal and professional costs of $513,988 and $57,528 respectively. These increases were offset by decreases in salary and salary related costs and advertising and marketing costs of $200,967 and $159,944, respectively.

Other Income (Expense). Other income (expense) was $(459,368) for the three months ended September 30, 2012 compared to $(96,181) for the three months ended September 30, 2011, an increase of expenses of $(363,185). The increase was primarily attributable to an increase in interest expense of $359,515 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, 2012 and 2011

Net Revenues. We generated net revenues of $901,182 for the nine months ended September 30, 2012 compared to $1,047,857 for the nine months ended September 30, 2011. Our ProBiora3 revenues decreased from Q3 2011 due primarily to a decline in advertising and promotional expenditures.

Cost of Goods Sold. Cost of goods sold decreased by $83,679 to $474,526 for the nine months ended September 30, 2012 compared to $558,205 for the nine months ended September 30, 2011. This decrease was primarily attributable to decreases in scrap expense and shipping and handling costs.

Research and Development. Research and development expenses were $7,130,780 for the nine months ended September 30, 2012 compared to $1,606,987 for the nine months ended September 30, 2011, an increase of $5,523,793 or 343.74%. This increase in research and development expenses was primarily due to the payment of the technology access fee in common stock to Intrexon pursuant to the terms of the Channel Agreement for a total expense of $5,798,001. This increase was offset by a decrease in salary and salary related costs of $220,609.

Selling, General and Administrative. Selling, general and administrative expenses were $3,740,022 for the nine months ended September 30, 2012 compared to $4,413,535 for the nine months ended September 30, 2011; a decrease of $673,513 or 15.26%. This decrease was due to reduced advertising and marketing expense of $494,035 due to the withdrawal from the mass retail channel in the first quarter of 2011, salary and compensation related costs of $533,727, which were offset by increases in legal and professional fees of $180,970 and consultant costs of $232,717. The decrease in salary and compensation costs was due to a reduction in headcount in an effort to control expenses. This reduction was partially offset by the engagement of consultants to fill critical functions.

Other Income (Expense). Other income (expense) was $(657,474) for the nine months ended September 30, 2012 compared to $(208,676) for the nine months ended September 30, 2011, an increase of expenses of $(448,795). The increase was primarily attributable to an increase in interest expense of $446,429 due to the conversion of the note payable with warrants to common stock and the write off of the remaining discount to interest expense.

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, 2012 and 2011, our operating activities used cash of $3,470,975 and $4,103,502, 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 (deficit) of $10,738,155 and $(8,328,004) at September 30, 2012 and December 31, 2011, respectively.

During the nine months ended September 30, 2012 and 2011, our investing activities provided/used cash of $0 and $0, respectively.

During the nine months ended September 30, 2012 and 2011, our financing activities provided cash of $15,057,011 and $3,791,399, respectively. The cash provided by financing activities during the nine months ended September 30, 2012 was primarily due to borrowings under a convertible revolving note payable, a new secured note payable both due to the same shareholder and the proceeds from the sale of our common stock through our Private Placement. The cash provided by financing activities during the nine months ended September 30, 2011 was primarily due to the release of restrictions on cash, borrowings under a convertible revolving note payable from a shareholder, offset by reductions in short term notes payable.

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

Prior to December 31, 2011, we had entered into a number of unsecured revolving credit agreements and amendments (the “Credit Facility”) with the Koski Family Limited Partnership (“KFLP”), and accredited investor and our largest shareholder. As of December 31, 2011 we had borrowed $7,500,000 under the Credit Facility. 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.

March 2012 Debt Exchange and Secured Debt Financing

On March 23, 2012, we entered into an Exchange of Notes for Equity Agreement (the “Debt Exchange Agreement”) with the Koski Family Limited Partnership (“KFLP”), an accredited investor and our largest shareholder. Pursuant to the terms of the Debt Exchange Agreement, we issued 6,285,619 shares of common stock and a warrant 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 our Credit Facility as amended. 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. As a result of the Debt Exchange Agreement, the Credit Facility was terminated and the previously issued promissory notes thereunder were cancelled. The warrant is exercisable immediately at a price per share of $2.00 and expires three years from the date of issuance. We have valued the common stock and warrant at $8,737,011 which equaled the carrying value of the Credit Facility

and related accrued interest. The market for our stock did not generate enough volume to provide accurate pricing for the block of stock and warrant covered by the Debt Exchange Agreement. A significant discount to the market for our stock would be needed to sell this number of shares and warrant, as such, the value of the existing indebtedness of $8,737,011 is more clearly indicative of the combined value of the transaction. As a result, no gain or loss was recognized on this exchange of debt for equity.

On March 23, 2012, we also entered into a new loan agreement (the "Loan Agreement") with the KFLP which provided us with up to $2.5 million in secured funding in two advances of $1,250,000, the first of which occurred on March 23, 2012 and the second on April 23, 2012. The Loan Agreement provided that borrowings would mature in three years and bear interest at the rate of 5.0% and were secured by select assets relating to or connected with the ProBiora3, SMaRT Replacement Therapy, MU1140 and LPT3-04 technologies. Amounts borrowed under the Loan Agreement were subject to automatic conversion upon a subsequent "qualified financing" by us 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 warrant is exercisable immediately at a price per share of $2.00 and expires three 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 has an initial value of $483,559. The value of the warrant was credited to Additional Paid-in Capital. This discount of $483,559 will be charged to interest expense over the life of the Loan Agreement.

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 its recently announced Exclusive Channel Collaboration Agreement with Intrexon Corporation ("Intrexon") relating to our lantibiotics program, sales and marketing of the 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.

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 and related agreements were terminated.

Other Financings

On March 3, 2011, we entered into a short-term notes payable for $48,988 bearing interest at 5.48% to finance product liability insurance. Payments on this note are 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% to finance a portion of the directors' and officers' liability insurance. Principal and interest payments on this note begin August 24, 2011 and are 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% to finance the product liability insurance. Principal and interest payments on this note begin April 10, 2012 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on January 10, 2013.

On August 24, 2012, we entered into a short-term note payable for $84,876 bearing interest at 4.75% to finance the director and officers and employment practices liability insurance premiums. Principal and interest payments on this note began August 24, 2012 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on May 24, 2013.

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 are to be 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.

Tax Credit

On November 1, 2010, we received notification that we were awarded federal grant funding for three of our therapeutic development programs under the Qualifying Therapeutic Discovery Project. The Qualifying Therapeutic Discovery Project, was recently enacted by Congress as part of the Patient Protection and Affordable Care Act of 2010, which was designed to provide grants or tax credits to qualified biotechnology companies that demonstrate the potential to either 1) develop new therapies to treat areas of unmet medical needs; 2) prevent, detect or treat chronic or acute diseases and conditions; 3) reduce long-term health care costs in United States; or 4) significantly advance the goal of curing cancer within the 30 year period beginning on May 21, 2010. We applied for funding on three of its programs: Prevention of Tooth Decay using Smart Replacement Therapy, Novel Antibiotics for the Treatment of Healthcare Associated Infections and Rapid and Sensitive Identification of Novel Diagnostic Biomarkers for Cancer and Infectious Diseases. We received a non-taxable cash grant award totaling $733,437 under the program. A payment of $371,219 was made to us in November 2010 and remaining grant award amount of $362,218 was received in February 2011.

Future Capital Requirements

Our capital requirements through 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 each of our technologies including continued increases in costs related to research, preclinical testing and clinical studies, as well as significant 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.

The report of our independent registered public accounting firm with respect to our financial statements for the year ended December 31, 2011 included in our Annual Report on Form 10-K contains an explanatory paragraph stating that our operating losses and negative cash flows from operations since inception, and our need to raise additional financing and/or financial support in order to continue to fund our operations, raise substantial doubt about our ability to continue as a going concern. We believe that the recent completion of our private placement offering will eliminate this doubt and enable us to continue as a going concern**.**

We believe that the net proceeds from our recent private placement offering, together with our existing cash and cash equivalents, and revenues from probiotic product sales, will allow us to fund our operating plan through at least the next 18 months. If our available cash and cash equivalents are insufficient to satisfy our liquidity requirements, or if we develop additional opportunities to do so, we may seek to sell additional equity or debt securities or obtain a credit facility. 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 may also require additional capital beyond our currently forecasted amounts, such as, if we determine to proceed independently with a Third Phase 1 or a Phase 2/3 clinical trial for our SMaRT Replacement Therapy. Any such required additional capital may not be available on reasonable terms, if at all. If we were 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 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;
- the cost of manufacturing our ProBiora3 products and product candidates and any products we successfully commercialize;
- our ability to establish strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- 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, 2011. There have been no material changes to our critical accounting estimates during the nine months ended September 30, 2012.

Recently Issued Accounting Pronouncements

There are no new accounting pronouncements issued or effective during 2012 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 former 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.

During 2010, 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 continued its efforts to remediate material weaknesses in the internal control over financial reporting. However, based on the continued existence of material weaknesses, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the quarter ended September 30, 2012, disclosure controls and procedures were not effective. 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 on September 30, 2012 Form 10-Q fairly presented, 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 are: (1) limited documentation of our system of internal control, (2) insufficient personnel to employ segregation of duties and (3) lack of formal written policies and procedures for accounting and financial reporting with respect to the requirements and application of GAAP and SEC disclosure requirements and related documentation. These deficiencies and weaknesses were largely attributable to the Company's limited available financial resources.

Management's Remediation Initiatives

Although management has not fully remediated the material weaknesses 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. At the end of 2011, the consulting firm completed an analysis of the Company's first, second and third quarter controls and reported that of 68 reporting controls tested there were no deficiencies identified. Management will continue to monitor and evaluate these and other factors affecting our internal controls as our resources and available liquidity permit. Until such time, our internal controls over financial reporting may be subject to additional material weaknesses and deficiencies that we have not yet identified. 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 has materially affected, or is 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 factors discussed in Part I, Item 1A, subsection "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 which could materially affect our business, financial condition or future results of operations. The risks described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 are not the only risks that we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition and future results of operations. The following information updates, and should be read in conjunction with, the risk factors previously disclosed in Item 1A, subsection "Risk Factors" to Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 filed on April 16, 2011.

You should carefully consider the Risk Factors 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.

Risks Related to Our Business

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 $11.1 million, $5.7 million, $7.6 million and $7.8 million for the nine months ended September 30, 2012 and 2011 and the years ended December 31, 2011 and 2010, respectively. As of September 30, 2012 our accumulated deficit was approximately $52.1 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 partnership with Intrexon Corporation and the development and commercialization of our product candidates, 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 $13 million in gross proceeds from our recent private placement of common stock, we anticipate that our cash resources as of July 31, 2012 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 lantibiotics and for ProBiora3 sales and marketing efforts, further progress with the development of our other product candidates including our SMaRT Replacement Therapy, MU1140-S and LPT3-04 product candidates may be significantly delayed and may depend on the success of our development efforts involving lantibiotics. 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 success will also depend on our ability to significantly increase sales of our ProBiora3 products which have only generated modest 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 $790,166 for the nine months ended September 30, 2012 and $1,229,510 and $1,128,895 for the years ended December 31, 2011 and 2010, respectively. While we plan to significantly 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 MU1140 and SMaRT Replacement Therapy product candidates and their successful commercialization.

Our MU1140 and SMaRT Replacement Therapy product candidates 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 MU1140 and SMaRT Replacement Therapy product candidates. We are currently in the process of commencing a second Phase 1 clinical trial to examine the safety and genetic stability of an attenuated version of the SMaRT strain in humans. We do not know whether our planned and current clinical trials for our SMaRT Replacement Therapy product candidate will be completed on schedule, if at all. For example, the current enrollment protocol is restrictive and we have had only limited enrollment to date. In order to move forward with the second Phase 1 clinical trial we would require the FDA to consider and approve a revised less restrictive enrollment protocol. 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 product candidate, 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 use Intrexon’s proprietary technologies for development of MU1140 and we also expect to conclude the preclinical testing of MU1140-S, including toxicity testing in rodent and non-rodent animal models, during the first half of 2013. If our preclinical work is successful, we intend to file an Investigational New Drug, or IND, application with the FDA in mid-

2014. 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 SMaRT Replacement Therapy or MU1140 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.

The channel partnering arrangement with Intrexon is based on an early stage technology in the field of lantibiotics.

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**.** Such technologies have a limited history of use in the design and development of active pharmaceutical ingredients and drug products involving the direct administration to humans or companion animals of a lantibiotic for the prevention or treatment of infectious disease and may therefore involve unanticipated risks or delays. The risk factors set forth herein that apply to our SMaRT Replacement Therapy, MU1140 and LPT3-04 product candidates, which are in various stages of development, also apply to product candidates that we seek to develop under our exclusive channel partnership with Intrexon.

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

Pursuant to our exclusive channel collaboration with Intrexon, we are responsible for future research and development expenses of product candidates developed under such collaboration, 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 exclusive channel collaboration with Intrexon.

Because our collaboration with Intrexon is relatively new, we have yet to assume development responsibility and costs associated with such program. In addition, because development activities are determined pursuant to a joint steering committee comprised of Intrexon and ourselves and we have not yet identified a specific product candidate from the Intrexon collaboration, 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 collaboration 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.

Under our exclusive channel collaboration agreement with Intrexon (the "ECC"), we are 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). During the first 18 months, neither we nor Intrexon may terminate the ECC, except under limited circumstances. Following the first 18 months, Intrexon may terminate such agreement if we do not perform certain specified requirements, including developing therapies indentified to us and considered superior by Intrexon. There can be no assurance that we will be able to successfully perform under the ECC and if the ECC is terminated it would prevent us from achieving our business objectives.

Our auditor has expressed substantial doubt about our ability to continue as a going concern.

In light of our recurring losses, accumulated deficit and negative cash flow, the report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2011 contains an explanatory paragraph raising substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that may be necessary in the event we are unable to continue as a going concern. If we are unable to establish to the satisfaction of our independent registered public accounting firm that the net proceeds from our financing efforts will be sufficient to allow for the removal of this going concern qualification, we may need to significantly modify our operational plans for us to continue as a going concern.

Our success will depend on our ability to partner or sub-license our SMaRT Replacement Therapy and MU1140 product candidates and their subsequent successful commercialization.

Our SMaRT Replacement Therapy and MU1140 product candidates are both in early stage development and will require partners with deep 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 are currently conducting a second Phase 1 clinical trial to examine the safety and genetic stability of an attenuated version of the SMaRT strain in humans. Currently our clinical trials for our SMaRT Replacement Therapy product candidate are ongoing. 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 product candidate, we have performed extensive preclinical testing using native MU1140 and expect to pursue the preclinical testing of MU1140-S, including *in vitro* and animal models, during 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 SMaRT Replacement Therapy and MU1140 product candidates. If our SMaRT Replacement Therapy or MU1140 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 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 SMaRT Replacement Therapy and MU1140, our licenses to these product candidates may be terminated and we will be unable to commercialize these products candidates.

We hold our SMaRT Replacement Therapy and MU1140 product candidates under licenses from the University of Florida Research Foundation, Inc., or UFRF. Under the terms of the licenses, we must spend at least $1,000,000 per year on development of those product candidates until the first commercial sale of products derived from those product candidates has occurred. In addition, we must pay $25,000 per quarter as minimum royalties to the UFRF under our license agreements. The UFRF may terminate our licenses to SMaRT Replacement Therapy and MU1140 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.

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 have contracted with multiple GMP-certified manufacturers to produce our active ingredient, ProBiora3, under GMPs. 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 profitability 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 and MU1140 product candidates under GMPs, as required by the FDA and other regulatory agencies. In order to continue to develop our product candidates, apply for regulatory approvals for our SMaRT Replacement Therapy and MU1140 product candidates, and commercialize our ProBiora3 and LPT3-04 products and other product candidates, 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 and SMaRT Replacement Therapy product candidate. Furthermore, manufacturing MU1140 on a commercial scale has not yet been achieved, 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 ProBiora3 products or our development stage product candidates, such as LPT3-04, 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 ProBiora3 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 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. We also recently 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. 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 is a highly exacting and complex process. Manufacturing MU1140 on a commercial scale has not yet been achieved so there are additional risks. We entered into an exclusive collaboration agreement with Intrexon Corporation to use Intrexon's technology to determine if it could result in large sale manufacturing capability for MU1140. The Intrexon technology may not be feasible to sufficient to develop large scale manufacturing of MU1140. Third-party manufacturers must have additional technical skills and must take multiple steps to attempt to control the manufacturing processes.

Our ProBiora3 products and our LPT3-04 Weight Loss, SMaRT Replacement Therapy and MU1140 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 LPT3-04 Weight Loss, SMaRT Replacement Therapy and MU1140 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 the LPT3-04 Weight Loss Agent, SMaRT Replacement Therapy and MU1140 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, if approved for the treatment of tooth decay, 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 in the last nine months.

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 our SMaRT Replacement Therapy and MU1140 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 SMaRT Replacement Therapy or MU1140 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 our SMaRT Replacement Therapy product candidate has been undertaken solely in animals and a limited number of humans. Studies have proven our genetically altered strain of *S. mutans* to be effective in preventing tooth decay in animals. It is possible that our strain of *S. mutans* will be shown to be less effective in preventing tooth decay in humans in clinical trials. If our SMaRT Replacement Therapy product candidate is shown to be ineffective in preventing tooth decay in humans, we will be unable to commercialize and generate revenues from this product candidate. 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 of MU1140. It is possible that when these studies are conducted, they will show that MU1140 is ineffective or harmful in humans. If MU1140 is 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 our SMaRT Replacement Therapy and MU1140 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 MU1140 and SMaRT Replacement Therapy 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 continue our operations.

As we continue our MU1140 and SMaRT Replacement Therapy product candidates, we intend to either license these product candidates to, or partner with, one or more major pharmaceutical companies 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. 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;
- the burden of complying with foreign laws ; and
- potential for fines and penalties 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 portfolio is protected by ten issued U.S. patents and nine filed U.S. 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.

We plan to discuss with the FDA whether the clinical hold for the non-attenuated SMaRT strain can be lifted after the completion of our second Phase 1 clinical trial using the attenuated strain, because we believe the results from the trial may address the FDA's concerns with the non-attenuated SMaRT strain. However, there is no guarantee that our 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. If the FDA does not lift the clinical hold on the non-attenuated SMaRT strain, we or a partner cannot commence our anticipated third Phase 1 trial and we may not be able to conduct the clinical trials necessary to obtain 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 SMaRT Replacement Therapy and MU1140 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 SMaRT Replacement Therapy and MU1140 product candidates and our ongoing research and development, preclinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities. Most of the 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.

The FDA accepted our protocols to conduct Phase 1 human clinical trials of our SMaRT Replacement Therapy product candidate. If we fail to maintain regulatory approval for the clinical trials of our SMaRT Replacement Therapy, if the FDA fails to lift the clinical hold on our IND for the non-attenuated version of the SMaRT strain, or if we fail to obtain regulatory approval for our MU1140 product candidate, we may have to cease further development. Clinical trials on our SMaRT Replacement Therapy and MU1140 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 our SMaRT Replacement Therapy or MU1140 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 product candidates. If they do not, we will be unable to generate significant revenues from our product candidates and our business, financial condition and results of operations will be materially adversely affected.

The commercial success of our ProBiora3, LPT3-04, MU1140, SMaRT Replacement Therapy and lantibiotics, and other product candidates 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 November 1, 2012 the KFLP, together with members of the Koski family, beneficially own approximately 46% (which reflects the July 31, 2012 conversion of the outstanding indebtedness of the Company to the KFLP into shares of common stock) 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, share voting and investment powers with two other Koski family members as general partners of the KFLP and serve on our Board of Directors. 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 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.

Our common stock is not listed on a national U.S. securities exchange and the application of the "penny stock" rules could adversely affect the market price of our common stock as well as increase your transaction costs to sell those shares.

Our common stock trades on the OTC Bulletin Board which generally has significantly less liquidity than securities traded on a national securities exchange, not only in the number of shares that can be bought and sold, but also through delays in the timing of transactions, reduction in securities analyst and news media coverage, and lower market prices than might otherwise be obtained. As a result, purchasers of shares of our common stock may find it difficult to resell their shares at prices quoted in the market or at all. In addition, if at any time the trading price of our stock is below $5.00 per share it is subject to the SEC's "penny stock" rules. Because the "penny stock" rules impose certain requirements on brokers, they may be less willing to execute transactions in our securities. Furthermore, because of the limited market and generally low volume of trading in our common stock, our common stock is more likely to be affected by broad market fluctuations, general market conditions, fluctuations in our operating results, changes in the market's perception of our business, and announcements made by us, our competitors or parties with whom we have business relationships. Our ability to issue additional securities for financing or other purposes, or to otherwise arrange for any financing we may need in the future, may also be materially and adversely affected by the fact that our securities are not traded on a national securities exchange.

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, 2012 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. 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.

Trading on the OTC Bulletin Board may be volatile and sporadic, which could depress the market price of our common stock and make it difficult for our stockholders to resell their shares.

Our common stock is quoted on the OTC Bulletin Board service of the Financial Industry Regulatory Authority (FINRA) and the OTCQB Market. Trading in stock quoted on these systems is often thin and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with our operations or business prospects. This volatility could depress the market price of our common stock for reasons unrelated to operating performance. Moreover, the OTC Bulletin Board is not a stock exchange, and trading of securities on the OTC Bulletin Board and OTCQB Market is often more sporadic than the trading of securities listed on a quotation system like NASDAQ or a stock exchange like AMEX. Accordingly, shareholders may have difficulty reselling any of their shares.

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. 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 27,382,830 as of November 1, 2012. You may incur additional dilution if 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.

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 November 1, 2012. 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 November 1, 2012, there were 27,382,830 shares of our common stock outstanding, with another 3,235,9823 shares of common stock issuable upon exercise of warrants to investors, 660,425 shares issuable upon exercise of options outstanding and an additional 2,760,548 shares available for option grants under our Amended and Restated 2012 Equity Incentive Plan (“Stock 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. 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.

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

The following table sets forth information with respect to purchases of our common stock during the three months ended September 30, 2012:

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs(2)	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs(2)
July1 – July 31, 2012			—	—
August 1–August 31, 2012	**46,287**	**$ 2.75**	—	—
September 1 – September 30, 2012			—	—
Total	**46,287**	**$ 2.75**	—	—

(1) Represents purchases of shares in connection with satisfying tax withholding obligations on the vesting of restricted stock awards to employees.

(2) The Company has no publicly announced share repurchase programs.

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 Exhibits filed after signature page.

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 13th day of November, 2012.

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

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No	Exhibit	Filing Date	
10.1	Stock Purchase Agreement by and between Oragenics, Inc. and the Purchasers dated July 30, 2012.	8-K	001-32188	10.1	8/2/12	
10.2	Registration Rights Agreement by and between Oragenics, Inc. and the Purchasers dated July 30, 2012.	8-K	001-32188	10.2	8/2/12	
10.3	Form of placement agent Warrant.	8-K	001-32188	10.3	8/2/12	
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					
101.SCH*	XBRL Taxonomy Extension Schema					
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase					
101.DEF*	XBRL Taxonomy Extension Definition Linkbase					
101.LAB*	XBRL Taxonomy Extension Label Linkbase					
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase					

* Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933 or Section 18 of the Securities Exchange Act of 1934 and otherwise are not subject to liability.

Exhibit 31.1

CERTIFICATION

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 officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. 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 (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2012

/s/ John N. Bonfiglio Ph.D.

John N. Bonfiglio Ph.D., President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

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 officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. 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 (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 2012

/s/ Michael Sullivan

Michael Sullivan, Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Oragenics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John N. Bonfiglio Ph.D., President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

A signed original of this written certification has been provided to the company and will be retained by the company and furnished to the Securities and Exchange Commission or its staff upon request.

Dated this 13th day of November, 2012.

/s/ John N. Bonfiglio Ph.D.
John N. Bonfiglio Ph.D.
President and Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. Section 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Oragenics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Sullivan, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

A signed original of this written certification has been provided to the company and will be retained by the company and furnished to the Securities and Exchange Commission or its staff upon request.

Dated this 13th day of November, 2012.

/s/ Michael Sullivan
Michael Sullivan
Chief Financial Officer