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, 2015.

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

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

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

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

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

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

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

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

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

As of November 6, 2015, there were 36,477,536 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, 2015 (Unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 6,738,734	$ 10,448,921
Accounts receivables, net	19,367	15,608
Inventory, net	299,316	439,189
Prepaid expenses and other current assets	173,252	119,410
Total current assets	7,230,669	11,023,128
Property and equipment, net	159,263	109,292
Total assets	$ 7,389,932	$ 11,132,420
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 761,830	$ 710,210
Short-term notes payable	109,510	64,840
Convertible note payable to shareholder	5,000,000	—
Deferred revenue	15,339	21,222
Total current liabilities	5,886,679	796,272
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 shares authorized 36,477,536 and 36,178,944 shares issued and outstanding at September 30, 2015 and December 31, 2014	36,478	36,179
Additional paid-in capital	86,903,334	86,244,604
Accumulated deficit	(85,436,559)	(75,944,635)
Total shareholders' equity	1,503,253	10,336,148
Total liabilities and shareholders' equity	$ 7,389,932	$ 11,132,420

See accompanying notes.

Oragenics, Inc.

Statements of Operations
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue, net	$ 329,795	$ 201,010	$ 935,607	$ 719,422
Cost of sales	134,591	73,711	389,370	279,076
Gross profit	195,204	127,299	546,237	440,346
Operating expenses:				
Research and development	1,170,802	597,034	7,459,318	2,516,826
Selling, general and administrative	853,918	565,114	2,543,013	2,509,843
Total operating expenses	2,024,720	1,162,148	10,002,331	5,026,669
Loss from operations	(1,829,516)	(1,034,849)	(9,456,094)	(4,586,323)
Other income (expense):				
Interest income	5,024	8,656	17,395	29,175
Interest expense	(39,564)	(1,305)	(50,201)	(2,856)
Local business tax	(900)	(2,046)	(3,800)	(5,740)
Other income (expense):	1,280	—	776	(203)
Total other income (expense), net	(34,160)	5,305	(35,830)	20,376
Loss before income taxes	(1,863,676)	(1,029,544)	(9,491,924)	(4,565,947)
Income tax benefit	—	—	—	—
Net loss	$ (1,863,676)	$ (1,029,544)	$ (9,491,924)	$ (4,565,947)
Basic and diluted net loss per share	$ (0.05)	$ (0.03)	$ (0.26)	$ (0.13)
Shares used to compute basic and diluted net loss per share	36,441,783	36,178,944	36,344,945	36,145,043

See accompanying notes.

Oragenics, Inc.

Statements of Cash Flows
(Unaudited)

	For the Nine Months Ended September 30,	
	2015	**2014**
Cash flows from operating activities:		
Net loss	$ (9,491,924)	$ (4,565,947)
Adjustments to reconcile net loss to net cash used in operating activities:		
Technology access fee paid in convertible note payable to shareholder	5,000,000	—
Depreciation and amortization	52,540	20,119
(Gain) Loss on sale of fixed assets	(1,280)	203
Stock issued as compensation to non-employee directors	198,000	102,500
Stock-based compensation expense	461,029	188,330
Changes in operating assets and liabilities:		
Accounts receivable, net	(3,759)	38,125
Inventory, net	139,873	24,523
Prepaid expenses and other current assets	104,620	112,604
Accounts payable and accrued expenses	51,620	(305,606)
Deferred revenue	(5,883)	6,753
Net cash used in operating activities	(3,495,164)	(4,378,396)
Cash flows from investing activities:		
Proceeds from sale of fixed asset	1,280	424
Purchase of property and equipment	(102,511)	(20,129)
Net cash used in investing activities	(101,231)	(19,705)
Cash flows from financing activities:		
Payments on short-term notes payable	(113,792)	(113,486)
Net cash used in financing activities	(113,792)	(113,486)
Net decrease in cash and cash equivalents	(3,710,187)	(4,511,587)
Cash and cash equivalents at beginning of period	10,448,921	16,276,510
Cash and cash equivalents at end of period	$ 6,738,734	$11,764,923
Supplemental disclosure of cash flow information:		
Interest paid	$ 1,230	$ 2,997
Non-cash investing and financing activities:		
Borrowings under short-term notes payable for prepaid expense	$ 158,462	$ 158,999
Par value of common stock issued for cashless exercise of warrants	$ 99	$ 135
Par value of restricted shares issued	$ 200	$ —

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. We are focused on becoming the world leader in novel antibiotics against infectious disease. We also develop, market and sell proprietary probiotics specifically designed to enhance oral health for humans and pets and on developing effective treatments for oral mucositis.

2. Basis of Presentation

The accompanying unaudited interim financial statements as of September 30, 2015 and December 31, 2014 (audited) and for the three and nine months ended September 30, 2015 and 2014 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 8 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 ending September 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015 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, 2014, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2015. 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 $935,607, incurred a net loss of $9,491,924, and used cash of $3,495,164 in its operating activities during the nine months ended September 30, 2015. As of September 30, 2015, the Company had an accumulated deficit of $85,436,559.

The Company expects to incur substantial expenditures to further develop each of its technologies. In June of 2015, the Company issued a convertible note payable to Intrexon Corporation ("Intrexon") as consideration for the Technology Access Fee associated with the Oral Mucositis Exclusive Channel Collaboration agreement ("ECC") (See Note 8). The Company currently intends to issue its common stock as payment of the convertible note payable and any accrued interest. Assuming the Company is able to issue its common stock as payment of its convertible note payable and accrued interest, the Company believes that its cash position as of September 30, 2015 will be sufficient to meet the business objectives as presently structured over the next nine 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, limitation of financial resources, or other developments. Additional financing will be required for the Company to fund our further work under the Lantibiotic ECC and our normal operating costs; inclusive of selling, general, and administrative costs through June 2016. We will need to raise additional capital to begin work under the Oral Mucositis ECC. 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 public or private financing, sublicensing arrangements, joint venturing or partnering, sales of rights to technology, or government grants. 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 substantially curtail their current development programs, cut operating costs and forego future development and other opportunities until such time as additional capital can be raised.

3. Significant Accounting Policies

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued guidance on Revenue from Contracts with Customers, to clarify the principles used to recognize revenue for all entities. The core principle of the new guidance is that an entity will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. The standard provides a five-step analysis of transactions to determine when and how revenue is recognized. Additionally, the guidance requires disaggregated disclosures related to the nature, amount, timing, and uncertainty of revenue that is recognized. The guidance is effective for annual and interim periods beginning after December 15, 2016. The FASB has subsequently delayed this standard by one year. Early adoption is permitted as of the original effective date.

The Company is currently evaluating the effects, if any, the adoption of this guidance will have on the Company's financial statements.

There are no additional accounting pronouncements issued or effective during the nine months ended September 30, 2015 that have had or are expected to have an impact on our financial statements.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. The principal areas of estimation reflected in the financial statements are 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 $15,339 and $21,222 of revenue deferred under guaranteed rights of return arrangements included in deferred revenue in the balance sheets as of September 30, 2015 and December 31, 2014, 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 $74,200 and $50,100 as of September 30, 2015 and December 31, 2014, 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. 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.

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.

The Company has granted guaranteed rights of return at various times to certain customers. At this time there are two dental distributors with guaranteed rights of return. Orders are processed and shipped on these accounts, however, the Company defers recognition of revenue until the customer provides notification to the Company that the product has sold to the end consumer. Once notification has been received and verified, the Company will record revenue in that accounting period.

Concentrations

The Company is dependent on key suppliers to provide probiotics, blending, warehousing and packaging of its EvoraPlus, EvoraKids, EvoraPro, EvoraPet, and Teddy’s Pride products. The Company had four key suppliers during the three and nine months ended September 30, 2015. The majority of the Company’s cost of revenues is from these key suppliers during the three and nine months ended September 30, 2015 and 2014. Accounts payable and accrued expenses for these vendors totaled approximately $-0- and $189,120 as of September 30, 2015 and December 31, 2014, 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, 2015, the uninsured portion of this balance was $6,488,734. As of December 31, 2014, the uninsured portion of this balance was $10,198,921.

4. Stock-based Compensation

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

	Three Months Ended September 30, 2015	Three Months Ended September 30, 2014	Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014
Research and development	$ 76,579	$ 18,217	$ 180,449	$ 155,984
Selling, general and administrative	196,170	15,892	478,580	134,846
Total Stock based compensation	$ 272,749	$ 34,109	$ 659,029	$ 290,830

The Company granted -0- and 910,000 stock options, with a weighted-average grant date fair value of -0- and $1.29 per share, during the three and nine months ended September 30, 2015, respectively. The Company granted -0- and 100,000 stock options, with a weighted-average grant date fair value of -0- and $2.81per share, during the three and nine months ended September 30, 2014.

During the nine months ended September 30, 2015, 28,333 stock options previously granted have vested and 278,334 stock options were forfeited and no stock options were exercised.

The Company's long-term performance-based incentive program for executive officers (the "Executive LTIP Program") and its long-term performance-based equity incentive based component for the non-employee directors ("Non-Employee Director LTIP Program" and together with the Executive LTIP the "LTIP Programs") expired and terminated in accordance with their terms on December 31, 2014. The Compensation Committee of the Board of Directors (the "Compensation Committee") recommended and approved, and the Board of Directors approved, a program of equity based awards from the Company's 2012 Equity Incentive Plan (the "2012 Plan") which are intended to align interests of executive officers and directors with stockholders over a long-term basis and thereby replace the expired LTIP Programs. The new equity based programs also include a minimum dollar value stock ownership holding requirement threshold before shares can be sold.

On March 16, 2015, in connection with and in furtherance of the new equity based award program, the Board of Directors of the Company approved stock option awards as previously recommended and approved by the Compensation Committee for the Company's named executive officers currently employed with the Company. Mr. Sullivan, the Company's Chief Financial Officer, Mr. Fosmoe, the Company's Senior Vice President of Operations/Product Development and Dr. Handfield, the Company's Senior Vice President of Discovery Research, were granted options to purchase 200,000, 150,000 and 150,000 shares of Company common stock, respectively, under the Company's 2012 Plan at an exercise price of $1.32 per share, the closing price on the date of grant. The options are subject to time-based vesting in equal annual installments over a three-year period on the first, second and third anniversaries of the date of the grant, provided that the recipient remains employed with the Company through the vesting dates.

Also on March 16, 2015, in connection with and in furtherance of the new equity based award program, the Board approved stock option awards in the amount of 80,000 to each of the Company's non-employee directors, Frederick Telling, Charles Pope, Alan Dunton, Christine Koski and Robert Koski under the Company's 2012 Plan at an exercise price of $1.32 per share, the closing price on the date of grant. Dr. Telling, Mr. Pope, Dr. Dunton, Ms. Koski and Mr. Koski were each also awarded 40,000 restricted shares of Company common stock under the Company's 2012 Plan, of which 10,000 restricted shares vest at the end of each calendar quarter in 2015, provided the recipient remains a director through the vesting date.

Each executive officer and non-employee director receiving the above equity based awards will be subject to a minimum dollar value stock ownership holding requirement with respect to the awards received as well as all prior equity awards under the 2012 Plan which requirements are intended to align the ability to sell shares with the performance of the Company's stock price. The above named executive officer recipients will each have a minimum dollar value stock ownership holding requirement threshold equal to two times (2x) their then base salaries below which dollar threshold they would be precluded from selling any shares of Company stock obtained from the Company under its 2012 Plan. Also, the above non-employee directors will each be subject to a minimum dollar value stock ownership holding requirement threshold equal to six times the annual Board retainer (equating to an amount of $270,000) below which dollar threshold they would be precluded from selling shares of Company stock acquired from the Company under its 2012 Plan.

5. Warrants

A summary of warrant activity for the year ended December 31, 2014 and the nine months ended September 30, 2015 is as follows:

	Warrants	Weighted Average Price
Balance – December 31, 2013	2,747,094	$ 1.91
Granted	—	—
Exercised	(210,000)	1.50
Expired	(5,000)	(10.00)
Balance – December 31, 2014	2,532,094	1.93
Granted	—	—
Exercised	(185,585)	1.50
Expired	(2,170,925)	(2.00)
Balance – September 30, 2015	175,584	$ 1.50

On March 23, 2015, warrants to acquire 2,170,925 shares of the Company's common stock at a price of $2.00 per share expired. On August 3, 2015, Griffin Securities Inc. exercised 185,585 of their previously issued warrants on a net issuance basis resulting in the issuance of 98,592 shares of our common stock.

The warrants outstanding as of September 30, 2015 are as follows:

Exercise Price	Warrants Outstanding	Expiration Dates
$1.50	175,584	7/31/17
	175,584	

6. Short-Term Notes Payable

As of September 30, 2015 and December 31, 2014, the Company had $109,510 and $64,840, respectively, in short-term notes payable for the financing of various insurance policies. 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 March 16, 2015, we entered into a short-term note payable for $49,395 bearing interest at 5.68% per annum to finance the product liability insurance. Principal and interest payments on this note began April 16, 2015 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on January 16, 2016. 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 made on June 22, 2015. On July 28, 2015, the Company entered into a short-term note payable for $109,067 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, 2015 and are made evenly based on a straight line amortization over an 11-month period with the final payment made on June 24, 2016.

7. Convertible Note Payable To Shareholder

On June 9, 2015, the Company entered into an unsecured short-term Convertible Promissory Note in the principal amount of $5,000,000 bearing interest at 3.00% as consideration for the Technology Access Fees associated with the Oral Mucositis ECC (discussed below) entered into with Intrexon. The Convertible Promissory Note is payable, at the Company's option, in cash or shares of the Company's common stock. Principal and accrued interest is due on December 31, 2015.

8. Commitments and Contingencies

The University of Florida Research Foundation (UFRF) Licenses

UFRF-MU1140 License. In the Company's UFRF amended license agreement 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 agreement, 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) April 1, 2013 and (2) the month of the first anniversary of a commercial sale. The post-commercialization minimum royalty payments of $50,000 annually would be due following payment of a commercialization fee. The one-time additional royalty payment would be due when total cumulative royalties paid to UFRF exceed $2.0 million, upon which we would be obligated to make a one-time additional payment to UFRF of 10% of the total royalties due to UFRF in the calendar year in which cumulative royalties exceeded $2.0 million.

The Company is required to make minimum annual maintenance payments to the UFRF for the term of the amended license agreement in the amount of $10,000. The aggregate minimum annual payments are required to be paid in advance on a quarterly basis (i.e. $2,500 per quarter). 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 agreement expire upon the earlier of (i) the date that no patents covered by the amended license agreement remain enforceable or (ii) the payment of earned royalties under the amended license agreement, 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 agreement if the Company breaches its obligations to timely pay any amounts due under the amended license agreement, to submit development reports as required under the amended license agreement or commit any other breach of any other covenants contained in the amended license agreement and the Company fails to remedy such breach within 90 days after written notice of such breach by UFRF.

The patent the Company had previously exclusively licensed from UFRF for its Replacement Therapy expired in June 2015 and the resulting license was terminated. The Company is currently evaluating its options with respect to the SMaRT Replacement Therapy technology.

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 is obligated to meet the following milestones 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, 2016, 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, negotiate the missed milestones or terminate the license agreement. On July 11, 2012 the Texas A&M license agreement was amended to add references to replacement therapy in the defined terms "Licensed Technology" and "Patent Rights". All other terms of the Texas A&M license agreement remain unchanged.

On May 18, 2015, the Texas A&M license agreement was amended to extend the enrollment of first patient in a Phase I clinical trial using the licensed technology, from on or before June 1, 2015, to on or before June 30, 2016. All other terms of the Texas A&M license agreement as amended remained unchanged. 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.

None of the Texas A&M milestones had been achieved as of September 30, 2015.

The Lantibiotic 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 nonclinical and clinical development of candidate lantibiotics, as well as for other aspects of manufacturing and the commercialization of the product(s). Among other things, Intrexon is responsible for technology discovery efforts, cell-engineering development, certain aspects of the manufacturing process, and costs of filing, prosecution and maintenance of Intrexon's patents.

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

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 ("SPIA"). 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 ("FDA") 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 FDA 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, 2015.

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 50% of the revenue obtained from a sublicensor 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 Oral Mucositis ECC

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

The Company will pay Intrexon on a quarterly basis 12% of the net sales derived from the sale of products developed from the exclusive channel collaboration. The Company has likewise agreed to pay Intrexon on a quarterly basis 50% of revenue obtained in that quarter from a sublicensor in the event of a sublicensing arrangement.

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 (based upon the fair market value of the shares otherwise required to be issued) unless the issuance of such shares would reasonably likely cause Intrexon to consolidate the Company's financial statements with Intrexon's financial statements, or at the Company's option make a cash payment to Intrexon. The Commercialization Milestone Events and amounts payable are as follows:

(i) two million United States dollars ($2,000,000) within thirty (30) days of the first instance of the achievement of the Phase II Milestone Event meaning the first dosing of a patient by or on behalf of Oragenics, or an Affiliate or permitted sublicensee of Oragenics, in a phase II 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 each different Oragenics Product;

(ii) five million United States dollars ($5,000,000) within thirty (30) days of the first instance of the achievement of the Phase IIb/III Milestone Event meaning meeting of the primary endpoint by or on behalf of Oragenics, or an Affiliate or permitted sublicensee of Oragenics, 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 each different Oragenics Product;

(iii) five million United States dollars ($5,000,000) within thirty (30) days of the first instance of the achievement of the Regulatory Approval Application Milestone Event for each different Oragenics Product which Regulatory Approval Application Milestone Event meaning for a given Oragenics Product, the first to occur of (a) the filing by Oragenics, an Affiliate thereof, or a permitted sublicensee thereof, of a FDA New Drug Application or a Biologics License Application with the FDA seeking approval of such Oragenics Product, or (b) the filing of an equivalent approval or marketing application for such Oragenics Product with an equivalent regulatory authority in a foreign jurisdiction;

(iv) ten million United States dollars ($10,000,000) within thirty (30) days of the first instance of the achievement of the Approval Milestone Event for each different Oragenics Product which Approval Milestone Event meaning the first to occur of (a) the First Commercial Sale of an Oragenics Product anywhere in the Territory, or (b) 90th day after the approval of a FDA New Drug Application for an Oragenics Product by the FDA or equivalent regulatory action in a foreign jurisdiction;

(v) Oragenics shall pay Intrexon a milestone payment of five million United States dollars ($5,000,000) within thirty (30) days of the first instance of the achievement of the New Indication Milestone Event meaning the filing by or on behalf of Oragenics, an Affiliate of Oragenics, or a permitted sublicensee of Oragenics a Supplemental FDA Application with the FDA or with another equivalent regulatory agency seeking approval of an indication for use of the product AG013 other than the current regulatory-approved indication; and

(vi) Oragenics shall pay Intrexon a milestone payment of five million United States dollars ($5,000,000) within thirty (30) days of the first instance of the achievement of the New Product Milestone Event meaning the filing of a

regulatory package filed with the FDA or with another equivalent regulatory agency by or on behalf of Oragenics, an Affiliate of Oragenics, or a permitted sublicensee of Oragenics, that is deemed (according to relevant FDA guideline) to be a different drug product than AG013.

None of the Oral Mucositis ECC milestones had been achieved as of September 30, 2015.

The Oral Mucositis ECC provides that in the event (i) Oragenics is required to make a milestone payment in cash as an issuance of shares would cause Intrexon to consolidate the Company's financial statements with Intrexon's financial statements, and (ii) Oragenics reasonably concludes that a cash milestone payment would have an adverse effect on its working capital needs over the next twelve (12) months, then such cash payment shall be in the form of an interest bearing promissory note with a maturity date of less than twelve (12) months and include other conventional market terms that would not be expected to unreasonably have an adverse effect on Oragenics working capital needs over such twelve (12) month period. The Company may voluntarily terminate the Oral Mucositis ECC upon 90 days written notice to Intrexon. Intrexon may also terminate the ECC if the Company breaches 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 ECC. Upon termination of the ECC, the Company may continue to develop and commercialize any Company Product that, at the time of termination that satisfies at least one of the following criteria:

(i) the particular Company Product is being sold by the Company triggering profit sharing payments under the ECC to Intrexon;

(ii) the particular Company Product has received regulatory approval;

(iii) the particular Company Product is a subject of an application for regulatory approval in the Field covered by the ECC that is pending before the applicable regulatory authority;

(iv) the particular Company Product is AG013, and such Company Product has been the subject of at least one completed phase II clinical trial (as such is defined by relevant FDA guidelines) during the Term; or

(v) the particular Company Product other than AGO13 and such Oragenics Product is the subject of at least an ongoing Phase 1, Phase 2 or Phase 3 clinical trial in the Field.

9. Related Party Transactions

During the three and nine months ended September 30, 2015 and 2014, we paid $120,214 and $8,093; $165,969 and $474,837, respectively, to Intrexon under the ECC agreements (See Note 8). Included in accounts payable and accrued expenses at September 30, 2015 and 2014 was $250,413 and $2,535, respectively, related to unpaid invoices received from Intrexon relating to work performed under the ECC Agreements. As of September 30, 2015 and 2014 Intrexon owned approximately 24% of our outstanding common stock.

On September 30 2015, the Company and Intrexon Corporation mutually agreed to terminate the Exclusive Channel Collaboration Agreement dated September 30, 2013 regarding the development and commercialization of probiotics (the "Live Biotherapeutic Products ECC"). The termination of the Live Biotherapeutic Products ECC was to enable Oragenics to focus its resources on the lantibiotic and oral mucositis programs.

10. Common Stock

On March 16, 2015, in connection with and in furtherance of the new equity based award program (see Note 4), the Board approved the award of 40,000 restricted shares of Company common stock to each of the Company's non-employee directors, Frederick Telling, Charles Pope, Alan Dunton, Christine Koski and Robert Koski under the Company's 2012 Plan of which a total of 30,000 restricted shares have vested on September 30, 2105 for each non-employee director and the remainder will vest at the end of each calendar quarter in 2015 provided the recipient remains a director through the vesting date. The awards are considered issued and outstanding as of the date of the grant and are eligible to be voted by the recipient. The Company has $66,000 in unrecognized compensation expense relating to these awards that will be recognized pro-rata through the remainder of 2015. On August 3, 2015, Griffin Securities Inc. exercised 185,585 of their previously issued warrants on a net issuances basis resulting in the issuance of 98,592 shares of our common stock.

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 on developing effective treatments for oral mucositis. We also develop, market, and sell proprietary probiotics specifically designed to enhance oral health for humans and pets, under the brand names Evora and ProBiora.

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. We believe lantibiotics are generally recognized by the scientific community to be potent antibiotic agents.

In nonclinical testing, MU1140 has shown activity 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.

Lantibiotics 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. Traditional fermentation methods can only produce minute amounts of the lantibiotic.

In June 2012, we entered into the Lantibiotic Exclusive Channel Collaboration agreement ("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. Through our work with Intrexon, we have been able to produce an exponential increase in the fermentation titer of MU1140 compared to standard fermentation methods and have discovered a new purification process for MU1140. Our work with Intrexon has generated a substantial number of homologs of MU1140, and we are continuing our research and development and collaboration efforts with Intrexon to develop potential derivatives of the MU1140 molecule using genetically modified bacteria.

In our pre-clinical studies to support a potential Investigational New Drug ("IND") filing with the FDA, we tested a total of six homologs of MU1140 for certain compound characteristics, including but not limited to: drug activity (based on minimum inhibitory concentration or "MIC") equal or better than "standard of care" drugs against certain drug-resistant bacteria, safety, toxicity, stability, and manufacturability. The study specifically evaluated homolog efficacy in relation to survival, measurable amounts of *c. diff* colony forming units, and toxin levels. Three homologs demonstrated promising results with one homolog , which is our current lead compound, achieving a 100% survival rate throughout the entire study in contrast to an approximately 30% survival rate for the vancomycin positive control.

We intend to move forward with our lead lantibiotic candidate with the goal of having a pre IND meeting with the FDA in the fourth quarter of 2015. Depending on the outcome of that meeting, we expect to file the IND for a first-in-human clinical study of a lead compound in the second half of 2016.

Our Oral Mucositis License (OM)

We have entered into a worldwide Exclusive Channel Collaboration Agreement with Intrexon and Intrexon Actobiotics NV, a wholly-owned subsidiary of Intrexon, pursuant to which we obtained certain exclusive rights to AG013. We intend to develop AG013 as a potential treatment of oral mucositis, or OM.

In a phase 1B clinical trial in 25 cancer patients with OM, AG013 was safe and well tolerated. Data published in the journal Cancer showed a 35% reduction of the duration of ulcerative OM in the AG013-treated patients versus the placebo-treated patients. Furthermore, close to 30% of the patients treated with AG013 were full responders while all placebo-treated patients developed ulcerative OM. Additionally, in a phase 1 pharmacokinetic (PK) study in 10 healthy volunteers, AG013 bacteria adhered to the buccal mucosa and actively secreted protein locally, resulting in homogeneous exposure to the entire mucosal surface up to 24 hours after administration of a rinse. AG013 has been granted Orphan Drug status in the European Union and we believe it may be eligible for Biologic License Application exclusivity as well as Fast Track designation with the United States Food and Drug Administration.

We are undertaking further studies on oral mucositis at this time before determining to proceed with a phase 2 clinical trial.

Our Probiotic Products

We also develop, market, and sell proprietary probiotics specifically designed to enhance oral health for humans and pets, under the brand names Evora and ProBiora.

The allocation of limited financial resources between research and development of lantibiotics for our other product candidates and sale and marketing efforts for our ProBiora3 products, among other factors, resulted in our December 2014 announcement that we would seek to explore strategic alternatives for the probiotic business. These alternatives could include joint ventures, strategic partnerships or alliances, a sale of the probiotic products business or other possible transactions. There can be no assurance that a transaction or agreement will be consummated with terms favorable to us, if at all.

Other

In addition to our lantibiotics and oral mucositis product candidates, we also have other candidates and technologies in the oral care and weight loss areas. We do not intend to continue to develop of these potential product candidates and technologies without partnering with a third party.

Recent Developments

On September 30 2015, the Company and Intrexon Corporation mutually agreed to terminate the Exclusive Channel Collaboration Agreement dated September 30, 2013 regarding the development and commercialization of probiotics (the "Live Biotherapeutic Products ECC"). The termination of the Live Biotherapeutic Products ECC was to enable Oragenics to focus its resources on the lantibiotic and oral mucositis programs.

We were incorporated in November 1996 and commenced operations in 1999. We consummated our initial public offering in June 2003. We have devoted substantially all of our available resources to the commercialization of our ProBiora3 products as well as our discovery efforts comprising research and development, clinical trials for our product candidates, protection of our intellectual property and the general and administrative support of these operations. We have generated limited revenues from grants and ProBiora3 product sales through September 30, 2015, 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 $935,607 and $719,422 for the nine months ended September 30, 2015 and 2014, respectively, and our net revenues were $939,926 and $1,032,233, for the years ended December 31, 2014 and 2013, respectively.

As of September 30, 2015, we had an accumulated deficit of $85,436,559 and we have yet to achieve profitability. We incurred net losses of $9,491,924 and $4,565,947 for the nine months ended September 30, 2015 and 2014, respectively, and $5,789,519 and $16,068,754 for the years ended December 31, 2014 and 2013, 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 seek to grow and continue to operate our business. There can be no assurance that additional capital will be available to us on acceptable terms, if at all.

Financial Overview

Net Revenues

Our revenues prior to 2008 consisted exclusively of grant funding from government agencies under the National Science Foundation's, or NSF, and National Institutes of Health's, or NIH, Small Business Innovation Research, or SBIR, grants. Since the initial launch of our ProBiora3 products in late 2008, our net revenues for the year ended December 31, 2008 and thereafter, also included sales of our ProBiora3 products. Sales of our ProBiora3 products were $939,926 and $949,593 for the years ended December 31, 2014 and 2013, respectively and $935,607 and $719,422 for the nine months ended September 30, 2015 and 2014, respectively. Future increases in net revenue for our ProBiora3 products will depend on a number of factors, including our ability to successfully engage in marketing efforts related to our ProBiora3 products, which we have substantially scaled back. Our marketing efforts for our ProBiora3 products have had limited success to date as revenues have not significantly increased from period to period. We may consider options for marketing our ProBiora3 Products that can be cost-effective as we seek to manage the use of our cash resources relative to the research and development we are conducting for our other product candidates while we explore and consider strategic alternatives for our consumer probiotic business.

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 Revenues

Our cost of revenues 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 that our costs of revenues would increase if we are able to expand our distribution and sales efforts for our ProBiora3 products.

Research and Development Expenses

Research and development consists of expenses incurred in connection with the discovery and development of our product candidates. These expenses consist primarily of employee-related expenses, which include salaries and benefits, expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our nonclinical 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 nonclinical 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) nonclinical research and development activities. Clinical research costs consist of clinical trials, manufacturing services, regulatory activities and related personnel costs, and other costs such as rent, utilities, depreciation and stock-based compensation. Nonclinical research and development costs consist of our research activities, nonclinical 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 $7,459,318 and $2,516,826 for the nine months ended September 30, 2015 and 2014, respectively.

Our current strategy is to manage our research and development expenses in the future as we continue the advancement of our clinical trials and nonclinical product development programs for our MU1140 product candidate, and our oral mucositis product candidate. The lengthy process of completing 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 nonclinical or 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. Certain of our current product development candidates are not expected to be commercially available until we are able to obtain regulatory approval from the FDA, which is not expected before 2017.

Our plan is to budget and manage expenditures in research and development such that they are undertaken in a cost-effective manner yet still advance the research and development efforts. While we have some control under our Lantibiotic ECC and Oral Mucositis ECC as to the planning and timing of the research and development and therefore the timing of when expenditures may be incurred for various phases of agreed upon projects, actual expenditures can vary from period to period. Subject to available capital, we expect overall research and development expenses to fluctuate as our financial resources permit. Our research and development projects are currently expected to be taken to the point where they can be licensed or partnered with larger pharmaceutical companies. Our recent Oral Mucositis ECC will require us to evaluate pursuit of further near term FDA clinical trials for our oral mucositis product candidate. To the extent such clinical trials are pursued our research and development expenditures would further increase.

Selling, General and Administrative Expenses

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

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

- the exploring of strategic alternatives for, and sales 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 efforts we undertake from, time to time, to raise additional capital; and
- the increased payroll, and stock based compensation, expanded infrastructure and higher consulting, legal, accounting and investor relations costs associated with being a public company.

Our Probiora3 marketing plans to date have attempted to strike a balance between the expenses of marketing and the achievement of improved sales. Striking this balance toward the goal of improving sales has been a challenge as we endeavor to achieve improved sales with an amount of marketing expenditures that are acceptable to us given our limited available cash resources and our need for the use of such resources on the development of our other product candidates. We expect to continue to consider our efforts to market ProBiora3 and evaluate such efforts and the amount of expense to be incurred relative to the expected improvement in sales and the goal of achieving improved sales while we explore strategic alternatives for the consumer probiotic business.

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 expense consists primarily of interest and costs associated with our short term indebtedness.

Income Taxes

As of December 31, 2014, we have net operating loss carryforwards of approximately $69,735,000 to offset future federal and state income taxes. We also have research and development tax credit carryforwards of approximately $1,355,000 as of December 31, 2014 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 2034 and 2024, respectively. Our ability to utilize our net operating loss and tax credit carryforwards may be limited in the event a change in ownership, as defined in Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, has occurred or may occur in the future. The private placement transaction with the Koski Family Limited Partnership ("KFLP") in June 2009 (the "June 2009 Private Placement") constituted such an event and the ability to use our historical loss carryforwards in the future to offset income after that point in time were limited. Furthermore, our transactions with Intrexon during 2013 constituted a second such event, and the ability to use our historical loss carryforwards up to December 2013 were further limited. In each period, 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, 2015 and 2014

Net Revenues. We generated net revenues of $329,795 for the three months ended September 30, 2015 compared to $201,010 for the three months ended September 30, 2014 an increase of $128,785. Our ProBiora3 revenues increased from September 30, 2014 due primarily to an increase in private label sales.

Cost of Sales. Cost of sales was $134,591 for the three months ended September 30, 2015 compared to $73,711 for the three months ended September 30, 2014, an increase of $60,880. This increase was due primarily to an increase in private label sales during the period. Gross margin for the three months ended September 30, 2015 was 59.2% versus 63.3% for the same period in 2014.

Research and Development. Research and development expenses were $1,170,802 for the three months ended September 30, 2015 compared to $597,034 for the three months ended September 30, 2014, an increase of $573,768. This increase was primarily due to increases in salary and salary related costs, costs associated with work under the ECC's, stock based compensation costs, and clinical trial costs of $100,286, $449,962, $58,361, and $21,341 respectively. These increases were partially offset by a decrease in patent costs of $66,939.

Selling, General and Administrative. Selling, general and administrative expenses were $853,918 for the three months ended September 30, 2015 compared to $565,114 for the three months ended September 30, 2014, an increase of $288,804 or 51.1%. This increase was primarily due to increases in stock based compensation, board fees, legal costs, travel, filing fees and registrations, and depreciation costs of $180,278, $78,375, $48,815, $21,430, $16,316 and $13,262, respectively. These increases were partially offset by a decrease in consulting costs of $73,643.

Other Income (Expense). Other income (expense), net was $(34,160) for the three months ended September 30, 2015 compared to $5,305 for the three months ended September 30, 2014, resulting in a net change of $(39,465). The net change was primarily attributable to a decrease in interest income of $3,632 due to decreased cash balances during 2015 and an increase in interest expense of $38,259 due to increased levels of borrowing in 2015 relating to the Convertible Note Payable to Shareholder.

Results of Operations for the Nine Months Ended September 30, 2015 and 2014

Net Revenues. We generated net revenues of $935,607 for the nine months ended September 30, 2015 compared to $719,422 for the nine months ended September 30, 2014 an increase of $216,185. Our ProBiora3 revenues increased from September 30, 2014 due primarily to an increase in private label sales.

Cost of Sales. Cost of sales was $389,370 for the nine months ended September 30, 2015 compared to $279,076 for the nine months ended September 30, 2014, an increase of $110,294. This increase was due primarily to an increase in revenues during the period. Gross margin for the nine months ended September 30, 2015 was 58.4% versus 61.2% for the same period in 2014.

Research and Development. Research and development expenses were $7,459,318 for the nine months ended September 30, 2015 compared to $2,516,826 for the nine months ended September 30, 2014, an increase of $4,942,492. This increase was primarily due to the payment of a $5.0 million technology access fee through the issuance of a Convertible Note payable to Intrexon pursuant to the terms of the our new Oral Mucositis ECC during the nine months ended September 30, 2015. There was no such payment of a

Technology Access Fee to Intrexon during the nine month period ending September 30, 2014. In addition, there was an increase in salary and salary related costs, stock based compensation and clinical trial costs of $325,110, $24,465 and $17,221, respectively. These increases were partially offset by decreases in costs associated with our ECC's and patent costs of $318,297 and $106,007, respectively.

Selling, General and Administrative. Selling, general and administrative expenses were $2,543,013 for the nine months ended September 30, 2015 compared to $2,509,843 for the nine months ended September 30, 2014, an increase of $33,170 or 1.3%. This increase is due to increases in board fees, stock option expense, registration fees, depreciation and selling expenses of $159,875, $261,539, $25,681, $32,421 and $14,995 respectively. These increases were partially offset by decreases in salaries, consulting, advertising and legal costs of $163,060, $206,357, $22,885 and $69,039, respectively.

Other Income (Expense). Other income (expense), net was $(35,830) for the nine months ended September 30, 2015 compared to $20,376 for the nine months ended September 30, 2014, resulting in a net change of $(56,206). The net change was primarily attributable to a decrease in interest income of $11,780 due to decreased cash balances during 2015 and an increase in interest expense of $47,345 due to increased levels of borrowing in 2015 relating to the Convertible Note Payable to Shareholder.

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, warrant exercises, public offerings, and grants. During the nine months ended September 30, 2015 and 2014, our operating activities used cash of $3,495,164 and $4,378,396, 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 $1,343,990 and $10,226,856 at September 30, 2015 and December 31, 2014, respectively.

During the nine months ended September 30, 2015 and 2014, our investing activities used cash of $101,231 and $19,705 respectively used primarily for the purchase of property and equipment.

During the nine months ended September 30, 2015 and 2014, our financing activities used cash of $113,792 and $113,486, respectively. The cash used by financing activities during the nine months ended September 30, 2015 and 2014 was primarily due to the reductions in short term notes payable.

Financing

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

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 an exclusive channel collaboration agreement for the development of probiotics. 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.

The June 2015 Convertible Note Payable To Shareholder

On June 9, 2015, the Company entered into an unsecured short-term Convertible Promissory Note in the principal amount of $5,000,000 bearing interest at 3.00% as consideration for the Technology Access Fees associated with the Oral Mucositis ECC entered into with Intrexon. The Convertible Promissory Note is payable, at the Company's option, in cash or shares of the Company's common stock. Principal and accrued interest are due on December 31, 2015.

Other Financings

We enter into short term financing arrangements for the payment of our annual insurance premiums for our products liability insurance and directors and officers and employment practices insurance.

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 being made 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 22, 2015.

On March 16, 2015, we entered into a short-term note payable for $49,395 bearing interest at 5.68% per annum to finance the product liability insurance. Principal and interest payments on this note began April 16, 2015 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on January 16, 2016.

On July 28, 2015, we entered into a short-term note payable for $109,067 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, 2015 and are made evenly based on a straight line amortization over an 11-month period with the final payment being made on June 24, 2016.

Future Capital Requirements

Our capital requirements for 2015 and 2016 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, nonclinical 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 nonclinical and Phase 1 clinical testing of our licensed, patented technologies and to conduct or 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.

We believe that our existing cash and cash equivalents will allow us to fund our further work under the Lantibiotics ECC and our normal operating costs inclusive of selling, general, and administrative costs through June 2016. We will need to raise additional capital to begin work under the Oral Mucositis ECC. We expect to continue to seek additional funding for our operations. The sale of additional equity or debt securities will 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 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 our lead lantibiotic candidate and other homologs, and our new Oral Mucositis 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, if any, 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 nonclinical and clinical trials including the research and development expenditures we expect to make in connection with our collaboration agreements with Intrexon;
- 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 under such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our products and future products, if any.

We have based our 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 when market conditions are favorable, 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, inventory obsolescence reserve, sales returns and allowances 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, 2014. There have been no material changes to our critical accounting estimates during the nine months ended September 30, 2015.

Recently Issued Accounting Pronouncements

In May 2014, the FASB issued guidance on Revenue from Contracts with Customers, to clarify the principles used to recognize revenue for all entities. The core principle of the new guidance is that an entity will recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. The standard provides a five-step analysis of transactions to determine when and how revenue is recognized. Additionally, the guidance requires disaggregated disclosures related to the nature, amount, timing, and uncertainty of revenue that is recognized. The guidance is effective for annual and interim periods beginning after December 15, 2016. The FASB has subsequently delayed this standard by one year. Early adoption is permitted as of the original effective date. The Company is currently evaluating the effects, if any, the adoption of this guidance will have on the Company’s financial statements.

There are no additional accounting pronouncements issued or effective during the nine months ended September 30, 2015 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 Interim Principal Executive Officer/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 Interim Principal Executive Officer/Chief Financial Officer, to allow timely decisions regarding required disclosures. Based upon that evaluation, our Interim Principal Executive Officer/Chief Financial Officer concluded that, as of the end of such period, our disclosure controls and procedures were effective as of September 30, 2015 in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported with the time periods specified in the Securities and Exchange Commission's rules and forms.

We have identified a material weakness in our internal controls over financial reporting relating to a lack of adequate segregation of duties. This material weakness has existed at the Company for some time and is expected to continue to exist for the foreseeable future. The material weakness is 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, 2015 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 Interim Principal Executive Officer/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 Interim Principal Executive Officer/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

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

Risks Related to Our Business

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

We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of approximately and $9.5 million and $4.6 million for the nine months ended September 30, 2015 and 2014, respectively, and approximately $5.8 million and $16.1 million for the years ended December 31, 2014, and 2013, respectively. As of September 30, 2015 our accumulated deficit was approximately $85.4 million. We have devoted a significant amount of our financial resources to research and development, including our nonclinical development activities and clinical trials, and currently we only have our ProBiora3 products available for commercial sale which to date have not generated significant revenue. We expect that the costs associated with our exclusive channel collaborations with Intrexon in the areas of lantibiotics ("Lantibiotics Program") and Oral Mucositis (Oral Mucositis Program) and the development and commercialization of our product candidates under the Lantibiotics Program (which includes MU1140), 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 nonclinical studies and clinical trials and establishing manufacturing capabilities, is expensive. We anticipate that our cash resources as of September 30, 2015 will be sufficient to fund our operations as presently structured over the next nine 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 existing nonclinical and planned clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure, and research and development activities. Specifically, we may need to raise additional capital to, among other things:

- expand our clinical laboratory operations;
- fund our clinical validation study activities;
- expand our research and development activities;
- sustain or achieve broader commercialization of our products;
- acquire or license products or technologies; and

- finance our capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- the level of research and development investment required to develop our current and future product candidates;
- costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- our need or decision to acquire or license complementary technologies or acquire complementary businesses;
- changes in test development plans needed to address any difficulties in product candidate selection for commercialization;
- competing technological and market developments;
- our interaction and relationship with the FDA, or other, regulatory agencies; and
- changes in regulatory policies or laws that affect our operations.

Additional capital, if needed, may not be available on satisfactory terms, or at all. Furthermore, if we raise additional funds by issuing equity securities, dilution to our existing stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or our products under development, or grant licenses on terms that are not favorable to us, which could lower the economic value of those programs to us. If adequate funds are not available, we may have to scale back our operations or limit our research and development activities, which may cause us to grow at a slower pace, or not at all, and our business could be adversely affected.

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.

If we are unable to successfully develop our product candidates, our operating results and competitive position could be harmed. Research and development involves a lengthy and complex process, and we may not be successful in our efforts to develop and commercialize our products candidates. The further development and ultimate commercialization of product candidates for lantibiotics and oral mucositis are keys to our growth strategy.

A key element of our strategy is to discover, develop, validate and commercialize a portfolio of additional antibiotic product candidates to combat multi drug resistant organism, or MDRO, outbreaks and the associated costs to patients, inpatient facilities and the health care industry and to develop, validate and commercialize a product candidate to treat oral mucositis. We cannot assure you that we will be able to successfully complete development of, or commercialize any of our planned future product candidates, or that they will be clinically usable. The product development process involves a high degree of risk and may take up to several years or more. Our new product development efforts may fail for many reasons, including:

- failure of future tests at the research or development stages;
- lack of clinical validation data to support the effectiveness of the test;
- delays resulting from the failure of third-party suppliers or contractors to meet their obligations in a timely and cost-effective manner;
- regulatory delays at the FDA;
- failure to obtain or maintain necessary certifications, licenses, clearances or approvals to market or perform the test; or
- lack of commercial acceptance by the health care marketplace.

Few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of new products, or we may be required to expend considerable resources repeating clinical studies or trials, which would adversely impact the timing for generating potential revenues from those new products. In addition, as we advance the development of new products through to the commercialization stage, we will have to make additional investments in our sales and marketing operations, which may be prematurely or unnecessarily incurred if the commercial launch of a product is abandoned or delayed.

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

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

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, $935,607, $719,442, and $574,272 for the nine months ended September 30, 2015, 2014, and 2013, respectively, and $921,075, $949,593, and $1,194,878, for the years ended December 31, 2014, 2013 and 2012, respectively. There can be no assurance our ProBiora3 product sales will ever generate significant revenue and cash flow for us.

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

Our product candidates under our Lantibiotics Program, and Oral Mucositis Program have not received regulatory approval in any jurisdiction and they may never receive approval or, if approvals are obtained, may never be commercialized successfully. We have incurred and will continue to incur significant costs relating to the nonclinical and clinical development of our antibiotic product candidates including MU1140 or any homologs thereof we may develop. We have performed extensive nonclinical testing using native MU1140 and have since entered into an Exclusive Channel Collaboration Agreement with Intrexon. We began nonclinical activities on homologs of MU1140 in the second half of 2014. Those activities include toxicity results, physicochemical characterizations, and efficacy studies in animals. This work will be done solely by us through the use of outside contractors. If our nonclinical work is successful, we would expect to file an Investigational New Drug application with the FDA by the second half of 2016. Even if we are able to conduct successful clinical trials or the required regulatory approvals are obtained, we may never be able to generate significant revenues from our product candidates. If our product candidates are unsuccessful, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, financial condition and results of operations will be materially adversely affected.

Our exclusive channel partnering arrangements with Intrexon are based on an early stage technology in their fields.

Our exclusive channel collaboration arrangement with Intrexon contemplates the use of Intrexon's advanced transgene and cell engineering platforms for the development and production of lantibiotics, and AG013**.** Such technologies have a limited history of use in the design and development of active pharmaceutical ingredients and drug products involving direct administration and may therefore involve unanticipated risks or delays.

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

Pursuant to our exclusive channel collaborations with Intrexon under our Lantibiotics Program, and Oral Mucositis Program, we are responsible for future research and development expenses of product candidates developed under such collaborations, including those incurred by Intrexon for research on our behalf as provided in the ECC Agreements with Intrexon. As a result we expect the level of our overall research and development expenses going forward will increase. The timing and amount of expenses under our ECCs are difficult to predict. Although all manufacturing, nonclinical studies and human clinical trials are expensive and difficult to design and implement, costs associated with the manufacturing, research and development of biologic product candidates are generally greater in comparison to small molecule product candidates. We expect to add additional personnel to support our Lantibiotics Program, and Oral Mucositis Program with Intrexon.

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

We may not be able to retain the exclusive rights licensed to us by Intrexon to develop and commercialize lantibiotics, and AG013.

Under our ECCs with Intrexon we are responsible for, among other things, funding the further anticipated development of lantibiotics, and AGO13 toward the goal of commercialization, conducting nonclinical and clinical development of product candidates, as well as for other aspects of manufacturing and the commercialization of the product(s). During the first 16 months of the Oral Mucositis ECC, Intrexon may not terminate such ECC, except under limited circumstances. Intrexon may terminate such agreements if we do not perform certain specified requirements, including exercising diligent efforts and developing therapies identified to us and considered superior by Intrexon. There can be no assurance that we will be able to successfully perform under the ECC's and if any of the ECC's are terminated it would prevent us from achieving our business objectives with respect to such ECC.

We are currently exploring strategic alternatives for our probiotic business and there can be no assurance that such strategic alternatives will result in any successful agreements or transactions.

In December of 2014, we announced that we would explore strategic alternatives for the probiotic business. These alternatives could include joint ventures, strategic partnerships or alliances, a sale of the probiotic products business or other possible transactions. There can be no assurance that the exploration of strategic alternatives will result in any agreements or transactions, or that, if completed, any agreements or transactions will be successful or on attractive terms.

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

Our MU1140 homologs and other product candidates are in early stage development and will require partners with substantial financial resources to continue the development of each of these products to commercialization. In addition, none of these product candidates have received regulatory approval in any jurisdiction and they may never receive approval or, if approvals are obtained, may never be commercialized successfully. There can be no assurance we will be able to establish a partner relationship or sublicense our Replacement Therapy technology for future development. In addition, we do not know whether any of our clinical trials will be successful or can be completed within our current expected budget. For our MU1140 homologs and other antibiotic product candidates, we have performed extensive nonclinical testing using native MU1140 and expect to continue to pursue the nonclinical testing of our MU1140 homologs and other antibiotic product candidates during the remainder of 2015. Even if we are able to partner and conduct successful clinical trials or the required regulatory approvals are obtained, we may never be able to generate significant revenues from our MU1140 homologs or other antibiotic product candidates or other product candidates. If our MU1140 homologs product candidate or our other product candidates under the Lantibiotics Program and Oral Mucositis Program or otherwise are unsuccessful, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, financial condition and results of operations will be materially adversely affected.

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

Our revenues and operating results could vary significantly from quarter to quarter due to a variety of factors, many of which are outside of our control. As a result, comparing our operating results on a period-to-period basis may not be meaningful. In addition, we may not be able to predict our future revenues or results of operations. We base our current and future expense levels on our internal operating plans and sales forecasts, and our operating costs are to a large extent fixed. As a result, we may not be able to reduce our costs sufficiently to compensate for an unexpected shortfall in revenues, and even a modest shortfall in revenues could

disproportionately and adversely affect financial results for that quarter. Individual products represent meaningful portions of our revenues in any quarter. We may incur significant or unanticipated expenses associated with our research and development efforts of our product candidates under development. In addition to other risk factors discussed in this section, factors that may contribute to the variability of our quarterly results include:

- the timing of release of new products and services by us and our competitors, particularly those that may represent a significant portion of revenues in any given period;
- the popularity of new products, and products released in prior periods;
- changes in pricing policies by us or our competitors;
- fluctuations in the size and rate of growth of overall consumer and retailer demand for our ProBiora3 products;
- our success in entering new geographic markets;
- decisions by us to incur additional expenses, such as increases in marketing or research and development;
- the level of expenses associated with our clinical trials;
- accounting rules governing recognition of revenues;
- the amount we reserve against returns and allowances; and
- the timing of compensation expense associated with equity compensation grants.

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

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

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

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

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

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

The processing, formulation, packaging, labeling and advertising of our probiotic products are subject to regulation by one or more federal agencies including the FDA, the Federal Trade Commission and the Environmental Protection Agency. Our activities are also

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

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

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

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

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

We hold our MU1140 product candidate under license from the University of Florida Research Foundation, Inc., or UFRF. We are required to make minimum annual maintenance payments to the UFRF for the term of the amended license agreements in the amount of $10,000. The aggregate minimum annual payments are required to be paid in advance on a quarterly basis. We are also required to pay all patent costs and expenses incurred by the UFRF for the preparation, filing, prosecution, issuance and maintenance of the patents.

The UFRF may terminate our license to MU1140 if we breach our obligations to timely pay these amounts, to submit development reports as required under the license agreement or commit any other breach of any other covenants contained in the license agreement and we fail to remedy such breach within 90 days after written notice of such breach by UFRF. There is no assurance that we will be able to comply with these conditions in a timely manner or at all. If our license agreements are terminated, we will be unable to commercialize these product candidates.

If we are able to commercialize any product candidates, we are obligated to pay 5% of the selling price of any products developed from the licensed technologies that we may sell as royalty to the UFRF. In addition, if we sublicense any rights granted by the amended license agreements, we are obligated to pay the UFRF 22% of all revenues received from the sublicenses, excluding monies received solely for development costs. We are also obligated to make the following payments to UFRF as follows: a one-time commercialization fee, post-commercialization minimum royalty payments, and a one-time cumulative royalty payment. The one-time commercialization fee would be due on the first anniversary of first commercial sale and is calculated at $5,000 per month between (1) April 1, 2013 for the MU1140 license agreement and (2) the month of the first anniversary of a commercial sale. The post-commercialization minimum royalty payments of $50,000 annually would be due following payment of a commercialization fee. The one-time additional royalty payment would be due when total cumulative royalties paid to UFRF exceed $2.0 million, upon which we would be obligated to make a one-time additional payment to UFRF of 10% of the total royalties due to UFRF in the calendar year in which cumulative royalties exceeded $2.0 million.

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

We depend on third-party manufacturers for our ProBiora3 products 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 had produced 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 second quarter of 2014, 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.

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

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

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

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

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

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

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

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

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

We rely on the significant experience and specialized expertise of our senior management and scientific team and the loss of any of our key personnel or our inability to successfully hire a permanent CEO could harm our business

Our performance is substantially dependent on the continued services and on the performance of our senior management and scientific team, who have extensive experience and specialized expertise in our business. Our performance also depends on our ability to retain and motivate our other key employees (Dr. Martin Handfield and Mr. Albert Fosmoe). In October 2014, our chief executive officer resigned and our Board of Directors is working to identify a successor. Mr. Michael Sullivan, Certified Public Accountant who was hired in February 2012 as our Chief Financial Officer, is currently acting as our Interim Principal Executive Officer while a replacement for the vacancy is being sought. The loss of the services of senior management or any key employees could harm our ability to develop and commercialize our product candidates. We have no key man life insurance policies.

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

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

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

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

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

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

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

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

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

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

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

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

Our product and product candidates are protected by patents and patent applications, including patents exclusively licensed from the University of Florida Research Foundation, Inc. ("UFRF") and Texas A&M University. We are the exclusive worldwide licensee to the patents for MU1140, which are owned by the UFRF. Our success depends in part on our ability to obtain patents or rights to patents, protect trade secrets, operate without infringing upon the proprietary rights of others, and prevent others from infringing on

our patents, trademarks and other intellectual property rights. We will be able to protect our intellectual property from unauthorized use by third parties only to the extent that it is covered by valid and enforceable patents, trademarks and licenses. Patent protection generally involves complex legal and factual questions and, therefore, enforceability of patent rights cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from others may not provide adequate protection against competitors. In addition, any future patent applications may fail to result in patents being issued. Also, those patents that are issued may not provide us with adequate proprietary protection or competitive advantages against competitors with similar product candidates. Moreover, the laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States.

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

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

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

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

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

We initiated our first Phase 1 clinical trial in April 2005, but we found it difficult to find subjects who fit the FDA's highly cautious inclusion and exclusion criteria, particularly with respect to the subjects' lack of dentition. We concluded this trial early after enrolling only two of the 15 planned subjects. The FDA then recommended that we revise the protocol for the evaluation of ten healthy male subjects, ranging from 18 to 30 years old and with normal dentition, in an institutionalized setting. After we submitted additional information, the FDA issued another clinical hold letter in June 2007 for the proposed trial with the attenuated strain, citing the need for a plan with respect to serious adverse effects; a plan for the eradication of the attenuated strain in trial subjects' offspring; and a required pregnancy test for female partners of subjects. We submitted additional protocols in response to the FDA's concerns. In August 2007, the FDA issued another clinical hold letter with required revisions to the protocol for offspring of subjects. We submitted a response to the clinical hold letter in September 2007, and the FDA removed the clinical hold for our Phase 1 trial in the attenuated strain in October 2007.

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

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

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

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

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

If we fail to obtain regulatory approval for our product candidates, we may have to cease further development. Clinical trials on our product candidates are expected to take several years to fully complete. The commencement or completion of nonclinical studies or clinical trials can be delayed or prevented for a number of reasons, including:

- difficulties in finding a partner with the resources to support large and expensive clinical development and commercialization costs;
- findings in nonclinical studies;
- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;
- difficulties obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;
- challenges recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including the size and nature of patient population, proximity of patients to clinical sites, eligibility criteria for the trial, nature of the trial protocol, the availability of approved effective treatments for the relevant condition and competition from other clinical trial programs for similar indications;
- severe or unexpected drug or biologic-related side effects experienced by patients in a clinical trial; and
- difficulties retaining patients who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the trial, lack of efficacy, side effects, or personal issues, or who are lost to further follow up.

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

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

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

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

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

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

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

The commercial success of our ProBiora3 products, our MU1140 and homologs antibiotic product candidates, and oral mucositis product candidates and any of our other product candidates and technologies, will depend in part on market acceptance by consumers. Biopharmaceutical companies have received substantial support from the scientific community, regulatory agencies and many governmental officials in the United States and internationally. Future scientific developments, media coverage and political events may diminish such support. Public attitudes may be influenced by claims that health products are unsafe for consumption or pose unknown risks to the environment or to traditional social or economic practices. Securing governmental approvals for, and consumer confidence in, such products poses numerous challenges, particularly outside the United States. The market success of product candidates developed by biopharmaceutical companies could be delayed or impaired in certain geographical areas as a result. Products based on our product candidates may compete with a number of traditional dental therapies and drugs manufactured and marketed by major pharmaceutical companies and biotechnology companies. Market acceptance of products based on our product candidates will depend on a number of factors including potential advantage over alternative treatment methods. We can offer you no assurance that dentists, physicians, patients or the medical and dental communities in general will accept and utilize products developed from our product candidates. If they do not, we may be unable to generate significant revenues from our product candidates and our business, financial condition and results of operations will be materially adversely affected.

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

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

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. For example, in certain foreign markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the United States, recent federal and state government initiatives have been directed at lowering the total cost of health care. In March 2010, President Obama signed into law

the Patient Protection and Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Federal and state legislatures will likely continue to focus on health care reform, controlling the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

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

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

Risks Related to Our Common Stock

Our principal shareholders have the ability to affect all actions requiring shareholder approval and your interests as a shareholder may conflict with the interests of those persons.

As of September 30, 2015, the Koski Family Limited Partnership (“KFLP”), together with members of the Koski family, beneficially owns approximately 29.9% of our outstanding shares of common stock. Additionally, Christine L. Koski and Robert C. Koski, serve on our Board of Directors. Intrexon, together with its CEO, beneficially owns approximately 26.6% of our outstanding shares of common stock. As a result, our principal shareholders have the ability to affect the outcome of all matters requiring shareholder approval, including the election and removal of directors, amending our charter or by-laws, and agreeing to or preventing mergers, consolidations or the sale of all or substantially all our assets. In particular, this concentration of ownership of our common stock could have the effect of delaying or preventing a change of control of us or otherwise discouraging or preventing a potential acquirer from attempting to obtain control of us. This, in turn, could have a negative effect on the market price of our common stock. It could also prevent our shareholders from realizing a premium over the market price for their shares of common stock. Moreover, the interests of this concentration of ownership may not always coincide with our interests or the interests of other shareholders, and, accordingly, our majority shareholders could cause us to enter into transactions or agreements that we would not otherwise consider. The significant concentration of stock ownership may also adversely affect the trading price of our common stock due to investors’ perception that conflicts of interest may exist or arise. However with respect to Intrexon, the Stock Issuance Agreement we entered into with Intrexon on June 9, 2015, contains a standstill provision pursuant to which, among other things, Intrexon has agreed that until June 9, 2018, subject to certain exceptions and unless invited in writing by the Company to do so, neither Intrexon nor its affiliates will, directly or indirectly: (i) effect or seek, initiate, offer or propose to effect, or cause or participate in any acquisition of securities or assets of the Company; any tender or exchange offer, merger, consolidation or other business combination involving the Company; any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to the Company; or any “solicitation” of “proxies” or consents to vote any voting securities of the Company, or in any way advise or, assist any other person in doing so; (ii) form, join or in any way participate in a “group” with respect to any securities of the Company; (iii) otherwise act to seek to control or influence the management, Board of Directors or policies of the Company; (iv) take any action reasonably expected to force the Company to make a public announcement regarding any such matters; or (v) enter into any agreements, discussions or arrangements with any third party with respect to any of the foregoing. This standstill provision could also have the effect of delaying, deferring or preventing a change in control that our shareholders might consider to be in their best interests.

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

Our board of directors has authority, without action or vote of our shareholders, to issue all or a part of our authorized but unissued shares, except where shareholder approval is required by law. Any issuance of additional equity securities by us in the future could result in dilution to our existing shareholders. Such issuances could be made at a price that reflects a discount or a premium to the then-current trading price of our common stock. In addition, our business strategy may include expansion through internal growth by acquiring complementary businesses, acquiring or licensing additional products or brands, or establishing strategic relationships with targeted customers and suppliers. In order to do so, or to finance the cost of our other activities, we may issue additional equity securities that could result in further dilution to our existing shareholders. These issuances would dilute your percentage ownership

interest, which would have the effect of reducing your influence on matters on which our shareholders vote, and might dilute the book value of our common stock. For example, we have recently issued a significant number of shares of our common stock in connection with financings and establishing strategic relationships and as a result our outstanding shares have increased from 27,382,830 shares as of December 31, 2012 to 36,178,944 shares as of December 30, 2014.

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

In connection with the new Oral Mucositis ECC we entered into on June 9, 2015, we will be required, at our option, to pay up to $32.0 million cash to Intrexon or issue up to $32.0 million of additional shares of our common stock to Intrexon upon meeting certain commercialization milestones. We also issued the Convertible Note in the amount of $5,000,000 which is payable, at our option, in cash or shares of our common stock.

You may also incur additional dilution if performance awards are made pursuant to any long term incentive programs for executives and non-employee directors we may put into place or holders of stock options, whether currently outstanding or subsequently granted, exercise their options, or if warrant holders exercise their warrants to purchase shares of our common stock. For example, during the year ended December 31, 2013 we issued an aggregate of 727,090 shares of our common stock to our executive officers and non-employee directors pursuant to performance awards under our long term incentive which expired on December 31, 2014. During the quarter ended March 31, 2015, as part of our non-employee director compensation program we issued an aggregate of 200,000 restricted shares of our common stock to our non-employee directors under the Company's 2012 Equity Incentive Plan.

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

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

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

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

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

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

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

The trading price of our common stock has historically been, and may in the future be, subject to wide fluctuations in response to a number of factors, many of which are beyond our control. These factors include:

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

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

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

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur. In addition, these factors could make it more difficult for us to raise funds through future offerings of common stock. We have recently issued a significant number of shares of common stock and the number of outstanding shares has increased from 27,382,830 shares as of December 31, 2012 to 36,477,536 as of September 30, 2015.

As of September 30, 2015, there were 36,477,536 shares of our common stock outstanding, with another 175,584 shares of common stock issuable upon exercise of warrants to investors, 1,452,531 shares issuable upon exercise of options outstanding and an additional 670,007 shares available for option grants under our 2012 Equity Incentive Plan. The issuance of shares of our common stock under our 2012 Equity Incentive Plan is covered by Form S-8 registration statements we filed with the Securities and Exchange Commission, or SEC, and upon exercise of the options, such shares may be resold into the market. We have also issued shares of common stock and warrants in connection with previous private placements. Such shares are available for resale as well as certain of the shares of common stock issuable upon exercise of the warrants. We have also issued shares of our common stock in the private placement and financing transaction, which are deemed to be "restricted securities," as that term is defined in Rule 144 promulgated under the Securities Act of 1933, as amended, or Securities Act, and such shares may be resold pursuant to the provisions of Rule 144. For example, on September 30, 2013 we issued 1,348,000 restricted shares of our common stock to Intrexon as part of the technology access fee for the LBPs ECC and on the same date we also sold 1,300,000 restricted shares of our common stock to Intrexon in a private placement. The resale of shares acquired from us in private transactions could cause our stock price to decline significantly.

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

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

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

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

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

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

(a) We issued the following restricted securities during the period covered by this report to the named individual pursuant to exemptions under the Securities Act of 1933 including Section 4(2):

On August 3, 2015, we issued 98,592 shares to Griffin Securities, Inc. ("Griffin") pursuant to Griffin's partial cashless exercise of 185,585 warrant shares issued to Griffin in connection with our July 2012 Private Financing.

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 6th day of November, 2015.

ORAGENICS, INC.

BY: /s/ Michael Sullivan

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

EXHIBIT INDEX

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (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

Exhibit 31.1

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 6th day of November, 2015

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

Exhibit 31.2

CERTIFICATION

I, Michael Sullivan, certify that:

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

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

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

4. The registrant's other certifying 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 6th day of November, 2015

By: /s/ Michael Sullivan
Michael Sullivan
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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, 2015 (the "Report") of Oragenics, 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 6, 2015

Exhibit 32.2

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, 2015 (the "Report") of Oragenics, 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 6, 2015