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

FORM 10-Q

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

For the quarterly period ended September 30, 2014.

OR

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

For the transition period from _____ to _____

Commission File Number: 001-32188

ORAGENICS, INC.

(Exact name of registrant as specified in its charter)

FLORIDA
(State or other jurisdiction of
incorporation or organization)

59-3410522
(IRS Employer
Identification No.)

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

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

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

As of November 3, 2014, there were 36,178,944 shares of Common Stock, \$.001 par value, outstanding.

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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Oragenics, Inc.

Balance Sheets

	September 30, 2014	December 31, 2013
	<u>(Unaudited)</u>	<u></u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 11,764,923	\$ 16,276,510
Accounts receivable, net	26,309	64,434
Inventory, net	263,860	288,383
Prepaid expenses and other current assets	221,637	175,242
Total current assets	<u>12,276,729</u>	<u>16,804,569</u>
Property and equipment, net	26,296	26,913
Total assets	<u>\$ 12,303,025</u>	<u>\$ 16,831,482</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 604,351	\$ 909,957
Short-term notes payable	109,564	64,051
Deferred revenue	25,592	18,839
Total current liabilities	<u>739,507</u>	<u>992,847</u>
Shareholders' equity:		
Preferred stock, no par value; 20,000,000 shares authorized; none issued and outstanding	—	—
Common stock, \$0.001 par value; 100,000,000 and 50,000,000 shares authorized as of September 30, 2014 and December 31, 2013, respectively; 36,178,944 and 35,993,944 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	36,179	35,994
Additional paid-in capital	86,248,402	85,957,757
Accumulated deficit	(74,721,063)	(70,155,116)
Total shareholders' equity	<u>11,563,518</u>	<u>15,838,635</u>
Total liabilities and shareholders' equity	<u>\$ 12,303,025</u>	<u>\$ 16,831,482</u>

See accompanying notes.

Oragenics, Inc.
Statements of Operations
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue, net	\$ 201,010	\$ 253,374	\$ 719,422	\$ 597,449
Cost of sales	73,711	113,384	279,076	263,990
Gross profit	127,299	139,990	440,346	333,459
Operating expenses:				
Research and development	597,034	6,907,250	2,516,826	8,289,614
Selling, general and administrative	565,114	2,558,205	2,509,843	5,180,702
Total operating expenses	1,162,148	9,465,455	5,026,669	13,470,316
Loss from operations	(1,034,849)	(9,325,465)	(4,586,323)	(13,136,857)
Other income (expense):				
Interest income	8,656	3,611	29,175	15,098
Interest expense	(1,305)	(1,546)	(2,856)	(3,339)
Local business tax	(2,046)	(2,024)	(5,740)	(8,824)
Other income (expense)	—	—	(203)	144,503
Total other income (expense), net	5,305	41	20,376	147,438
Loss before income taxes	(1,029,544)	(9,325,424)	(4,565,947)	(12,989,419)
Income tax benefit	—	—	—	—
Net loss	\$ (1,029,544)	\$ (9,325,424)	\$ (4,565,947)	\$ (12,989,419)
Basic and diluted net loss per share	\$ (0.03)	\$ (0.34)	\$ (0.13)	\$ (0.47)
Shares used to compute basic and diluted net loss per share	36,178,944	27,515,372	36,145,043	27,496,676

See accompanying notes.

Oragenics, Inc.
Statements of Cash Flows
(Unaudited)

	For the Nine Months Ended	
	September 30,	
	2014	2013
Cash flows from operating activities:		
Net loss	\$(4,565,947)	\$(12,989,419)
Adjustments to reconcile net loss to net cash used in operating activities:		
Technology access fee paid in common stock and convertible note payable to shareholder	—	6,000,000
Depreciation and amortization	20,119	64,042
Loss on sale of property and equipment	203	—
Stock issued as compensation to non-employee directors	102,500	—
Stock-based compensation expense	188,330	1,624,165
Write off of expired inventory	—	(240,005)
Changes in operating assets and liabilities:		
Accounts receivable, net	38,125	10,917
Inventory, net	24,523	140,865
Prepaid expenses and other current assets	112,604	151,861
Accounts payable and accrued expenses	(305,606)	(280,353)
Deferred revenue	6,753	(27,278)
Net cash used in operating activities	<u>(4,378,396)</u>	<u>(5,545,205)</u>
Cash flows from investing activities:		
Proceeds from sale of property and equipment	424	—
Purchase of property and equipment	(20,129)	(17,649)
Net cash used in investing activities	<u>(19,705)</u>	<u>(17,649)</u>
Cash flows from financing activities:		
Payments on short-term notes payable	(113,486)	(96,788)
Net proceeds from issuance of common stock	—	3,939,800
Restricted cash released	—	61,763
Net cash (used in) provided by financing activities	<u>(113,486)</u>	<u>3,904,775</u>
Net decrease in cash and cash equivalents	(4,511,587)	(1,658,079)
Cash and cash equivalents at beginning of period	16,276,510	9,925,967
Cash and cash equivalents at end of period	<u>\$11,764,923</u>	<u>\$ 8,267,888</u>
<i>Supplemental disclosure of cash flow information:</i>		
Interest paid	<u>\$ 2,997</u>	<u>\$ 3,108</u>
<i>Non-cash investing and financing activities:</i>		
Borrowings under short-term notes payable for prepaid expense	<u>\$ 158,999</u>	<u>\$ 157,031</u>
Par value of common stock issued for cashless exercise of warrants	<u>\$ 135</u>	<u>\$ 106</u>

See accompanying notes.

Oragenics, Inc.
Notes to Financial Statements
(Unaudited)

1. Organization

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

2. Basis of Presentation

The accompanying unaudited interim financial statements as of September 30, 2014 and December 31, 2013 (audited) and for the three and nine months ended September 30, 2014 and 2013 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, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014 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, 2013, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2014. The Company has incurred recurring losses and negative cash flows from operations since inception. To date the Company has not generated significant revenues from operations. The Company generated revenues of \$719,422, incurred a net loss of \$4,565,947, and used cash of \$4,378,396 in its operating activities during the nine months ended September 30, 2014. As of September 30, 2014, the Company had an accumulated deficit of \$74,721,063.

During 2012 and 2011, a significant source of debt and equity funding was provided to the Company by its largest shareholder, the Koski Family Limited Partnership (the “KFLP”). In addition, in 2013 and 2012 the Company raised \$14,900,000 and \$13,000,000 in gross proceeds through the private placement sale of its common stock. The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes the working capital at September 30, 2014 will be sufficient to meet the business objectives as presently structured over the next twelve months.

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

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

3. Significant Accounting Policies

Recently Issued Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40) Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." ASU 2014-15 provides guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and about related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company's ability to continue as a going concern within one year from the date the financial statements are issued. Management will also be required to evaluate and disclose whether its plans alleviate that doubt. ASU 2014 - 15 is effective for the annual period ending after December 15, 2016, and for interim periods within annual periods ending after December 15, 2016. Earlier application is permitted. The Company is currently evaluating the requirements of ASU 2014-15 and has not yet determined its impact on the Company's financial statements.

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, "Revenue from Contracts with Customers (Topic 606)." ASU 2014-09 completes the joint effort by the FASB and International Accounting Standards Board (IASB) to improve financial reporting by creating common revenue recognition guidance for U.S. GAAP and International Financial Reporting Standards (IFRS). ASU 2014-09 applies to all companies that enter into contracts with customers to transfer goods or services. ASU 2014-09 is effective for public entities for interim and annual reporting periods beginning after December 15, 2016. Early application is not permitted and entities have the choice to apply ASU 2014-09 either retrospectively to each reporting period presented or by recognizing the cumulative effect of applying ASU 2014-09 at the date of initial application and not adjusting comparative information. The Company is currently evaluating the requirements of ASU 2014-09 and has not yet determined its impact on the Company's financial statements.

In July 2013, the FASB issued new accounting guidance on the presentation of unrecognized tax benefits, Accounting Standards Update No. 2013-11, "Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists," for fiscal years, and interim periods within those years, beginning after December 15, 2013. The new guidance requires an entity to present an unrecognized tax benefit, or a portion of an unrecognized tax benefit, as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward, except as follows: to the extent a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the applicable jurisdiction to settle any additional income taxes that would result from the disallowance of a tax position or the tax law of the applicable jurisdiction does not require the entity to use, and the entity does not intend to use the deferred tax asset for such purpose, then the unrecognized tax benefit should be presented in the financial statements as a liability and should not be combined with deferred tax assets. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2013, with early adoption permitted. Accordingly, we adopted these presentation requirements during the first quarter of 2014. The adoption of this new guidance did not have a material impact on our financial statements or related disclosures.

There are no other new accounting pronouncements issued or effective during the third quarter of 2014 that have had or are expected to have an impact on the Company's financial statements.

Use of Estimates

The preparation of financial statements in conformity with U.S. 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 anticipated milestone payments, stock based compensation, valuation of warrants, income tax valuation allowance, inventory obsolescence reserve, sales returns and allowances and the allowance for doubtful accounts.

Guaranteed Rights of Return

The Company has granted guaranteed rights of return to two dental distributors. The Company defers recognition of revenue on these accounts until either the distributor provides notification to the Company that the product has been sold to the end consumer or the guaranteed right of return period expires. Once notification has been received and verified, the Company records revenue in that accounting period. The Company had \$25,592 and \$18,839 of revenue deferred under guaranteed rights of return arrangements included in deferred revenue in the balance sheets as of September 30, 2014 and December 31, 2013, respectively.

Inventory

Inventory is stated at the lower of cost or market. Cost, which includes material, labor and overhead, is determined on a first-in, first-out basis. On a quarterly basis, we analyze our inventory levels and reserve for inventory that is expected to expire prior to being sold, inventory that has a cost basis in excess of its expected net realizable value, inventory in excess of expected sales requirements, or inventory that fails to meet commercial sale specifications. Expired inventory is disposed of and the related costs are written off to the reserve for inventory obsolescence. The inventory reserve was approximately \$41,200 and \$31,500 as of September 30, 2014 and December 31, 2013, respectively.

Stock-Based Payment Arrangements

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

Stock-Based Compensation

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

For awards with market-based performance conditions, we recognize the grant-date fair value of the award over the derived service period regardless of whether the underlying performance condition is met.

Warrants

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

Net Loss Per Share

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

Revenue Recognition

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

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

Concentrations

The Company is dependent on key suppliers to provide probiotics, blending, warehousing and packaging of its EvoraPlus, EvoraKids, EvoraPro, and Teddy's Pride products. The Company had four key suppliers during the three and nine months ended September 30, 2014 and 2013. The majority of the Company's cost of sales are from these key suppliers during the three and nine months ended September 30, 2014 and 2013. Accounts payable and accrued expenses for these vendors totaled approximately \$90,504 and \$146,284 as of September 30, 2014 and December 31, 2013, respectively.

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains cash accounts in commercial banks, which may, at times, exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash and cash equivalents. As of September 30, 2014, the uninsured portion of this balance was \$11,514,923. As of December 31, 2013, the uninsured portion of this balance was \$16,026,510.

4. Stock-based Compensation

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

	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Research and development	\$ 18,217	\$ 183,168	\$ 155,984	\$ 158,575
Selling, general and administrative	15,892	1,355,175	134,846	1,465,590
Total Stock based compensation	\$ 34,109	\$ 1,538,343	\$ 290,830	\$ 1,624,165

The Company granted -0- and 100,000 stock options, with a weighted-average grant date fair value of -0- and \$2.81 per share, during the three and nine months ended September 30, 2014, respectively. The Company granted -0- and 35,000 stock options, with a weighted-average grant date fair value of \$0.00 and \$3.41 per share, during the three and nine months ended September 30, 2013, respectively.

During the nine months ended September 30, 2014, 67,391 stock options previously granted have vested and 37,142 stock options were forfeited.

As part of the Company's non-employee Director compensation program and in connection with the Company's annual meeting, on May 30, 2014 each continuing non-employee Director, Frederick Telling, Charles Pope, Alan Dunton, Christine Koski and Robert Koski was granted an award of 10,000 fully vested shares of the Company's common stock under the Company's 2012 Equity Incentive Plan. The grant date fair value of the 50,000 shares issued under the non-employee Director compensation program was determined to be \$102,500.

5. Warrants

A summary of warrant activity for the year ended December 31, 2013 and the nine months ended September 30, 2014 is as follows:

	Warrants	Weighted Average Price
Balance – December 31, 2012	3,235,982	\$ 3.53
Granted	—	—
Exercised	(200,000)	1.50
Expired	(288,888)	19.87
Balance – December 31, 2013	2,747,094	1.91
Granted	—	—
Exercised	(210,000)	1.50
Expired	(5,000)	10.00
Balance – September 30, 2014	2,532,094	\$ 1.93

On January 13, 2014, we issued 135,000 shares of our common stock pursuant to a partial cashless exercise of 210,000 warrant shares relating to the warrants we issued to Griffin Securities, Inc. and its designees in connection with its service as placement agent in our July 2012 Private Financing. On April 15, 2014, warrants to acquire 5,000 shares of the Company's common stock at a price of \$10.00 per share expired.

The warrants outstanding as of September 30, 2014 are as follows:

Exercise Price	Warrants Outstanding	Expiration Dates
\$1.50	361,169	7/31/17
\$2.00	2,170,925	3/23/15
	<u>2,532,094</u>	

6. Short-Term Notes Payable

As of September 30, 2014 and December 31, 2013, the Company had \$109,564 and \$64,051 respectively, in short-term notes payable for the financing of various insurance policies. On March 8, 2013, the Company entered into a short-term note payable for \$50,037 bearing interest at 6.57% to finance the product liability insurance. Principal and interest payments on this note began April 10, 2013 and are made evenly based on a straight line amortization over a 10-month period with the final payment being made on January 10, 2014. On June 20, 2013, we entered into a short-term note payable for \$106,994 bearing interest at 4.64% to finance a portion of the directors' and officers' liability insurance and employment practices liability insurance premiums. Principal and interest payments on this note began August 24, 2013 and are made evenly based on a straight line amortization over an 11-month period with the final payment due on June 24, 2014. On March 10, 2014, the Company entered into a short-term note payable for \$50,694 bearing interest at 6.57% to finance the product liability insurance. Principal and interest payments on this note began April 10, 2014 and are made evenly based on a straight line amortization over a 10-month period with the final payment being made on January 10, 2015. On July 24, 2014, the Company entered into a short-term note payable for \$108,306 bearing interest at 4.647% to finance a portion of the directors' and officers' liability insurance and employment practices liability insurance premiums. Principal and interest payments on this note began August 24, 2014 and are made evenly based on a straight line amortization over an 11-month period with the final payment being made on June 24, 2015.

7. Commitments and Contingencies

The University of Florida Research Foundation Licenses

UFRF-MU1140 and Replacement Therapy Licenses. In the Company's UFRF amended license agreements for SMaRT Replacement Therapy and MU1140, the Company is obligated to pay 5% of the selling price of any products developed from the UFRF 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 to the UFRF 22% of all revenues received from the sublicenses, excluding monies received solely for development costs. The Company is also obligated to make the following payments to UFRF as follows: a one-time commercialization fee, post-commercialization minimum royalty payments, and a one-time cumulative royalty payment. The one-time commercialization fee would be due on the first anniversary of first commercial sale and is calculated at \$5,000 per month between (1) May 1, 2013 (for the SMaRT Replacement Therapy license agreement) and April 1, 2013 (for the MU1140 license agreement) and (2) the month of the first anniversary of a commercial sale. No commercial sales have occurred and as such no commercialization fees have been paid. The post-commercialization minimum royalty payments of \$50,000 annually would be due following payment of a commercialization fee. The one-time additional royalty payment would be due when total cumulative royalties paid to UFRF exceed \$2.0 million, upon which we would be obligated to make a one-time additional payment to UFRF of 10% of the total royalties due to UFRF in the calendar year in which cumulative royalties exceeded \$2.0 million.

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

The terms of the UFRF amended license agreements expire upon the earlier of (i) the date that no patents covered by the amended license agreements remain enforceable or (ii) the payment of earned royalties under the amended license agreements, once begun, ceases for more than three calendar quarters. The Company may voluntarily terminate the license agreement upon 90 days written notice to UFRF. UFRF may terminate the amended license agreements if the Company breaches its obligations to timely pay any amounts due under the amended license agreements, to submit development reports as required under the amended license agreements or commit any other breach of any other covenants contained in the amended license agreements and the Company fails to remedy such breach within 90 days after written notice of such breach by UFRF.

After the effective date of termination of the SMaRT Replacement Therapy amended license agreement, the Company may sell all licensed products and complete licensed products in the process of manufacture at the time of such termination and sell the same, provided the Company makes the royalty payments described above and submit the reports required under the SMaRT Replacement Therapy amended license agreement.

Texas A&M License Agreement

Under the terms of the Texas A&M license agreement, the Company made an initial payment of five thousand dollars (\$5,000) to Texas A&M. The Company must also pay to Texas A&M a royalty of five percent (5%) of net sales of products that include the licensed technology, subject to royalty stacking provisions with a two percent (2%) minimum royalty. Additionally, in order to maintain the exclusive license, commencing in 2014 and each year thereafter prior to the calendar year of the first sale of products using the licensed technology, the Company must pay Texas A&M \$15,000 as minimum consideration for the continuation of the license agreement. Once the Company commences the sale of products that include the technology the Company licenses from Texas A&M the Company must pay a minimum annual amount of \$100,000 to Texas A&M and every year thereafter through the expiration of the Agreement. However, once sales begin, any royalty payments the Company makes on net sales will be credited against the \$100,000 required maintenance payment.

The Company must also pay all patent costs and expenses for the preparation, filing, prosecution, issuance and maintenance of the patent rights. Sales by sublicensees are subject to the royalty rate above, and the Company is responsible for certain payments to Texas A&M for any other consideration received that is not in the form of a royalty.

Pursuant to the Texas A&M license agreement, the Company shall use commercially reasonable efforts to achieve the following milestones to the satisfaction of Texas A&M and make milestone payments: (i) enrollment of first patient in a Phase I clinical trial using the licensed technology, to occur on or before June 1, 2015, with a milestone achievement payment of \$50,000, (ii) completion of Phase II clinical trial using the licensed technology to occur on or before June 1, 2019, with a milestone achievement payment of \$100,000, (iii) completion of Phase III clinical trial of the licensed technology to occur on or before June 1, 2022, with a milestone achievement payment of \$150,000, and (iv) first sale of the licensed technology to occur on or before June 1, 2025 with a milestone achievement payment of \$400,000. If we fail to accomplish the milestones or fail to achieve net sales of products including the licensed technology for two consecutive calendar years Texas A&M at its sole option may waive the requirement, renegotiate the missed milestones or terminate the license agreement. None of the Texas A&M milestones had been achieved as of September 30, 2014.

The term of the Texas A&M license agreement expires upon (i) the expiration of the applicable patent rights covered by the license agreement, (ii) the failure of any patent filed pursuant to the license agreement to issue, or (iii) the final and unappealable determination by a court that the patent rights are invalid. The Company may voluntarily terminate the license agreement upon 90 days written notice to Texas A&M. Texas A&M can terminate the license agreement if the Company materially breaches the license agreement and does not cure such breach within 60 days of receiving notice of such breach from Texas A&M.

The Lantibiotic Exclusive Channel Collaboration ("ECC")

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

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

In addition, in partial consideration for each party's execution and delivery of the Lantibiotic ECC, the Company entered into a Stock Issuance Agreement with Intrexon. Pursuant to the Stock Issuance Agreement, the Company issued to Intrexon 4,392,425 shares of the Company's common stock as an initial technology access fee, in consideration for the execution and delivery of the Lantibiotic ECC and granted Intrexon certain equity participation rights and registration rights. Under the Stock Issuance Agreement and as part of the Lantibiotic ECC, the Company has also agreed to make certain payments to Intrexon upon the Company's achievement of designated milestones in the form of shares of Company common stock or, at the Company's option, make a cash payment to Intrexon (based upon the fair market value of the shares otherwise required to be issued). The milestone events and amounts payable are as follows:

- (i) upon filing of the first Investigational New Drug application with the U.S. Food and Drug Administration for an Oragenics Product, that number of shares equal to the number of shares of common stock comprising 1.0% of the Base Shares (as defined below);
- (ii) upon the dosing of the first patient in the first Phase 2 clinical study with an Oragenics Product, that number of shares equal to the number of shares of common stock comprising 1.5% of the Base Shares;
- (iii) upon the dosing of the first patient in the first Phase 3 clinical study with an Oragenics Product, that number of shares equal to the number of shares of common stock comprising 2% of the Base Shares;
- (iv) upon the filing of the first New Drug Application ("NDA") or Biologics License Application ("BLA") with the U.S. Food and Drug Administration for an Oragenics Product, or alternatively the filing of the first equivalent regulatory filing with a foreign regulatory agency, that number of shares equal to the number of shares of Common Stock comprising 2.5% of the Base Shares; and
- (v) upon the granting of the first regulatory approval of an Oragenics Product, that number of shares equal to the number of shares of Common Stock comprising 3% of the Base Shares.

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

None of the Lantibiotic ECC milestones had been achieved as of September 30, 2014.

Intrexon may terminate the Lantibiotic ECC 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 Lantibiotic ECC. We may voluntarily terminate the Lantibiotic ECC at any time upon 90 days written notice to Intrexon.

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

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

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

The Probiotic ECC

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

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

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

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

None of the Probiotic ECC milestones had been achieved as of September 30, 2014.

The Company may voluntarily terminate the Probiotic ECC upon 90 days written notice to Intrexon. Intrexon may also terminate the Probiotic ECC if the Company breaches the Probiotic ECC and fails to cure the breach within 60 days or the Company does not pursue development of the Superior Therapy under the probiotics identified by Intrexon that is a "Superior Therapy" as defined in the Probiotic ECC. Upon termination of the Probiotic ECC, the Company may continue to develop and commercialize any Company Product that, at the time of termination, satisfies at least one of the following criteria:

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

The Company's obligation to pay 10% of net sales and the milestone payments described above with respect to these "retained" products as well as to use diligent efforts to develop and commercialize these "retained" Company Products will survive termination of the Probiotic ECC.

8. Related Party Transactions

During the three and nine months ended September 30, 2014 and 2013, we paid \$8,093 and \$909,411; and \$474,837 and \$1,245,535, respectively, to Intrexon Corporation (Intrexon) under the Exclusive Channel Collaboration Agreements (ECC Agreements) (See Note 7). Included in accounts payable and accrued expenses at September 30, 2014 and 2013 was \$2,535 and \$81,073, respectively, related to unpaid invoices received from Intrexon relating to work performed under the ECC Agreements. As of September 30, 2014 and 2013 Intrexon owned approximately 24% and 23%, respectively, of our outstanding common stock.

9. Common Stock

On May 30, 2014 the Company held its Annual meeting of Shareholders, at which, the Company's shareholders authorized the amendment to our Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock from 50,000,000 shares to 100,000,000 shares, upon a determination by our Board of Directors that such an increase is in the best interests of our Company and our shareholders.

As part of the Company's non-employee Director compensation program and in connection with the Company's annual meeting, on May 30, 2014 each continuing non-employee Director, Frederick Telling, Charles Pope, Alan Dunton, Christine Koski and Robert Koski was granted an award of 10,000 fully vested shares of the Company's common stock under the Company's 2012 Equity Incentive Plan.

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

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

Forward-Looking Statements

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

Overview

We are focused on becoming the world leader in novel antibiotics against infectious disease and probiotics for oral health in humans and pets. We also develop, market, and sell proprietary OTC probiotics specifically designed to enhance oral health for humans and pets, under the brand names Evora and ProBiora in more than 13 countries worldwide.

Our Antibiotics

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

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

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

In order to meet the challenge associated with producing sufficient quantities of MU1140 for our clinical trials and ultimately our commercialization efforts, in June 2012, we entered into the Lantibiotic ECC with Intrexon for the development and commercialization of the native strain of MU1140 and related homologs using Intrexon's advanced transgene and cell engineering platforms. We continue to pursue our research and development and collaboration efforts with Intrexon in accordance with the terms of the Lantibiotic ECC toward the development of the MU1140 molecule and potential derivatives of the molecule. We commenced limited preclinical activities on MU1140 developed under the Lantibiotic ECC with Intrexon, in the second half of 2013. Through our work with Intrexon, we have been able to produce an exponential increase in the fermentation titer of the target compound MU1140.

and the discovery of a new purification process for MU1140. Since then, our exclusive collaboration generated a substantial number of homologs of MU1140, and we are focused on screening these homologs to find several candidates with either enhanced therapeutic profiles or different specificities against resistant bacteria from that of the parent compound, MU1140. The decision to examine these new homologs of MU1140 meant we had to reproduce the fermentation and purification steps on at least 10-15 homologs. Each homolog requires different optimizations for both the fermentation and purification steps and in many cases required a new approach. As such our work on the development of new lantibiotic homologs using genetically modified bacteria continues.

We are working with a third party manufacturer to produce additional quantities of designated homologs, based upon the developments achieved from our work with Intrexon and outside contractors. The additional quantities of designated homologs that are needed for the consummation and pursuit of our preclinical testing activities including the pre-IND meeting, technology transfer to a GLP manufacturing facility and the drug product necessary for completing all pre-IND studies are underway. We had previously expected we would engage in pre Investigational New Drug (“IND”) meetings with the FDA in the second half of 2014 and thereafter be in a position to file an IND application with the FDA by the second half of 2015. The current expectation is to have the pre-IND meeting in the second half of 2015 and thereafter be in a position to file the IND for a first-in-man clinical study in 2016. We will work aggressively in the course of our research and development to accelerate these events.

Our Probiotic Products

We are marketing a variety of probiotic products that we developed. Our probiotic products contain the active ingredient ProBiora3, a patented blend of oral care probiotics that promote fresher breath, whiter teeth and support overall oral health. We have conducted scientific studies on ProBiora3 in order to market our products under self-affirmed Generally Recognized As Safe status (“GRAS”). We have historically sold our ProBiora3 products through multiple distribution channels. We continue to seek improvement in the performance of our oral care probiotics products, to better serve our customers, and we continue to evaluate new delivery systems, which we believe will enable us to deliver ProBiora3 to new markets and end-users.

In order to better understand and define our customer base, we conducted detailed market research utilizing outside consultants at the end of 2012. The goal of the research was to develop a plan to improve market awareness and sales of our oral probiotic product line. The effort produced strategic marketing and sales plans that we commenced at the end of the quarter ended June 30, 2013. The plan focused our efforts on our direct-to-consumer channel, including internet, as well as on our Dental channel, which entailed sales and marketing to dentists. Despite increased spending, the results for the year ended December 31, 2013 did not meet expectations. Given the initial results, we scaled back on our expenses for outside sales consultants and marketing. During the nine months ended September 30, 2014 our probiotic sales continue to lag expectations due primarily to the scaled back marketing. While it has been a challenge for us to achieve the most cost-effective marketing strategy to achieve future growth, we continue to review and assess our probiotic business toward the goal of achieving improvement in this line of business.

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

In December of 2013, we completed a pilot clinical study at Salus Research Center utilizing a standardized oral care clinical study design. The study was designed to probe potential indications for multiple different ProBiora3 dose forms and administration formats using a variety of standard clinical and analytical endpoints. Although positive trends were noted among some of the groups, we have concluded that there were no groups that demonstrated a clear statistically significant improvement against the existing once-a-day tablet format in this placebo controlled trial. We have supplied product in support of a two-year study in children in Scandinavia. No results from the two-year study are currently available.

During the quarter ended June 30, 2014, we received notice from our supplier of two of the three main ingredients of our ProBiora products that the supplier would discontinue manufacturing such products effective December 20, 2014. Until such time, we will be able to continue to have orders filled from this supplier. We believe that we will have sufficient product to meet our needs through December 2015. In the intervening period we are actively seeking out an alternative supplier.

Our Therapeutic Probiotics

On September 30, 2013, we entered into the Probiotic ECC, a second worldwide exclusive channel collaboration agreement with Intrexon that governs a “channel collaboration” arrangement in which we will use Intrexon’s proprietary technology relating to the

identification, design, culturing and/or production of genetically modified cells, DNA vectors and in vivo control of expression for the development and commercialization of probiotics, specifically the direct administration to humans of genetically modified probiotics for the treatment of diseases of the oral cavity, throat, sinus and esophagus, including, but not limited to, aphthous stomatitis and Behcet's disease. Our efforts in connection with developing bacteria-based biotherapeutics for oral cavity, throat, sinus and esophagus diseases are just getting underway. Our initial focus will be on developing novel probiotics, or genetically engineered bacterial strains designed to deliver and release therapeutics locally at disease sites to target pain management, reduce inflammation, and improve patient outcomes. We anticipated research to provide bacterial prototypes commencing in the second half of 2014, however, in mid-2014, we convened a Key Opinion Leader (KOL) meeting with Intrexon. The result of this meeting was a rethinking of the strategy for the first indication and consequently we will not begin laboratory research with Intrexon until early 2015. We expect to identify and begin testing on genetically modified probiotics that can produce cytokine therapeutics in late 2015 toward the goal of proof of concept studies in animals.

We will also consider strategic opportunities as they may arise in the future with respect to our existing products and technologies and as to potential new areas that may be complementary to our current efforts and plans.

Other Product Candidates and Technologies

We also possess and have developed other product candidates and technologies that originated from the discoveries of our scientific team. These other product candidates and technologies include our SMaRT Replacement Therapy and our weight loss agent, LPT3-04. For our other product candidates and technologies, we do not expect to devote financial resources toward continued research and development.

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

Our Weight Loss Agent-LPT3-04. In December 2013 we entered into an exclusive licensing agreement for our LPT3-04 weight-loss product candidate with LPThera LLC for further development of this technology. LPT3-04 is a natural occurring dietary substance with an excellent safety and tolerance profile that is believed to support weight loss in overweight men and women. LPT3-04 is normally consumed in the human diet in small amounts, in the course of our SMaRT Replacement Therapy research; our scientific team also discovered that consumption of a significant amount of LPT3-04 resulted in dose-dependent weight loss in experimental animal models. In April of 2014, the Chief Executive Officer of LPThera became an employee of Oragenics.

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 December 31, 2013, and have principally funded our operations through the sale of debt and equity securities, including the exercise of warrants issued in connection with these financing transactions. Prior to 2008 our revenues were derived solely from research grants. Since 2008, our revenues have also included sales of our ProBiora3 products, which we initiated in late 2008. Our net revenues were \$719,422 and \$597,449 for the nine months ended September 30, 2014 and 2013, respectively, and our net revenues were \$1,032,233 and \$1,331,764, for the years ended December 31, 2013 and 2012, respectively.

As of September 30, 2014, we had an accumulated deficit of \$74,721,063 and we have yet to achieve profitability. We incurred net losses of \$4,565,947 and \$12,989,419 for the nine months ended September 30, 2014 and 2013, respectively, and \$16,068,754 and \$13,090,446 for the years ended December 31, 2013 and 2012, 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 will need to raise additional capital. Adequate additional funding may not be available to us on acceptable terms, or at all. We expect that research and development expenses will increase along with general and administrative costs, as we grow and operate our business. There can be no assurance that additional capital will be available to us on acceptable terms, if at all.

Recent Developments

On May 30, 2014 we held our Annual meeting of Shareholders, at which, our shareholders approved and authorized the amendment to our Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock from 50,000,000 shares to 100,000,000.

Financial Overview

Net Revenues

Our revenues prior to 2008 consisted exclusively of grant funding from government agencies under the National Science Foundation's, or NSF, and National Institutes of Health's, or NIH, Small Business Innovation Research, or SBIR, grants. Since the initial launch of our ProBiora3 products in late 2008, our net revenues for the year ended December 31, 2008 and thereafter, also included sales of our ProBiora3 products. Sales of our ProBiora3 products were \$949,593 and \$1,194,878 for the years ended December 31, 2013 and 2012, respectively, and \$719,422 and \$597,449 for the nine months ended September 30, 2014 and 2013, respectively. Because we determined to scale back our efforts to expand distribution of our ProBiora3 products, we expect net revenue to be relatively flat until such time as we are able to devote more resources to marketing and advertising. Our ability to achieve future increases in ProBiora3 product revenues will depend on a number of factors, including primarily the development of, and success of, our marketing efforts related to our ProBiora3 products.

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

Cost of Sales

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

Research and Development Expenses

Research and development consists of expenses incurred in connection with the discovery and development of our product candidates. These expenses consist primarily of employee-related expenses, which include salaries and benefits and attending science conferences; expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies; the cost of acquiring and manufacturing clinical trial materials; facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, and depreciation of fixed assets; license fees for and milestone payments related to in-licensed products and technology; stock-based compensation expense; and costs associated with non-clinical activities and regulatory approvals. We expense research and development costs as incurred.

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

Our research and development expenses were \$2,516,826 and \$8,289,614 for the nine months ended September 30, 2014 and 2013, respectively.

Our current strategy is to increase our research and development expenses in the future as we continue the advancement of preclinical product development programs for our MU1140 product candidate and with respect to our probiotic projects. The lengthy process of completing preclinical and clinical trials; seeking regulatory approval for our product candidates; and expanding the claims we are able to make, requires expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenues and cause our research and development expenses to increase and, in

turn, have a material adverse effect on our operations. Our current MU1140 product development candidate is not expected to be commercially available until sometime after 2016. For our other product candidates and technologies, we expect to consider possible licensing or partnering opportunities with other companies while committing limited research and development expenditures.

Selling, General and Administrative Expenses

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

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

- the costs associated with the advertising and marketing of our ProBiora3 products;
- to support our research and development activities, which, subject to available capital, we expect to expand as we continue the development of our product candidates;
- the costs associated with pursuing strategic opportunities that may arise from time to time; 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 (expense) includes local business taxes, as well as interest income and expense. Interest income consists of interest earned on our cash and cash equivalents. The primary objective of our investment policy is capital preservation. Interest income consists primarily of interest associated with our cash balance and interest expense in the prior comparative period associated with our indebtedness.

Income Taxes

As of December 31, 2013, we have net operating loss carryforwards of approximately \$64,151,000 to offset future federal and state income taxes. We also have research and development and investment tax credit carryforwards of approximately \$1,242,000 as of December 31, 2013 to offset future federal and state income taxes. Our net operating loss and research and development tax credit carryforwards will expire if not used by 2033 and 2023, respectively. Our ability to utilize our net operating loss and tax credit carryforwards may be limited in the event of 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 in June 2009 with the Koski Family Limited Partnership, constituted such an event and our historical loss carryforwards up to such point in time 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, 2014 and 2013

Net Revenues. We generated net revenues of \$201,010 for the three months ended September 30, 2014 compared to \$253,374 for the three months ended September 30, 2013 a decrease of \$52,364. Our ProBiora3 revenues decreased from September 30, 2013 due primarily to decreased sales of Evora Pro to our private label customers and dental distributors.

Cost of Sales. Cost of sales was \$73,711 for the three months ended September 30, 2014 compared to \$113,384 for the three months ended September 30, 2013, a decrease of \$39,673. This decrease was due primarily to a decrease in revenues during the period and lower scrap expense.

Research and Development. Research and development expenses were \$597,034 for the three months ended September 30, 2014 compared to \$6,907,250 for the three months ended September 30, 2013, a decrease of \$6,310,216 or 91.4%. This decrease in research and development expenses was primarily due to a one-time up-front payment of a \$6.0 million technology access fee through the issuance of common stock and a Convertible Note payable to Intrexon Corporation pursuant to the terms of the Probiotic ECC during the three months ended September 30, 2013. There was no such payment of a Technology Access Fee to Intrexon Corporation during the three month period ending September 30, 2014. There were also decreases in stock-based compensation of \$164,951 relating to the award of shares during the three months ended September 30, 2013 under the Company LTIP. There was no such award made during the three months ended September 30, 2014. In addition, there were decreases in consulting, clinical trials, and bonus costs of

\$396,108, \$100,419, and \$35,875 respectively. These decreases were offset by increases in costs associated with the continued development of our lantibiotic candidate, salary and salary related costs, and patent costs of \$214,619, \$126,809 and \$59,601, respectively.

Selling, General and Administrative. Selling, general and administrative expenses were \$565,114 for the three months ended September 30, 2014 compared to \$2,558,205 for the three months ended September 30, 2013, a decrease of \$1,993,091 or 77.9%. This decrease was primarily due to a decrease in stock-based compensation costs, the majority of which related to share based awards made under the Company's LTIP plan, of \$1,339,283 during the three months ended September 30, 2013. There was no such share based awards made during the three month period ending September 30, 2014. In addition there were decreases in advertising, salary and salary related costs, travel, commissions, and tradeshow of \$303,996, \$98,429, \$54,340, \$21,225, and \$13,493 respectively. These decreases were attributable to the scaling back of our efforts to expand distribution of our ProBiora3 products. In addition, there were decreases in bonus, legal, and filing and registration costs of \$76,875, \$24,498 and \$16,070, respectively.

Other Income (Expense). Other income (expense), net was \$5,305 for the three months ended September 30, 2014 compared to \$41 for the three months ended September 30, 2013, resulting in a net change of \$5,264. The net change was primarily attributable to an increase in interest income of \$5,045 due to increased cash balances during 2014.

Results of Operations for the Nine Months Ended September 30, 2014 and 2013

Net Revenues. We generated net revenues of \$719,422 for the nine months ended September 30, 2014 compared to \$597,449 for the nine months ended September 30, 2013 an increase of \$121,973. Our ProBiora3 revenues increased from September 30, 2013 due primarily to an increase in advertising in prior periods which was offset by a decline in grant revenues reflecting the completion of the work.

Cost of Sales. Cost of sales was \$279,076 for the nine months ended September 30, 2014 compared to \$263,990 for the nine months ended September 30, 2013, an increase of \$15,086. This increase was due primarily to an increase in revenues during the period which was partially offset by lower scrap and shipping and warehousing expense.

Research and Development. Research and development expenses were \$2,516,826 for the nine months ended September 30, 2014 compared to \$8,289,614 for the nine months ended September 30, 2013, a decrease of \$5,772,788 or 69.6%. This decrease in research and development expenses was primarily due to a one time up-front payment of a \$6.0 million technology access fee through the issuance of common stock and a Convertible Note payable to Intrexon Corporation pursuant to the terms of the Probiotic ECC during the nine months ended September 30, 2013. There was no such payment of a Technology Access Fee to Intrexon Corporation during the nine month period ending September 30, 2014. In addition, there were decreases in consulting and clinical trials costs of \$1,181,897 and \$193,198 respectively. These decreases were offset by increases in costs associated with the continued development of our lantibiotic candidate and salary and salary related costs of \$1,354,164 and \$203,125, respectively.

Selling, General and Administrative. Selling, general and administrative expenses were \$2,509,843 for the nine months ended September 30, 2014 compared to \$5,180,702 for the nine months ended September 30, 2013, a decrease of \$2,670,859 or 51.6%. This decrease was primarily due to a decrease in stock-based compensation costs, the majority of which related to share based awards made under the Company's LTIP plan, of \$1,330,745 during the nine months ended September 30, 2013. There was no such share based awards made during the nine month period ending September 30, 2014. In addition there were decrease in advertising, salary and salary related costs, travel, consulting, and tradeshow of \$868,352, \$192,248, \$115,085, \$113,906, and \$33,688 respectively. These decreases were attributable to the scaling back of our efforts to expand distribution of our ProBiora3 products. In addition, there was a decrease in filing and registration costs of \$63,826.

Other Income (Expense). Other income (expense), net was \$20,376 for the nine months ended September 30, 2014 compared to \$147,438 for the nine months ended September 30, 2013, resulting in a net change of \$127,062. The net change was primarily attributable to a net change in other income of \$144,706 due to the receipt of cash relating to the purchase of our membership interest in our mutual insurer by an unrelated third party during the nine months ended September 30, 2013. A similar type of transaction did not occur during the nine months ended September 30, 2014.

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, 2014 and 2013, our operating activities used cash of \$4,378,396 and \$5,545,205, respectively. The use of cash in all periods primarily resulted from our net losses adjusted for non-cash items and changes in operating assets and liabilities. We had a working capital surplus of \$11,537,222 and \$15,811,722 at September 30, 2014 and December 31, 2013, respectively.

During the nine months ended September 30, 2014 and 2013, our investing activities used cash of \$19,705 and \$17,649 respectively.

During the nine months ended September 30, 2014 and 2013, our financing activities used cash of \$113,486 and provided cash of \$3,904,775, respectively. The cash used in financing activities during the nine months ended September 30, 2014 was primarily due to the payments on short term notes payable. The cash provided by financing activities for the nine months ended September 30, 2013 was primarily due to the proceeds from the issuance of common stock and the release of restricted cash. These increases were offset by payments on short term notes payable.

Financing

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

The KFLP Credit Facility

On July 30, 2010, we entered into an unsecured revolving credit agreement (the "Credit Facility") with the Koski Family Limited Partnership ("KFLP") an accredited investor and our largest shareholder. Pursuant to the Credit Facility, as amended by amendments one through five, we borrowed an aggregate of \$8,250,000 between July 2010 and July 2012 from the KFLP at LIBOR plus 6.0%. The term of the Credit Facility was initially for 12 months commencing August 1, 2010 and extended by the second amendment to July 31, 2013.

The Termination of Credit Facility for Equity

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

The New KFLP Loan Agreement

On March 23, 2012, we also entered into a new loan agreement (the "Loan Agreement") with the KFLP. It provided us with up to \$2.5 million in secured funding in two advances of \$1,250,000 each with the first advance occurring on March 23, 2012 and the second advance able to be made within 30 days thereafter, subject to the continued accuracy of representations and warranties made by us and that no material adverse events have occurred in connection with the our business. Borrowings under the Loan Agreement matured in three years with interest at the rate of 5.0% and are secured by select assets of us relating to or connected with the ProBiora3, SMaRT Replacement Therapy, MU1140 and LPT3-04 technologies. The amount borrowed under the Loan Agreement was subject to automatic conversion upon a subsequent qualified equity financing by the Company of \$5,000,000 (excluding any converted debt amount). Pursuant to the Loan Agreement we also issued a warrant to the KFLP to acquire 599,520 shares of our common stock. The warrants are exercisable immediately at a price per share of \$2.00 and expire three (3) years from the date of issuance. The fair value of the warrant using the Black Scholes Model is \$599,520. The first funding has a fair value of \$1,250,000. Using the relative fair value method, the first funding has an initial value of \$766,441 and the warrant had an initial value of \$483,559. The value of the warrant was credited to Additional Paid-in Capital. This discount of \$483,559 was being charged to interest expense over the life of the Loan Agreement until the loan was terminated as disclosed below.

The July 2012 Private Placement

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

Griffin Securities, Inc. (the "Placement Agent") served as the placement agent for the Offering. In consideration for services rendered as the Placement Agent in the Offering, we agreed to (i) pay to the Placement Agent cash commissions equal to \$899,698, or 7.0% of the gross proceeds received in the Offering, less certain excluded proceeds, (ii) issue to the Placement Agent, or its designee, a five-year warrant to purchase up to 771,169 shares of our Common Stock (representing 9% of the Common Shares sold in the Offering) with an exercise price of \$1.50 per share (the "Agent Warrants"); and (iii) reimburse the Placement Agent for its reasonable actual

out-of-pocket expenses, incurred in connection with the Offering, including reasonable legal fees and disbursements up to a maximum aggregate amount of \$50,000. The determination of the Placement Agent's fees did not include any shares issued to the KFLP, (in connection with the automatic conversion of its secured debt with us described below) or shares acquired by any officers or directors participating in the Offering. The warrants were valued at \$2.40 per share.

Conversion of KFLP Loan Agreement to Equity

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

The September 2013 Private Placement and Convertible Note Payable to Shareholder

On September 30, 2013, we entered into a Stock Purchase and Issuance Agreement and a First Amendment to the Stock Purchase and Issuance Agreement (collectively the "SPIA") with Intrexon. Pursuant to the SPIA, we sold to Intrexon 1,300,000 shares of our common stock at a price per share of \$3.00 for gross proceeds of \$3,900,000. The proceeds from this sale of common stock are expected to be used for the development of our key initiatives relating to the Probiotic ECC, and general corporate purposes.

Pursuant to the SPIA, we also paid Intrexon an up-front technology access fee of \$6,000,000 (the "Technology Access Fee") in consideration for the execution of the Probiotics ECC. The Technology Access Fee was paid to Intrexon by us through the (i) issuance of 1,348,000 (at \$3.00 per share) shares of our common stock (the "Technology Access Shares"), and (ii) a convertible promissory note in the amount of \$1,956,000 which was payable, at our option, in cash or shares of our common stock (the "Convertible Note"). The Convertible Note matured on December 31, 2013 and required us to obtain shareholder approval prior to conversion of the Convertible Note. On December 18, 2013, we issued 698,241 shares of our common stock to Intrexon in satisfaction of principal and interest due on the Convertible Note at a conversion price of \$2.82 per share. The conversion price was equal to the closing price per share of our common stock on the last trading day immediately prior to the date of conversion.

The November 2013 Underwritten Public Offering

On November 20, 2013, we completed an underwritten public offering of 4,400,000 shares of our common stock at a public offering price of \$2.50 per share. The net proceeds to us, after underwriting discounts and commissions and estimated offering expenses, were \$9,904,996.

Other Financings

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.

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

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

On March 10, 2014, we entered into a short-term note payable for \$50,694 bearing interest at 6.57% per annum to finance the product liability insurance. Principal and interest payments on this note began April 10, 2014 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on January 10, 2015.

On July 24, 2014, we entered into a short-term note payable for \$108,306 bearing interest at 4.647% to finance a portion of the directors' and officers' liability insurance and employment practices liability insurance premiums. Principal and interest payments on this note began August 24, 2014 and are made evenly based on a straight line amortization over an 11-month period with the final payment being made on June 24, 2015.

Future Capital Requirements

Our capital requirements for 2014 and 2015 will depend on numerous factors, including the success of our commercialization efforts and of our research and development, the resources we devote to develop and support our technologies and our success in pursuing strategic licensing and funded product development relationships with external partners. Subject to our ability to generate revenues and cash flow from our ProBiora3 products and our ability to raise additional capital including through possible joint ventures and/or partnerships, we expect to incur substantial expenditures to further commercialize or develop our technologies including continued increases in costs related to research, preclinical testing and clinical studies, as well as costs associated with our capital raising efforts and being a public company. We will require substantial funds to conduct research and development and preclinical and Phase 1 clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase 2 and 3 clinical testing and manufacture and marketing of any products that are approved for commercial sale. Our plans include seeking both equity and debt financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to ensure continuation of our operations and research and development programs.

Our current available cash and cash equivalents are sufficient to satisfy our liquidity requirements. We believe our existing cash and cash equivalents will allow us to fund our operating plan as presently structured over the next twelve months. We expect to continue to seek additional funding for our operations. The sale of additional equity or debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We also will likely require additional capital beyond our currently forecasted amounts, for example, as we continue to work with Intrexon under the Lantibiotic ECC for the development of MU1140 and in our new Probiotic ECC. 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 our product candidates, 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 agreements with Intrexon Corporation;
- the costs of pursuing strategic opportunities as they may arise from time to time;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities for our ProBiora3 products and, if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- our ability to maintain current research and development licensing agreements and to establish new strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- our ability to achieve our milestones under our ECC agreements and licensing arrangements and the payment obligations we may have;
- 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 estimates 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 anticipated milestone payments, stock-based compensation, valuation of warrants, income tax valuation allowance, 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, 2013. There have been no material changes to our critical accounting estimates during the nine months ended September 30, 2014.

Recently Issued Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40) Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern.” ASU 2014-15 provides guidance on management’s responsibility in evaluating whether there is substantial doubt about a company’s ability to continue as a going concern and about related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company’s ability to continue as a going concern within one year from the date the financial statements are issued. Management will also be required to evaluate and disclose whether its plans alleviate that doubt. ASU 2014 – 15 is effective for the annual period ending after December 15, 2016, and for interim periods within annual periods ending after December 15, 2016. Earlier application is permitted. The Company is currently evaluating the requirements of ASU 2014-15 and has not yet determined its impact on the Company’s financial statements.

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09, “Revenue from Contracts with Customers (Topic 606).” ASU 2014-09 completes the joint effort by the FASB and International Accounting Standards Board (IASB) to improve financial reporting by creating common revenue recognition guidance for U.S. GAAP and International Financial Reporting Standards (IFRS). ASU 2014-09 applies to all companies that enter into contracts with customers to transfer goods or services. ASU 2014-09 is effective for public entities for interim and annual reporting periods beginning after December 15, 2016. Early application is not permitted and entities have the choice to apply ASU 2014-09 either retrospectively to each reporting period presented or by recognizing the cumulative effect of applying ASU 2014-09 at the date of initial application and not adjusting comparative information. The Company is currently evaluating the requirements of ASU 2014-09 and has not yet determined its impact on the Company’s financial statements.

In July 2013, the FASB issued new accounting guidance on the presentation of unrecognized tax benefits, Accounting Standards Update No. 2013-11, “Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists,” for fiscal years, and interim periods within those years, beginning after December 15, 2013. The new guidance requires an entity to present an unrecognized tax benefit, or a portion of an unrecognized tax benefit, as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward, except as follows: to the extent a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the applicable jurisdiction to settle any additional income taxes that would result from the disallowance of a tax position or the tax law of the applicable jurisdiction does not require the entity to use, and the entity does not intend to use the deferred tax asset for such purpose, then the unrecognized tax benefit should be presented in the financial statements as a liability and should not be combined with deferred tax assets. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2013, with early adoption permitted. Accordingly, we adopted these presentation requirements during this quarter. The adoption of this new guidance did not have a material impact on our financial statements or related disclosures.

Other than disclosed, there are no new accounting pronouncements issued or effective during the nine months ended September 30, 2014 that have had or are expected to have an impact on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

We have had, and continue to have, a material weakness relating to a lack of adequate segregation of duties due to our small number of employees. 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 Form 10-Q on September 30, 2014 fairly present, in all material respects, our financial position, results of operations, and cash flows for the periods presented in conformity with GAAP.

While segregation of duties remains a challenge for us, management has taken steps to reduce this risk by continuing to limit access to the accounting systems wherever possible. This control weakness is expected to remain until such time as we expand and hire more accounting and finance staff. With the exception of segregation of duties management believes that, existing controls were effective and operating properly as designed. During the reporting period, management believes that the Company maintained a consistent and verifiable financial reporting organization and internal control procedures.

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

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

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, 2013 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, 2013 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, 2013 filed on February 28, 2014.

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.

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 and \$4.6 million and \$13.0 million for the nine months ended September 30, 2014 and 2013, respectively and approximately \$16.1 million and \$13.1 million for the years ended December 31, 2013, and 2012, respectively. As of September 30, 2014 our accumulated deficit was approximately \$74.7 million. We have devoted a significant amount of our financial resources to research and development, including our preclinical development activities and clinical trials, and currently we only have our ProBiora3 products available for commercial sale which to date has not generated significant revenue. We expect that the costs associated with our exclusive channel partnerships with Intrexon Corporation in the areas of lantibiotics (“Lantibiotics Program”) and probiotics (“Probiotics Program”) and the development and commercialization of our product candidates under the Lantibiotics Program (which includes MU1140) and Probiotics Program using Intrexon’s advanced transgene and cell engineering platforms will continue to 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 generate the revenue necessary to achieve or maintain 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. We anticipate that our cash resources as of September 30, 2014 will be sufficient to fund our operations as presently structured over the next twelve 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. 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. Our current cash, cash equivalents and short-term investments are not sufficient to fully implement our business strategy and sustain our operations over a longer period of time. Accordingly, we will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development and commercialization of one or more of our product candidates, curtail or forego sales and marketing efforts, and/or forego licensing attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

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

Currently our sole source of product revenues is from sales of our ProBiora3 products, which have generated only modest revenues to date. Sales of our ProBiora3 products were \$719,442, \$574,272, and \$790,166 for the nine months ended September 30, 2014, 2013, and 2012, respectively, and \$949,593, \$1,194,878, and \$1,229,510 for the years ended December 31, 2013, 2012 and 2011, respectively. There can be no assurance our ProBiora3 product sales will ever generate significant revenue.

We depend on third-party manufacturers for our ProBiora3 products and we recently received notice from a supplier that it would discontinue producing two of the three strains of bacteria needed to produce ProBiora3. 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. 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. One supplier produces two of the three strains of bacteria needed to produce ProBiora3 and one supplier is able to produce one of the strains of bacteria needed to produce ProBiora3. These suppliers use proprietary methodologies to produce these three strains of bacteria. During the quarter we received notice from the supplier producing two of the three bacteria strains needed to produce our ProBiora3 products, that it will discontinue manufacturing such strains effective December 20, 2014. While we are actively seeking another supplier, there can be no assurances that we will be able to secure an alternate supplier or that the terms of such arrangements would be economically viable. 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.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Incorporated by reference to 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 3rd day of November, 2014.

ORAGENICS, INC.

BY: /s/ Michael Sullivan

Michael Sullivan, Interim Principal Executive
Officer, Chief Financial Officer and Principal
Accounting Officer

EXHIBIT INDEX

<u>Exhibit number</u>	<u>Exhibit description</u>	<u>Incorporated by Reference</u>			<u>Filing date</u>	<u>Filed herewith</u>
		<u>Form</u>	<u>File no.</u>	<u>Exhibit</u>		
10.1	Lease Agreement between the Company and Hawley-Wiggins LLC dated October 28, 2011 (13700 Progress Blvd. Alachua FL 32615)	10-K	001-32188	10.20	4/16/12	
3.2	Amendment to Lease Agreement between the Company and Hawley Wiggins LLC dated July 13, 2014 (13700 Progress Blvd. Alachua FL 32615)	10-Q	001-32188	10.2	8/7/14	
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 (Principal 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					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase					X
101.LAB	XBRL Taxonomy Extension Label Linkbase					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase					X

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

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

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

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

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

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

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

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

Dated this 3rd day of November, 2014

By: /s/ Michael Sullivan
Michael Sullivan
Interim Principal Executive Officer
(Principal Executive Officer)

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

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

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

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

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

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

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

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

Dated this 3rd day of November, 2014

By: /s/ Michael Sullivan

Michael Sullivan
Chief Financial Officer
(Principal Financial Officer and Principal
Accounting Officer)

Certification

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

In connection with the Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 (the "Report") of Orogenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Michael Sullivan, hereby certify, to the best of my knowledge, that:

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

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

/s/ Michael Sullivan

Name: Michael Sullivan
Interim Principal Executive Officer
(Principal Executive Officer)
Date: November 3, 2014

Certification

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

In connection with the Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 (the "Report") of Orogenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Michael Sullivan, hereby certify, to the best of my knowledge, that:

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

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

/s/ Michael Sullivan

Name: Michael Sullivan
Chief Financial Officer
(Principal Financial Officer)
Date: November 3, 2014