# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

	FORM 10-Q	
	T TO SECTION 13 OR 15(d) OF THE SECURITI	IES EXCHANGE
For the	quarterly period ended March 31, 2015.	
	OR	
☐ TRANSITION REPORT PURSUANT ACT OF 1934	T TO SECTION 13 OR 15(d) OF THE SECURITI	IES EXCHANGE
For the trai	nsition period from to	
Co	ommission File Number: 001-32188	
	AGENICS, INC. ume of registrant as specified in its charter)	
FLORIDA (State or other jurisdiction of incorporation or organization)	59-3410522 (IRS Employer Identification No.	.)
	4902 Eisenhower Blvd., Suite 125 Tampa, Florida 33634 (Address of principal executive offices)	
	813-286-7900 (Issuer's telephone number)	
	s filed all reports required to be filed by Section 13 or 15(d) of this (or for such shorter period that the registrant was required the past 90 days. Yes 🗵 No 🗆	
	bmitted electronically and posted on its corporate Web site, if ant to Rule 405 of Regulation S-T during the preceding 12 morpost such files). Yes ⊠ No □	
	rge accelerated filer, an accelerated filer, a non-accelerated filer, "accelerated filer," "non-accelerated filer," and "smaller re	
Large accelerated filer □	Acce	elerated filer
Non-accelerated filer □	Smal	ller reporting company 🗵
Indicate by check mark whether the registrant is a sh	nell company (as defined in Rule 12b-2 of the Exchange Act).	Yes □ No ⊠
State the number of shares outstanding of each of the	e issuer's classes of common equity, as of the latest practicable	e date:
As of May 8, 2015, there were 36,378,944 shares of	Common Stock, \$.001 par value, outstanding.	

PART I -	- FINANCIAL INFORMATION	Page
Item 1.	Financial Statements	3
	Balance Sheets as of March 31, 2015 (unaudited) and December 31, 2014	3
	Statements of Operations for the Three Months Ended March 31, 2015 and 2014 (unaudited)	4
	Statements of Cash Flows for the Three Months Ended March 31, 2015 and 2014 (unaudited)	4
	Notes to Financial Statements (unaudited)	(
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	14
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	23
Item 4.	Controls and Procedures	23
PART II	- OTHER INFORMATION	24
Item 1.	<u>Legal Proceedings</u>	24
Item 1A.	Risk Factors	24
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	26
Item 3.	<u>Defaults Upon Senior Securities</u>	26
Item 4.	Mine Safety Disclosures	26
Item 5.	Other Information	26
Item 6.	<u>Exhibits</u>	26
Signature	S	27

# PART I - FINANCIAL INFORMATION ITEM 1. FINANCIAL STATEMENTS

# Oragenics, Inc.

# **Balance Sheets**

	March 31, 2015	December 31, 2014
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,053,468	\$ 10,448,921
Accounts receivables, net	29,561	15,608
Inventory, net	377,016	439,189
Prepaid expenses and other current assets	133,793	119,410
Total current assets	9,593,838	11,023,128
Property and equipment, net	167,657	109,292
Total assets	\$ 9,761,495	\$ 11,132,420
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 509,318	\$ 710,210
Short-term notes payable	79,390	64,840
Deferred revenue	17,276	21,222
Total current liabilities	605,984	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 36,378,944 and 36,178,944		
shares issued and outstanding at March 31, 2015 and December 31, 2014	36,379	36,179
Additional paid-in capital	86,356,544	86,244,604
Accumulated deficit	(77,237,412)	(75,944,635)
Total shareholders' equity	9,155,511	10,336,148
Total liabilities and shareholders' equity	\$ 9,761,495	\$ 11,132,420

See accompanying notes.

# Oragenics, Inc.

# Statements of Operations (Unaudited)

	For the Three <b>N</b> Marc	
	2015	2014
Revenue, net	\$ 363,774	\$ 214,660
Cost of revenue	167,997	79,760
Gross profit	195,777	134,900
Operating expenses:		
Research and development	676,595	1,016,464
Selling, general and administrative	815,465	767,394
Total operating expenses	1,492,060	1,783,858
Loss from operations	(1,296,283)	(1,648,958)
Other income (expense):		
Interest income	6,616	10,839
Interest expense	(606)	(571)
Local business tax	(2,000)	(2,194)
Other expense	(504)	
Total other income (expense), net	3,506	8,074
Loss before income taxes	(1,292,777)	(1,640,884)
Income tax benefit	<u> </u>	
Net loss	\$ (1,292,777)	\$(1,640,884)
Basic and diluted net loss per share	\$ (0.04)	\$ (0.05)
Shares used to compute basic and diluted net loss per share	36,212,278	36,109,444

See accompanying notes.

# Oragenics, Inc.

# Statements of Cash Flows (Unaudited)

		For the Three Months Ended March 31,		
	2015	2014		
Cash flows from operating activities:				
Net loss	\$ (1,292,777)	\$ (1,640,884)		
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	13,872	6,487		
Stock issued as compensation to non-employee directors	66,000	5,545		
Stock-based compensation expense	46,140			
Changes in operating assets and liabilities:				
Accounts receivable, net	(13,953)	21,550		
Inventory, net	62,173	22,500		
Prepaid expenses and other current assets	35,012	71,574		
Accounts payable and accrued expenses	(200,892)	(102,581)		
Deferred revenue	(3,946)	31,561		
Net cash used in operating activities	(1,288,371)	(1,584,248)		
Cash flows from investing activities:				
Purchase of property and equipment	(72,237)	(18,889)		
Net cash used in investing activities	(72,237)	(18,889)		
Cash flows from financing activities:				
Payments on short-term notes payable	(34,845)	(34,419)		
Net cash used in financing activities	(34,845)	(34,419)		
Net decrease in cash and cash equivalents	(1,395,453)	(1,637,556)		
Cash and cash equivalents at beginning of period	10,448,921	16,276,510		
Cash and cash equivalents at end of period	\$ 9,053,468	\$14,638,954		
Supplemental disclosure of cash flow information:				
Interest paid	\$ 606	\$ 599		
Non-cash investing and financing activities:				
Borrowings under short term notes payable for prepaid expense	40.005	<b>* * * 0 * 0 1</b>		
	\$ 49,395	\$ 50,694		
Par value of common stock issued for cashless exercise of warrants	<u> </u>	\$ 135		
Par value of restricted shares issued	\$ 200	<u>\$</u>		

See accompanying notes.

#### Oragenics, Inc.

# Notes to Financial Statements (Unaudited)

#### 1. Organization

Oragenics, Inc. (formerly known as Oragen, Inc.) (the "Company" or "we") was incorporated in November 1996; however, operating activity did not commence until 1999. 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.

#### 2. Basis of Presentation

The accompanying unaudited interim financial statements as of March 31, 2015 and December 31, 2014 (audited) and for the three months ended March 31, 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 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the financial condition, results of operations and cash flows for the periods presented. The results of operations for the interim period March 31, 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 \$363,774, incurred a net loss of \$1,292,777, and used cash of \$1,288,371 in its operating activities during the three months ended March 31, 2015. As of March 31, 2015, the Company had an accumulated deficit of \$77,237,412.

During 2012 and 2011, a significant source of debt and equity funding was provided to the Company by its largest shareholder, the Koski Family Limited Partnership (the "KFLP"). In 2013 the Company raised \$3,900,000 in gross proceeds through a private placement sale of its common stock and \$9,904,996 in net proceeds through an underwritten public offering. The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes the working capital at March 31, 2015 will be sufficient to meet the business objectives as presently structured over the next twelve months.

The Company's ability to continue operations after its current cash resources are exhausted depends on its ability to obtain additional financing or achieve profitable operations, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in the Company's focus and direction of its research and development programs, competitive and technical advances, limitation of financial resources, or other developments. Additional financing will be required for the Company to continue operations beyond March 31, 2016. 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**

There are no new accounting pronouncements issued or effective during the three months ended March 31, 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 U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. The principal areas of estimation reflected in the financial statements are anticipated milestone payments, stock based compensation, valuation of warrants, income tax valuation allowance, inventory obsolescence reserve, sales returns and allowances and the allowance for doubtful accounts.

# **Guaranteed Rights of Return**

The Company has granted guaranteed rights of return to two dental distributors. The Company defers recognition of revenue on these accounts until either the distributor provides notification to the Company that the product has been sold to the end consumer or the guaranteed right of return period expires. Once notification has been received and verified, the Company records revenue in that accounting period. The Company had \$17,276 and \$21,222 of revenue deferred under guaranteed rights of return arrangements included in deferred revenue in the balance sheets as of March 31, 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 \$59,200 and \$50,100 as of March 31, 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, shares associated with the stock options and warrants are not included because they are antidilutive. Basic and diluted net loss per share amounts are the same for the periods presented. Net loss per share is computed using the weighted average number of shares of common stock outstanding.

#### **Revenue Recognition**

The Company recognizes revenues from the sales of product when title and risk of loss pass to the customer, which is generally when the product is shipped.

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 months ended March 31, 2015. The majority of the Company's cost of revenues is from these key suppliers during the three months ended March 31, 2015 and 2014. Accounts payable and accrued expenses for these vendors totaled approximately \$-0- and \$189,120 as of March 31, 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 March 31, 2015, the uninsured portion of this balance was \$8,803,091. 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:

	Months Ended ch 31, 2015	Three Months Ended March 31, 2014		
Research and development	\$ 20,917	\$	10,037	
Selling, general and administrative	 91,223		(4,492)	
Total Stock based compensation	\$ 112,140	\$	5,545	

The Company granted 900,000 stock options, with a weighted-average grant date fair value of \$1.30 per share, during the three months ended March 31, 2015. The Company did not grant stock options during the three months ended March 31, 2014.

During the three months ended March 31, 2015, 6,667 stock options previously granted have vested and 80,000 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 March 16, 2015, 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 March 16, 2015, 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 (\$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 three months ended March 31, 2015 is as follows:

		Weighted Average	
	Warrants	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	_	_	
Expired	(2,170,925)	(2.00)	
Balance - March 31, 2015	361,169	\$ 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.

The warrants outstanding as of March 31, 2015 are as follows:

Exercise Price	Warrants Outstanding	<b>Expiration Dates</b>
\$1.50	361,169	7/31/17
	361,169	

#### 6. Short-Term Notes Payable

As of March 31, 2015 and December 31, 2014, the Company had \$79,390 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 July 24, 2014, the Company entered into a short-term note payable for \$108,306 bearing interest at 4.647% to finance a portion of the directors' and officers' liability insurance and employment practices liability insurance premiums. Principal and interest payments on this note began August 24, 2014 and are made evenly based on a straight line amortization over an 11-month period with the final payment being due on June 24, 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.

#### 7. Commitments and Contingencies

The University of Florida Research Foundation Licenses

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

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

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

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

#### Texas A&M License Agreement

Under the terms of the Texas A&M license agreement, the Company made an initial payment of five thousand dollars (\$5,000) to Texas A&M. The Company must also pay to Texas A&M a royalty of five percent (5%) of net sales of products that include the licensed technology, subject to royalty stacking provisions with a two percent (2%) minimum royalty. Additionally, in order to

maintain the exclusive license, commencing in 2014 and each year thereafter prior to the calendar year of the first sale of products using the licensed technology, the Company must pay Texas A&M \$15,000 as minimum consideration for the continuation of the license agreement. Once the Company commences the sale of products that include the technology the Company licenses from Texas A&M the Company must pay a minimum annual amount of \$100,000 to Texas A&M and every year thereafter through the expiration of the Agreement. However, once sales begin, any royalty payments the Company makes on net sales will be credited against the \$100,000 required maintenance payment.

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

Pursuant to the Texas A&M license agreement, the Company 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, 2015, with a milestone achievement payment of \$50,000, (ii) completion of Phase II clinical trial using the licensed technology to occur on or before June 1, 2019, with a milestone achievement payment of \$100,000, (iii) completion of Phase III clinical trial of the licensed technology to occur on or before June 1, 2022, with a milestone achievement payment of \$150,000, and (iv) first sale of the licensed technology to occur on or before June 1, 2025 with a milestone achievement payment of \$400,000. If we fail to accomplish the milestones or fail to achieve net sales of products including the licensed technology for two consecutive calendar years Texas A&M at its sole option may waive the requirement, negotiate the missed milestones or terminate the license agreement. None of the Texas A&M milestones had been achieved as of March 31, 2013. The Company plans to seek an extension of the first enrollment of a patient milestone referred to above prior to the due date.

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

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

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

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

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

None of the Lantibiotic ECC milestones had been achieved as of March 31, 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 revenue and milestone payments described above with respect to these "retained" products as well as to use diligent efforts to develop and commercialize these "retained" Oragenics Products will survive termination of the Lantibiotic ECC.

#### The LBPs ECC

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

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

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

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

• \$10,000,000 within thirty (30) days of the first to occur of (a) the First Commercial Sale (as that term is defined in the LBPs ECC) of a Company Product, or (b) the approval of a New Drug Application (as that term is defined in the LBPs ECC) for a Company Product by the FDA or equivalent regulatory action in a foreign jurisdiction.

None of the LBPs ECC milestones had been achieved as of March 31, 2015.

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

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

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

# 8. Related Party Transactions

During the three months ended March 31, 2015 and 2014, we paid \$13,828 and \$540,025, respectively, to Intrexon Corporation (Intrexon) under the Exclusive Channel Collaboration Agreements (ECC Agreements) (See Note 7). Included in accounts payable and accrued expenses at March 31, 2015 and 2014 was \$2,871 and \$316,353, respectively, related to unpaid invoices received from Intrexon relating to work performed under the ECC Agreements. As of March 31, 2015 and 2014 Intrexon owned approximately 24% of our outstanding common stock.

#### 9. 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 10,000 restricted shares vested on March 31, 2105 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 \$198,000 in unrecognized compensation expense relating to these awards that will be recognized pro-rata through the remainder of 2015.

#### 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-O.

#### 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. 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 since 1927 when the first lantibiotic, Nisin, was discovered. We believe lantibiotics are generally recognized by the scientific community to be potent antibiotic agents.

We have performed nonclinical testing on MU1140, which has demonstrated the molecule's novel mechanism of action. 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.

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

In order to meet the challenge associated with producing sufficient quantities of MU1140 for our clinical trials and ultimately our commercialization efforts, in June 2012, we entered into the Lantibiotic Exclusive Channel Collaboration agreement ("ECC") with Intrexon for the development and commercialization of the native strain of MU1140 and related homologs using Intrexon's advanced transgene and cell engineering platforms. We continue to pursue our research and development and collaboration efforts with Intrexon in accordance with the terms of the Lantibiotic ECC toward the development of the MU1140 molecule and potential derivatives of the molecule. We commenced limited nonclinical activities on MU1140 developed under the Lantibiotic ECC with Intrexon, in the second half of 2013. Through our work with Intrexon, we have been able to produce an exponential increase in the fermentation titer of the target compound MU1140 and the discovery of a new purification process for MU1140. Since then, our exclusive collaboration generated a substantial number of homologs of MU1140, and we screened these homologs and found several candidates with either enhanced therapeutic profiles or different specificities against resistant bacteria from that of the parent compound, MU1140. The decision to examine these new homologs of MU1140 meant we had to reproduce the fermentation and purification steps on at least 10-15 homologs. Each homolog requires different optimizations for both the fermentation and purification steps and in many cases required a new approach. As such our work on the development of new lantibiotic homologs using genetically modified bacteria continues.

We are working with third party manufacturers to produce additional quantities of designated homologs, based upon the developments achieved from our work with Intrexon and outside contractors. The additional quantities of designated homologs that are needed for the consummation and pursuit of our nonclinical testing activities including the pre-IND meeting, technology transfer to a GLP manufacturing facility and the drug product necessary for completing all pre-IND studies are underway. In support of a pre Investigational New Drug ("IND") filing with the FDA to study lantibiotics for the treatment of a *c. diff* infection, a specific animal model is traditionally utilized as part of the IND submission to show efficacy against the infection. The Syrian Golden Hamster model has been accepted by the FDA as the model to show efficacy of any investigational product. Completing the animal studies based on the Syrian Golden Hamster model with lantibiotics has presented some additional unforeseen challenges to us and hence the animal model study has been slightly delayed. We, however, remain optimistic that we will be able to work through such challenges and as such we continue to expect to have a pre IND meeting with the FDA in the second half of 2015 and thereafter be in a position to file the IND for a first-in-human clinical study in 2016.

#### Our Probiotic Products

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

Since initial commercialization of our ProBiora3 products we have attempted to improve market awareness and sales of our oral probiotic product line with limited success to date and we have reduced our marketing expenditures accordingly to focus more on lantibiotics. 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. While exploring strategic alternatives we expect to continue to operate the consumer probiotic business, but we do not expect any significant increase in sales in the near future due to the limited amount of marketing resources we are committing to this product at this time.

#### Live Biotherapeutic Products (LBPs)

On September 30, 2013, we entered into a second worldwide exclusive channel collaboration agreement with Intrexon that governs a "channel collaboration" arrangement in which we will use Intrexon's proprietary technology relating to the identification, design, culturing and/or production of genetically modified cells, DNA vectors and in vivo control of expression for the development and commercialization of LBPs, specifically the direct administration to humans of genetically modified bacterial LBPs for the treatment of diseases of the oral cavity, throat, sinus and esophagus, including, but not limited to, aphthous stomatitis and Behcet's disease (the "LBPs ECC"). Our efforts in connection with developing bacteria-based biotherapeutics for oral cavity, throat, sinus and esophagus diseases, is being reconsidered. Our initial planned focus was to develop a genetically engineered bacterial strain designed to deliver and release a therapeutic locally at the oral disease sites to target pain management, reduce inflammation, and improve patient outcomes in Behcets Disease (and/or Aphtous Stomatitis). In reviewing and considering the potential opportunities, we concluded that other therapeutic indications may be more commercially viable, and as such, we are exploring other options for the planned focus areas with respect to this collaboration.

# Other Product Candidates and Technologies

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

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

enrollment difficulties we encountered with our initial Phase 1a clinical trial and with our phase 1b clinical trial, we determined to discontinue pursuit of our Phase 1b clinical trial. Our focus for the SMaRT Replacement Therapy technology is on possible partnering opportunities that may exist or for consideration in our LBP program.

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

#### About Us

We were incorporated in November 1996 and commenced operations in 1999. We consummated our initial public offering in June 2003. We have devoted substantially all of our available resources to the commercialization of our ProBiora3 products as well as our discovery efforts comprising research and development, clinical trials for our product candidates, protection of our intellectual property and the general and administrative support of these operations. We have generated limited revenues from grants and ProBiora3 product sales through March 31, 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 \$363.774 and \$214,660 for the three months ended March 31, 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 March 31, 2015, we had an accumulated deficit of \$77,237,412 and we have yet to achieve profitability. We incurred net losses of \$1,292,777 and \$1,640,884 for the three months ended March 31, 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 \$363,774 for the three months ended March 31, 2015. 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 continue to 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.

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 \$676,595 and \$1,016,464 for the three months ended March 31, 2015 and 2014, respectively.

Our current strategy is to increase 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 with respect to our LBPs projects. 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 LBPs 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.

# 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 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 our historical loss carryforwards up to such point in time were limited. Furthermore, our transactions with Intrexon during 2013 constituted a second such event, and 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 March 31, 2015 and 2014

*Net Revenues.* We generated net revenues of \$363,774 for the three months ended March 31, 2015 compared to \$214,660 for the three months ended March 31, 2014 an increase of \$149,114. Our ProBiora3 revenues increased from March 31, 2014 due primarily to increased sales to our international distributors.

Cost of Revenue. Cost of revenue was \$167,997 for the three months ended March 31, 2015 compared to \$79,760 for the three months ended March 31, 2014, an increase of \$88,237. This increase was due primarily to an increase in revenues during the period from sales to our international distributors and an increase in scrap expense. Gross margin for the three months ended March 31, 2015 was 53.8% versus 62.8% for the same period in 2014. The decrease in margin was attributable to the sales to our international distributors which occur at lower margin rates.

**Research and Development.** Research and development expenses were \$676,595 for the three months ended March 31, 2015 compared to \$1,016,464 for the three months ended March 31, 2014, a decrease of \$339,869 or 33.4%. This decrease was primarily due to decreases in consulting costs, costs associated continued development of our lantibiotic candidate or probiotic candidate, and patent costs of \$22,600, \$471,486 and \$15,100, respectively which were partially offset by increases in salary related costs of \$160,199.

*Selling, General and Administrative.* Selling, general and administrative expenses were \$815,465 for the three months ended March 31, 2015 compared to \$767,394 for the three months ended March 31, 2014, an increase of \$48,071 or 6.3%. This increase was primarily due to increases in stock-based compensation costs, legal costs, accounting costs, board costs and filing fees of \$95,715, \$13,572, \$10,417, \$38,250, and \$24,381, respectively, which were partially offset by decreases in salary and bonus costs of \$67,981 and \$48,125 respectively.

*Other Income (Expense).* Other income (expense), net was \$3,506 for the three months ended March 31, 2015 compared to \$8,074 for the three months ended March 31, 2014, resulting in a net change of \$4,568. The net change was primarily attributable to a decrease in interest income of \$4,223 due to lower cash balances.

# **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 three months ended March 31, 2015 and 2014, our operating activities used cash of \$1,288,371 and \$1,584,248, 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 \$8,987,854 and \$10,226,856 at March 31, 2015 and December 31, 2014, respectively.

During the three months ended March 31, 2015 and 2014, our investing activities used cash of \$72,237 and \$18,889, respectively.

During the three months ended March 31, 2015 and 2014, our financing activities used cash of \$34,845 and \$34,419, respectively. The cash used by financing activities during the three months ended March 31, 2015 was primarily due to the payments made on 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 the Probiotics ECC. The Technology Access Fee was paid to Intrexon by us through the (i) issuance of 1,348,000 (at \$3.00 per share) shares of our common stock (the "Technology Access Shares"), and (ii) a convertible promissory note in the amount of \$1,956,000 which was payable, at our option, in cash or shares of our common stock (the "Convertible Note"). The Convertible Note matured on December 31, 2013 and required us to obtain shareholder approval prior to conversion of the Convertible Note. On December 18, 2013, we issued 698,241 shares of our common stock to Intrexon in satisfaction of principal and interest due on the Convertible Note at a conversion price of \$2.82 per share. The conversion price was equal to the closing price per share of our common stock on the last trading day immediately prior to the date of conversion.

### The November 2013 Underwritten Public Offering

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

# Other Financings

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

On March 10, 2014, we entered into a short-term note payable for \$50,694 bearing interest at 6.57% per annum to finance the product liability insurance. Principal and interest payments on this note began April 10, 2014 and are made evenly based on a straight line amortization over a 10-month period with the final payment 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 due on June 24, 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.

# **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 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 our existing cash and cash equivalents will allow us to fund our operating plan through March 2016. We expect to continue to seek additional funding for our operations. The sale of additional equity or debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We also will require additional capital beyond our currently forecasted amounts, for example, as we continue to work with Intrexon under the Lantibiotic ECC for the development of MU1140 and in our new LBPs 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 Corporation;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities for our ProBiora3 products and, if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- 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 three months ended March 31, 2015.

# **Recently Issued Accounting Pronouncements**

There are no new accounting pronouncements issued or effective during the three months ended March 31, 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 March 31, 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 March 31, 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

In addition to the other information set forth in this Form 10-Q, you should carefully consider the factors discussed in Part I, Item 1A, subsection "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 which could materially affect our business, financial condition or future results of operations. The risks described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 are not the only risks that we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition and future results of operations. The following information updates, and should be read in conjunction with, the risk factors previously disclosed in Item 1A, subsection "Risk Factors" to Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 filed on February 27, 2015.

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

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

We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of approximately and \$1.3 million and \$1.6 million for the three months ended March 31, 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 March 31, 2015 our accumulated deficit was approximately \$77.2 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 Corporation in the areas of lantibiotics ("Lantibiotics Program") and probiotics ("Probiotics Program") and the development and commercialization of our product candidates under the Lantibiotics Program (which includes MU1140) and Probiotics Program using Intrexon's advanced transgene and cell engineering platforms will continue to increase the level of our overall expenses significantly going forward. As a result, we expect to continue to incur substantial net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' equity and working capital. Because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to accurately predict the timing or amount of substantial expenses or when, or if, we will be able to generate the revenue necessary to achieve or maintain profitability.

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

Developing and commercializing biopharmaceutical products, including conducting nonclinical studies and clinical trials and establishing manufacturing capabilities, is expensive. We anticipate that our cash resources as of March 31, 2015 will be sufficient to fund our operations as presently structured over the next twelve months. However, changes may occur that would consume our existing capital prior to that time, including the scope and progress of our efforts to develop and commercialize our product candidates. Our actual costs, as well as the actual revenues from sales of our ProBiora3 products, may ultimately vary from our current expectations, which could materially impact our use of capital and our forecast of the period of time through which our financial resources will be adequate to support our operations. Our current cash, cash equivalents and short-term investments are not sufficient to fully implement our business strategy and sustain our operations over a longer period of time. Accordingly, we will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete existing nonclinical and planned clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development and commercialization of one or more of our product candidates, curtail or forego sales and marketing efforts, and/or forego licensing attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

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

Currently our sole source of product revenues is from sales of our ProBiora3 products, which have generated only modest revenues to date. Sales of our ProBiora3 products were \$363,774, \$214,660, and \$153,673 for the three months ended March 31, 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.

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 is able to produce one of the strains of bacteria needed to produce ProBiora3. This supplier uses proprietary methodologies to produce this strain of bacteria. We had previously received notice from a supplier producing two of the three bacteria strains needed to produce our ProBiora3 products, that it was discontinuing 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.

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

Under our ECCs with Intrexon we are responsible for, among other things, funding the further anticipated development of lantibiotics and LBPs 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 18 months, neither we nor Intrexon may terminate the ECC's, except under limited circumstances. Intrexon may terminate such agreements if we do not perform certain specified requirements, including developing therapies identified to us and considered superior by Intrexon. There can be no assurance that we will be able to successfully perform under the ECC's and if the ECC's are terminated it would prevent us from achieving our business objectives.

# Our 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 March 31, 2015, the Koski Family Limited Partnership ("KFLP"), together with members of the Koski family, beneficially owns approximately 30.7% 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 27.0% 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 September 30, 2013, contains a standstill provision pursuant to which, among other things, Intrexon has agreed that until September 30, 2016, 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.

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

None.

#### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

#### ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

#### **ITEM 5. OTHER INFORMATION**

None.

#### **ITEM 6. EXHIBITS**

Incorporated by reference to Exhibits filed after signature page.

# **SIGNATURES**

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 8th day of May, 2015.

# ORAGENICS, INC.

BY: /s/ Michael Sullivan

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

# EXHIBIT INDEX

F 100		Incorporated by Reference				
Exhibit number	Exhibit description	Form	File no.	Exhibit	Filing date	Filed herewith
10.1+	Amended and Restated Executive Employment Agreement Of Michael Sullivan dated effective January 1, 2015	8-K	001-32188	10.1	2/25/15	
10.2+	Executive Employment Agreement Of Albert Fosmoe dated effective January 1, 2015	8-K	001-32188	10.2	2/25/15	
10.3+	Form of Notice of Grant of Stock Options (Employee)	8-K	001-32188	10.1	3/18/15	
10.4+	Form of Notice of Grant of Stock Options (Directors)	8-K	001-32188	10.2	3/18/15	
10.5+	Form Of Director Restricted Stock Award Agreement	8-K	001-32188	10.3	3/18/15	
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

<sup>+</sup> Executive management contract or compensatory plan or arrangement.

#### 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 8th day of May, 2015

By: /s/ Michael Sullivan

Michael Sullivan Interim Principal Executive Officer (Principal Executive Officer)

#### CERTIFICATION

- I, Michael Sullivan, certify that:
- 1. I have reviewed this Quarterly Report on Form 10-Q of Oragenics, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
- (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
- (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
- (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
- (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors:
- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated this 8th day of May, 2015

By: /s/ Michael Sullivan

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

#### Certification

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

In connection with the Quarterly Report on Form 10-Q for the quarter ended March 31, 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: May 8, 2015

#### 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 March 31, 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: May 8, 2015