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

FORM 10-Q

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

For the quarterly period ended March 31, 2016.

OR

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

For the transition period from _____ to _____

Commission File Number: 001-32188

ORAGENICS, INC.

(Exact name of registrant as specified in its charter)

FLORIDA
(State or other jurisdiction of
incorporation or organization)

59-3410522
(IRS Employer
Identification No.)

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

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

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

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

As of May 16, 2016, there were 40,058,540 shares of Common Stock, \$.001 par value, outstanding.

Table of Contents

	Page
<u>PART I – FINANCIAL INFORMATION</u>	
Item 1. <u>Financial Statements.</u>	3
<u>Balance Sheets as of March 31, 2016 (unaudited) and December 31, 2015</u>	3
<u>Statements of Operations for the Three Months Ended March 31, 2016 and 2015 (unaudited)</u>	4
<u>Statements of Cash Flows for the Three Months Ended March 31, 2016 and 2015 (unaudited)</u>	5
<u>Notes to Financial Statements (unaudited)</u>	6
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations.</u>	14
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk.</u>	20
Item 4. <u>Controls and Procedures.</u>	20
<u>PART II – OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings.</u>	21
Item 1A. <u>Risk Factors.</u>	21
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds.</u>	23
Item 3. <u>Defaults Upon Senior Securities.</u>	23
Item 4. <u>Mine Safety Disclosures.</u>	23
Item 5. <u>Other Information.</u>	23
Item 6. <u>Exhibits.</u>	23
<u>Signatures</u>	24

[Table of Contents](#)

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Oragenics, Inc.

Balance Sheets

	<u>March 31, 2016</u> (Unaudited)	<u>December 31,</u> <u>2015</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,367,647	\$ 5,083,355
Accounts receivables, net	32,748	21,115
Inventory, net	241,482	321,509
Prepaid expenses and other current assets	<u>192,891</u>	<u>211,749</u>
Total current assets	3,834,768	5,637,728
Property and equipment, net	<u>122,364</u>	<u>140,651</u>
Total assets	<u>\$ 3,957,132</u>	<u>\$ 5,778,379</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 986,744	\$ 969,787
Short-term notes payable	78,800	63,352
Deferred revenue	<u>17,687</u>	<u>14,215</u>
Total current liabilities	1,083,231	1,047,354
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 40,058,540 and 39,858,540 shares issued and outstanding at March 31, 2016 and December 31, 2015	40,059	39,859
Additional paid-in capital	92,552,695	92,347,134
Accumulated deficit	<u>(89,718,853)</u>	<u>(87,655,968)</u>
Total shareholders' equity	<u>2,873,901</u>	<u>4,731,025</u>
Total liabilities and shareholders' equity	<u>\$ 3,957,132</u>	<u>\$ 5,778,379</u>

See accompanying notes.

[Table of Contents](#)

Oragenics, Inc.

Statements of Operations
(Unaudited)

	For the Three Months Ended March 31,	
	2016	2015
Revenue, net	\$ 262,258	\$ 363,774
Cost of revenue	89,954	167,997
Gross profit	172,304	195,777
Operating expenses:		
Research and development	1,241,410	676,595
Selling, general and administrative	994,426	815,465
Total operating expenses	2,235,836	1,492,060
Loss from operations	(2,063,532)	(1,296,283)
Other income (expense):		
Interest income	2,596	6,616
Interest expense	(771)	(606)
Local business tax	(1,178)	(2,000)
Other expense	—	(504)
Total other income (expense), net	647	3,506
Loss before income taxes	(2,062,885)	(1,292,777)
Income tax benefit	—	—
Net loss	\$ (2,062,885)	\$ (1,292,777)
Basic and diluted net loss per share	\$ (0.05)	\$ (0.04)
Shares used to compute basic and diluted net loss per share	39,956,318	36,212,278

See accompanying notes.

[Table of Contents](#)

Oragenics, Inc.

Statements of Cash Flows
(Unaudited)

	For the Three Months Ended	
	March 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	\$(2,062,885)	\$(1,292,777)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	18,287	13,872
Stock issued as compensation to non-employee directors	42,000	66,000
Stock-based compensation expense	163,761	46,140
Changes in operating assets and liabilities:		
Accounts receivable, net	(11,633)	(13,953)
Inventory, net	80,027	62,173
Prepaid expenses and other current assets	68,253	35,012
Accounts payable and accrued expenses	16,957	(200,892)
Deferred revenue	3,472	(3,946)
Net cash used in operating activities	<u>(1,681,761)</u>	<u>(1,288,371)</u>
Cash flows from investing activities:		
Purchase of property and equipment	<u>—</u>	<u>(72,237)</u>
Net cash used in investing activities	<u>—</u>	<u>(72,237)</u>
Cash flows from financing activities:		
Payments on short-term notes payable	<u>(33,947)</u>	<u>(34,845)</u>
Net cash used in financing activities	<u>(33,947)</u>	<u>(34,845)</u>
Net decrease in cash and cash equivalents	(1,715,708)	(1,395,453)
Cash and cash equivalents at beginning of period	<u>5,083,355</u>	<u>10,448,921</u>
Cash and cash equivalents at end of period	<u>\$ 3,367,647</u>	<u>\$ 9,053,468</u>
<i>Supplemental disclosure of cash flow information:</i>		
Interest paid	<u>\$ 771</u>	<u>\$ 606</u>
<i>Non-cash investing and financing activities:</i>		
Borrowings under short term notes payable for prepaid expense	<u>\$ 49,395</u>	<u>\$ 49,395</u>
Par value of restricted shares issued	<u>\$ 200</u>	<u>\$ 200</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 and on developing effective treatments for oral mucositis. We also develop, market, and sell proprietary probiotics specifically designed to enhance oral health for humans and pets, under the brand names Evora and ProBiora.

2. Basis of Presentation

The accompanying unaudited interim financial statements as of March 31, 2016 and December 31, 2015 (audited) and for the three months ended March 31, 2016 and 2015 have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by US GAAP for complete financial statements. In the opinion of management, the accompanying financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the financial condition, results of operations and cash flows for the periods presented. The results of operations for the interim period ending March 31, 2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016 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, 2015, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2016. 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 \$262,258, incurred a net loss of \$2,062,885, and used cash of \$1,681,761 in its operating activities during the three months ended March 31, 2016. As of March 31, 2016, the Company had an accumulated deficit of \$89,718,853.

The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes the working capital at March 31, 2016 will be sufficient to meet the business objectives as presently structured through June of 2016. As such, there is substantial doubt that we can continue as a going concern.

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

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

3. Significant Accounting Policies

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board issued Accounting Standards Update (ASU) 2016-02, Leases (Topic 842). ASU 2016-02 provides guidance to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the Accounting balance sheet and disclosing key information about leasing arrangements. Previous leases accounting was criticized for failing to meet the needs of users of financial statements because it did not always provide a faithful representation of leasing transactions. In particular, it did not require lessees to recognize assets and liabilities arising from operating leases on the balance sheet.

[Table of Contents](#)

The guidance is effective for annual and interim periods beginning after December 15, 2018.

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

There are no additional accounting pronouncements issued or effective during the three months ended March 31, 2016 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 US 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 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 \$17,687 and \$14,215 of revenue deferred under guaranteed rights of return arrangements included in deferred revenue in the balance sheets as of March 31, 2016 and December 31, 2015, respectively.

Inventory

Inventories are 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 at March 31, 2016 and December 31, 2015 was \$60,660 and \$60,660, 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

US GAAP requires all stock-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.

[Table of Contents](#)

Warrants

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

Net Loss Per Share

During all periods presented, the Company had securities outstanding that could potentially dilute basic earnings per share in the future, but were excluded from the computation of diluted net loss per share, as their effect would have been antidilutive because the Company reported a net loss for all periods presented. 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, 2016. The majority of the Company's cost of revenues is from these key suppliers during the three months ended March 31, 2016 and 2015. Accounts payable and accrued expenses for these vendors totaled approximately \$0- and \$91,138 as of March 31, 2016 and December 31, 2015, 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, 2016, the uninsured portion of this balance was \$3,117,647. As of December 31, 2015, the uninsured portion of this balance was \$4,833,355.

4. Stock-based Compensation

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

	Three Months Ended March 31, 2016	Three Months Ended March 31, 2015
Research and development	\$ 33,633	\$ 20,917
Selling, general and administrative	172,128	91,223
Total Stock based compensation	\$ 205,761	\$ 112,140

Table of Contents

The Company granted 400,000 stock options, with a weighted-average grant date fair value of \$0.82 per share, during the three months ended March 31, 2016. 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.

During the three months ended March 31, 2016, no stock options previously granted have vested and no stock options were forfeited and no stock options were exercised.

In March 2015, the Compensation Committee of the Board of Directors (the "Compensation Committee") recommended and approved, and the Board of Directors approved, a program of annual equity based awards for directors 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. . 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 which vested at the end of each calendar quarter in 2015, provided the recipient remained a director through the vesting date.

The new equity based programs also include a minimum dollar value stock ownership holding requirement threshold before shares can be sold.

On February 15, 2016, 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 \$0.84 per share, the closing price on the February 16, 2016, 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 2016, provided the recipient remains a director through the vesting date.

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, and Dr. Handfield, the Company's Senior Vice President of Discovery Research, were granted options to purchase 200,000 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.

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, 2015 and the three months ended March 31, 2016 is as follows:

	<u>Warrants</u>	<u>Weighted Average Price</u>
Balance – December 31, 2014	2,532,094	\$ 1.93
Granted	—	—
Exercised	(185,585)	1.50
Expired	(2,170,925)	(2.00)
Balance – December 31, 2015	175,584	1.50
Granted	—	—
Exercised	—	—
Expired	—	—
Balance – March 31, 2016	<u>175,584</u>	<u>\$ 1.50</u>

Table of Contents

The warrants outstanding as of March 31, 2016 are as follows:

Exercise Price	Warrants Outstanding	Expiration Dates
\$1.50	175,584	7/31/17
	<u>175,584</u>	

6. Short-Term Notes Payable

As of March 31, 2016 and December 31, 2015, the Company had \$78,800 and \$63,352, respectively, in short-term notes payable for the financing of various insurance policies. On March 1, 2016, we entered into a short-term note payable for \$49,395 bearing interest at 5.93% per annum to finance the product liability insurance. Principal and interest payments on this note began April 10, 2016 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on January 10, 2017.

On March 19, 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 being made on January 13, 2016.

On July 28, 2015, the Company entered into a short-term note payable for \$109,067 bearing interest at 4.64% to finance a portion of the directors' and officers' liability insurance and employment practices liability insurance premiums. Principal and interest payments on this note began August 24, 2015 and are made evenly based on a straight line amortization over an 11-month period with the final payment due on June 24, 2016.

7. Commitments and Contingencies

The University of Florida Research Foundation Licenses

UFRF-MU1140 License. In the Company's UFRF amended license agreement for MU1140, the Company is obligated to pay 5% of the selling price of any products developed from the UFRF licensed technology that the Company may sell as royalty to the UFRF. In addition, if the Company sublicenses any rights granted by the amended license agreement, the Company is obligated to pay to the UFRF 22% of all revenues received from the sublicenses, excluding monies received solely for development costs. The Company is also obligated to make the following payments to UFRF as follows: a one-time commercialization fee, post-commercialization minimum royalty payments, and a one-time cumulative royalty payment. The one-time commercialization fee would be due on the first anniversary of first commercial sale and is calculated at \$5,000 per month between (1) April 1, 2013 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 agreement in the amount of \$10,000 for the license agreement. The aggregate minimum annual payments are required to be paid in advance on a quarterly basis (i.e. \$2,500 per quarter) for the license. The Company must also pay all patent costs and expenses incurred by the UFRF for the preparation, filing, prosecution, issuance and maintenance of the patents.

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

Table of Contents

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

Texas A&M License Agreement

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

The Company must also pay all patent costs and expenses for the preparation, filing, prosecution, issuance and maintenance of the patent rights. Sales by sublicensees are subject to the royalty rate above, and the Company is responsible for certain payments to Texas A&M for any other consideration received that are 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 1 clinical trial using the licensed technology, to occur on or before June 1, 2016, with a milestone achievement payment of \$50,000, (ii) completion of Phase 2 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 3 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, 2016. The Company plans to seek an extension of the first enrollment of a patient milestone referred to above prior to the due date.

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 sublicensee in the event of a sublicensing arrangement.

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

- (i) upon filing of the first Investigational New Drug application with the U.S. Food and Drug Administration for an Oragenics Product, that number of shares equal to the number of shares of common stock comprising 1.0% of the Base Shares (as defined below);
- (ii) upon the dosing of the first patient in the first Phase 2 clinical study with an Oragenics Product, that number of shares equal to the number of shares of common stock comprising 1.5% of the Base Shares;
- (iii) upon the dosing of the first patient in the first Phase 3 clinical study with an Oragenics Product, that number of shares equal to the number of shares of common stock comprising 2% of the Base Shares;

Table of Contents

- (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, 2016.

The Oral Mucositis ECC

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

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

The Company has also agreed to make certain payments to Intrexon upon the Company’s achievement of designated milestones in the form of shares of Company Common Stock (based upon the fair market value of the shares otherwise required to be issued) unless the issuance of such shares would reasonably likely cause Intrexon to consolidate the Company’s financial statements with Intrexon’s financial statements, or at the Company’s option make a cash payment to Intrexon. The Commercialization Milestone Events and amounts payable are as follows:

- (i) two million United States dollars (\$2,000,000) within thirty (30) days of the first instance of the achievement of the Phase 2 Milestone Event meaning the first dosing of a patient by or on behalf of Oragenics, or an Affiliate or permitted sublicensee of Oragenics, in a Phase 2 clinical trial, whether such occurs in the United States of America under the jurisdiction of the FDA or elsewhere under the jurisdiction of a foreign regulatory agency, for each different Oragenics Product;
- (ii) five million United States dollars (\$5,000,000) within thirty (30) days of the first instance of the achievement of the Phase 2b/3 Milestone Event meaning meeting of the primary endpoint by or on behalf of Oragenics, or an Affiliate or permitted sublicensee of Oragenics, in a Phase 3 clinical trial, whether such occurs in the United States of America under the jurisdiction of the FDA or elsewhere under the jurisdiction of a foreign regulatory agency, for each different Oragenics Product;
- (iii) five million United States dollars (\$5,000,000) within thirty (30) days of the first instance of the achievement of the Regulatory Approval Application Milestone Event for each different Oragenics Product which Regulatory Approval Application Milestone Event meaning for a given Oragenics Product, the first to occur of (a) the filing by Oragenics, an Affiliate thereof, or a permitted sublicensee thereof, of a FDA New Drug Application or a Biologics License Application with the FDA seeking approval of such Oragenics Product, or (b) the filing of an equivalent approval or marketing application for such Oragenics Product with an equivalent regulatory authority in a foreign jurisdiction;
- (iv) ten million United States dollars (\$10,000,000) within thirty (30) days of the first instance of the achievement of the Approval Milestone Event for each different Oragenics Product which Approval Milestone Event meaning the first to occur of (a) the First Commercial Sale of an Oragenics Product anywhere in the Territory, or (b) 90th day after the approval of a FDA New Drug Application for an Oragenics Product by the FDA or equivalent regulatory action in a foreign jurisdiction;
- (v) Oragenics shall pay Intrexon a milestone payment of five million United States dollars (\$5,000,000) within thirty (30) days of the first instance of the achievement of the New Indication Milestone Event meaning the filing by or on behalf of Oragenics, an Affiliate of Oragenics, or a permitted sublicensee of Oragenics a Supplemental FDA Application with the FDA or with another equivalent regulatory agency seeking approval of an indication for use of the product AG013 other than the current regulatory-approved indication; and

Table of Contents

- (vi) Orogenics shall pay Intrexon a milestone payment of five million United States dollars (\$5,000,000) within thirty (30) days of the first instance of the achievement of the New Product Milestone Event meaning the filing of a regulatory package filed with the FDA or with another equivalent regulatory agency by or on behalf of Orogenics, an Affiliate of Orogenics, or a permitted sublicensee of Orogenics, that is deemed (according to relevant FDA guideline) to be a different drug product than AG013.

None of the Oral Mucositis ECC milestones had been achieved as of March 31, 2016.

The Oral Mucositis ECC provides that in the event (i) Orogenics is required to make a milestone payment in cash as an issuance of shares would cause Intrexon to consolidate the Company's financial statements with Intrexon's financial statements, and (ii) Orogenics reasonably concludes that a cash milestone payment would have an adverse effect on its working capital needs over the next twelve (12) months, then such cash payment shall be in the form of an interest bearing promissory note with a maturity date of less than twelve (12) months and include other conventional market terms that would not be expected to unreasonably have an adverse effect on Orogenics working capital needs over such twelve (12) month period.

8. Related Party Transactions

During the three months ended March 31, 2016 and 2015, we paid \$432,605 and \$13,828, respectively, to Intrexon under the ECC agreements (See Note 7). Included in accounts payable and accrued expenses at March 31, 2016 and 2015 was \$407,941 and \$2,871, respectively, related to unpaid invoices received from Intrexon relating to work performed under the ECC Agreements. As of March 31, 2016 and 2015 Intrexon owned approximately 33% of our outstanding common stock.

9. Common Stock

On February 15, 2016, in connection with and in furtherance of the new equity based award program (see Note 4), the Board approved the award of 40,000 restricted shares of Company common stock to each of the Company's non-employee directors, Frederick Telling, Charles Pope, Alan Dunton, Christine Koski and Robert Koski under the Company's 2012 Plan of which a total of 10,000 restricted shares have vested on March 31, 2016 for each non-employee director and the remainder will vest at the end of each calendar quarter in 2016 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. At March 31, 2016, the Company has \$126,000 in unrecognized compensation expense relating to these awards that will be recognized pro-rata through the remainder of 2016.

[Table of Contents](#)

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

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

Forward-Looking Statements

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

Overview

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

Recent Developments

On May 10, 2016, we received notification from the NYSE MKT LLC that we are not in compliance with certain NYSE MKT continued listing standards relating to stockholders' equity as of December 31, 2015. Specifically, we are not in compliance with Section 1003(a)(iii) (requiring stockholders' equity of \$6.0 million or more if it has reported losses from continuing operations and/or net losses in its five most recent fiscal years). As of December 31, 2015, we had stockholders' equity of \$4.7 million. We are required to submit a plan to the NYSE MKT by June 10, 2016 advising of actions we have taken or will take to regain compliance with the continued listing standards by November 10, 2017. We intend to submit a plan by the June 10, 2016 deadline. If we fail to submit a plan, or if our plan is not accepted or if we fail to regain compliance by the deadline, the NYSE MKT may commence delisting procedures.

Our Antibiotic Product Candidate

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

In nonclinical testing, MU1140 has shown activity against all Gram positive bacteria against which it has been tested, including those responsible for a number of healthcare associated infections, or HAIs. A high percentage of hospital-acquired infections are caused by highly resistant bacteria such as methicillin-resistant *Staphylococcus aureus* (MRSA) or multidrug-resistant Gram-negative bacteria. We believe the need for novel antibiotics is increasing as a result of the growing resistance of target pathogens to existing FDA approved antibiotics on the market.

Lantibiotics have been difficult to investigate for their clinical usefulness as a therapeutic agent in the treatment of infectious diseases due to a general inability to produce or synthesize sufficient quantities of pure amounts of these molecules. Traditional fermentation methods can only produce minute amounts of the lantibiotic.

In June 2012, we entered into the Lantibiotic Exclusive Channel Collaboration agreement ("Lantibiotic ECC") with Intrexon Corporation ("Intrexon") for the development and commercialization of the native strain of MU1140 and related homologs using Intrexon's advanced transgene and cell engineering platforms. Through our work with Intrexon, we have been able to produce a significant increase in the fermentation titer of MU1140 compared to standard fermentation methods and have discovered a new purification process for MU1140. Our work with Intrexon has generated a substantial number of homologs of MU1140, and we are continuing our research and development and collaboration efforts with Intrexon to develop potential derivatives of the MU1140 molecule using genetically modified bacteria.

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

Table of Contents

We have selected a lead candidate, OG253, and have had a pre IND meeting with the FDA in November of 2015. We will continue our research and development activities on OG253 and other potential homologs. Subject to sufficient available capital, we expect to file the IND for a first-in-human clinical study of OG253 in the second half of 2016.

Our Oral Mucositis Product Candidate

In June of 2015, we entered into a worldwide Exclusive Channel Collaboration Agreement (“Oral Mucositis ECC”) with Intrexon and Intrexon Actobiotics NV, a wholly-owned subsidiary of Intrexon, pursuant to which we obtained certain exclusive rights to AG013 as a potential treatment of oral mucositis, or OM, which we intend to continue to develop.

In a Phase 1b clinical trial in 25 cancer patients with OM, AG013 was safe and well tolerated. Data published in the journal Cancer showed a 35% reduction of the duration of ulcerative OM in the AG013-treated patients versus the placebo-treated patients. Furthermore, close to 30% of the patients treated with AG013 were full responders while all placebo-treated patients developed ulcerative OM. Additionally, in a Phase 1 pharmacokinetic (PK) study in 10 healthy volunteers, During the first quarter of 2016, we conducted a confirmatory animal study on AG013. We will use the results from that confirmatory study as we move towards a meeting with the Food and Drug Administration with the goal of launching a Phase 2 trial on AG013 for the treatment of oral mucositis in head and neck cancer patients. AG013 bacteria adhered to the buccal mucosa and actively secreted protein locally, resulting in homogeneous exposure to the entire mucosal surface up to 24 hours after administration of a rinse. AG013 has been granted Orphan Drug status in the European Union and we believe it may be eligible for Biologic License Application exclusivity as well as Fast Track designation with the United States Food and Drug Administration.

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

Our Probiotic Products

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

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.

Other Product Candidates and Technologies.

In addition to our lantibiotics and oral mucositis product candidates, we also have other candidates and technologies in the oral care and weight loss areas. We do not intend to continue to develop these potential product candidates and technologies without partnering with a third party. We out-licensed the continued research and development of our weight loss product candidate in December 2013 to, LPThera LLC.

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, 2016, 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 \$262,258 and \$363,774 for the three months ended March 31, 2016 and 2015, respectively, and our net revenues were \$1,175,841 and \$939,926, for the years ended December 31, 2015 and 2014, respectively.

Table of Contents

As of March 31, 2016, we had an accumulated deficit of \$89,718,853 and we have yet to achieve profitability. We incurred net losses of \$2,062,885 and \$1,292,777 for the three months ended March 31, 2016 and 2015, respectively, and \$11,711,333 and \$5,789,519 for the years ended December 31, 2015 and 2014, 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 are derived from sales of our ProBiora3 products which were \$1,175,841 and \$939,926 for the years ended December 31, 2015 and 2014, respectively and \$262,258 and \$363,774 for the three months ended March 31, 2016 and 2015, respectively. Future increases in net revenue for our ProBiora3 products will depend on a number of factors, including our ability to successfully engage in marketing efforts related to our ProBiora3 products, which we have substantially scaled back. Our marketing efforts for our ProBiora3 products have had limited success to date as revenues have not significantly increased from period to period. We may consider options for marketing our ProBiora3 Products that can be cost-effective as we seek to manage the use of our cash resources relative to the research and development we are conducting for our other product candidates while we explore and consider strategic alternatives for our consumer probiotic business.

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

Cost of Revenues

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

Research and Development Expenses

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

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

Our research and development expenses were \$1,241,410 and \$676,595 for the three months ended March 31, 2016 and 2015, respectively.

Our current strategy is to manage our research and development expenses in the future as we continue the advancement of our clinical trials and nonclinical product development programs for our MU1140 product candidate, and our oral mucositis product candidate.

Table of Contents

The lengthy process of completing clinical trials; seeking regulatory approval for our product candidates; and expanding the claims we are able to make, requires expenditure of substantial resources. Any failure or delay in completing nonclinical or clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenues and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Certain of our current product development candidates are not expected to be commercially available until we are able to obtain regulatory approval from the FDA, which is not expected before 2017.

Our plan is to budget and manage expenditures in research and development such that they are undertaken in a cost-effective manner yet still advance the research and development efforts. While we have some control under our Lantibiotic ECC and Oral Mucositis ECC as to the planning and timing of the research and development and therefore the timing of when expenditures may be incurred for various phases of agreed upon projects, actual expenditures can vary from period to period. Subject to available capital, we expect overall research and development expenses to fluctuate as our financial resources permit. Our research and development projects are currently expected to be taken to the point where they can be licensed or partnered with larger pharmaceutical companies.

Selling, General and Administrative Expenses

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

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

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

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

Other Income (Expense)

Other income (expense) includes local business taxes, as well as interest income and expense. Interest income consists of interest earned on our cash and cash equivalents. The primary objective of our investment policy is capital preservation. Interest expense consists primarily of interest and costs associated with our short term indebtedness.

Income Taxes

As of December 31, 2015, we have net operating loss carryforwards of approximately \$81,059,000 to offset future federal and state income taxes. We also have research and development tax credit carryforwards of approximately \$1,708,000 as of December 31, 2015 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 2035 and 2025, 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 one of our significant shareholders, the Koski Family Limited Partnership in June 2009 constituted such an event and the ability to use our historical loss carryforwards to offset income after that point in time were limited. Furthermore, our transactions with Intrexon during 2013 constituted a second such event, and the ability to use our historical loss carryforwards up to December 2013 were further limited. In each period, we have recorded a 100% valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal tax benefit in our statements of operations.

[Table of Contents](#)

Results of Operations for the Three Months Ended March 31, 2016 and 2015

Net Revenues. We generated net revenues of \$262,258 for the three months ended March 31, 2016 compared to \$363,774 for the three months ended March 31, 2015 a decrease of \$101,516. Our ProBiora3 revenues decreased from March 31, 2015 due primarily to a decrease in private label sales.

Cost of Sales. Cost of sales was \$89,954 for the three months ended March 31, 2016 compared to \$167,997 for the three months ended March 31, 2015, a decrease of \$78,043. This decrease was due primarily to a decrease in private label sales during the period. Gross margin for the three months ended March 31, 2016 was 65.7% versus 53.8% for the same period in 2015.

Research and Development. Research and development expenses were \$1,241,410 for the three months ended March 31, 2016 compared to \$676,595 for the three months ended March 31, 2015, an increase of \$564,815. This increase was primarily due to increases in costs associated with work under the ECC's, patent costs, salary and salary related costs, and stock based compensation costs of \$544,339, \$29,090, \$15,708 and \$12,716, respectively. These increases were partially offset by a decrease in consulting costs of \$36,362.

Selling, General and Administrative. Selling, general and administrative expenses were \$994,426 for the three months ended March 31, 2016 compared to \$815,465 for the three months ended March 31, 2015, an increase of \$178,961 or 21.9%. This increase was primarily due to increases in option costs, legal costs, filing and registration fees, selling costs, board fees, employee costs, rent costs, depreciation costs and supplies of \$72,443, \$45,593, \$42,225, \$29,489, \$10,405, \$7,946, \$4,525, \$4,416 and \$4,383, respectively. These increases were partially offset by decreases in consulting costs and accounting fees of \$26,471 and \$15,512, respectively.

Other Income (Expense). Other income, net was \$647 for the three months ended March 31, 2016 compared to \$3,506 for the three months ended March 31, 2015, resulting in a decrease of \$2,859. The net change was primarily attributable to a decrease in interest income of \$4,020 due to decreased cash balances during 2016 partially offset by a decrease in tax expense of \$822.

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, 2016 and 2015, our operating activities used cash of \$1,681,761 and \$1,288,371, 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 \$2,751,537 and \$4,590,374 at March 31, 2016 and December 31, 2015, respectively.

During the three months ended March 31, 2016 and 2015, our investing activities used cash of \$-0- and \$72,237 respectively used primarily for the purchase of property and equipment.

During the three months ended March 31, 2016 and 2015, our financing activities used cash of \$33,947 and \$34,485, respectively. The cash used by financing activities during the three months ended March 31, 2016 and 2015 was primarily due to the reductions in short term notes payable.

Financing

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

Other Financings

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

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

On July 24, 2014, we entered into a short-term note payable for \$108,306 bearing interest at 4.647% to finance a portion of the directors' and officers' liability insurance and employment practices liability insurance premiums. Principal and interest payments on this note began August 24, 2014 and are made evenly based on a straight line amortization over an 11-month period with the final payment being made on June 22, 2015.

Table of Contents

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 being made on January 13, 2016.

On July 28, 2015, we entered into a short-term note payable for \$109,067 bearing interest at 4.64% per annum to finance a portion of the directors' and officers' liability insurance and employment practices liability insurance premiums. Principal and interest payments on this note begin August 24, 2015 and are made evenly based on a straight line amortization over an 11-month period with the final payment due on June 24, 2016.

On March 1, 2016, we entered into a short-term note payable for \$49,395 bearing interest at 5.93% per annum to finance the product liability insurance. Principal and interest payments on this note began April 10, 2016 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on January 10, 2017.

Future Capital Requirements

Our capital requirements for 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 and Phase 2 clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase 2 and 3 clinical testing and manufacture and marketing of any products that are approved for commercial sale. Our plans include seeking both equity and debt financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to ensure continuation of our operations and research and development programs.

Our current available cash and cash equivalents are insufficient to satisfy our liquidity requirements. We believe our existing cash and cash equivalents will allow us to fund our operating plan through June 2016. As such, there is substantial doubt that we can continue as a going concern. We expect to continue to seek additional funding for our operations. 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. 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 Oral Mucositis ECC, we will require additional capital.

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;
- 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.

[Table of Contents](#)

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

Critical Accounting Estimates and Policies

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”). The preparation of financial statements in accordance with US 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, 2015. There have been no material changes to our critical accounting estimates during the three months ended March 31, 2016.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued guidance to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Previous leases accounting was criticized for failing to meet the needs of users of financial statements because it did not always provide a faithful representation of leasing transactions. In particular, it did not require lessees to recognize assets and liabilities arising from operating leases on the balance sheet. The guidance is effective for annual and interim periods beginning after December 15, 2018.

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

There are no additional accounting pronouncements issued or effective during the three months ended March 31, 2016 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 Securities Exchange Act was performed under the supervision and participation of our senior management, including our Interim Principal Executive Officer and Chief Financial Officer. The purpose of disclosure controls and procedures is to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to management, including our Interim Principal Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures. Based upon that evaluation, our Interim Principal Executive Officer and Chief Financial Officer concluded that, as of the end of such period, our disclosure controls and procedures were effective as of March 31, 2016 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.

During 2011, we disclosed and identified several material weaknesses in our internal controls over financial reporting. As of December 31, 2014 we remediated all but one of the identified material weaknesses. The remaining material weakness related to a lack of adequate segregation of duties due to our small number of employees. During the year ended December 31, 2015, we analyzed our processes and systems. Based upon that analysis, we implemented during the fourth quarter several additional processes and system controls that lead us to conclude that we no longer have a lack of adequate segregation of duties. Management believes that the financial statements in our Quarterly Report on March 31, 2016 Form 10-Q fairly present, in all material respects, our financial position, results of operations, and cash flows for the periods presented in conformity with US GAAP.

Table of Contents

Management believes that, existing controls were effective and operating properly as designed. During the three months ended March 31, 2016, 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 and Chief Financial Officer, has concluded there were no other significant changes in our internal controls over financial reporting that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

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

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

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

In addition to the other information set forth in this Form 10-Q, you should carefully consider the factors discussed in Part I, Item 1A, subsection "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 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, 2015 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, 2015 filed on March 31, 2016.

Risks Related to Our Business

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

We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of approximately and \$2.1 million and \$1.3 million for the three months ended March 31, 2016 and 2015, respectively, and approximately \$11.7 million and \$5.8 million for the years ended December 31, 2015, and 2014, respectively. As of March 31, 2016 our accumulated deficit was approximately \$89.7 million. We have devoted a significant amount of our financial resources to research and development, including our nonclinical development activities and clinical trials, and currently we only have our ProBiora3 products available for commercial sale which to date have not generated significant revenue. We expect that the costs associated with our exclusive channel collaborations with Intrexon in the areas of lantibiotics ("Lantibiotics Program") and Oral Mucositis (Oral Mucositis Program) and the

Table of Contents

development and commercialization of our product candidates under the Lantibiotics Program (which includes MU1140), using Intrexon's advanced transgene and cell engineering platforms will continue to increase the level of our overall expenses significantly going forward. As a result, we expect to continue to incur substantial net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' equity and working capital. Because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to accurately predict the timing or amount of substantial expenses or when, or if, we will be able to generate the revenue necessary to achieve or maintain profitability.

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

Developing and commercializing biopharmaceutical products, including conducting nonclinical studies and clinical trials and establishing manufacturing capabilities, is expensive. We anticipate that our cash resources as of March 31, 2016 will be sufficient to fund our operations as presently structured over the next three months. However, changes may occur that would consume our existing capital prior to that time, including the scope and progress of our efforts to develop and commercialize our product candidates. Our actual costs, as well as the actual revenues from sales of our ProBiora3 products, may ultimately vary from our current expectations, which could materially impact our use of capital and our forecast of the period of time through which our financial resources will be adequate to support our operations. Our current cash, cash equivalents and short-term investments are not sufficient to fully implement our business strategy and sustain our operations over a longer period of time. Accordingly, we will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete existing nonclinical and planned clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure, and research and development activities. Specifically, we may need to raise additional capital to, among other things:

- expand our clinical laboratory operations;
- fund our clinical validation study activities;
- expand our research and development activities;
- sustain or achieve broader commercialization of our products;
- acquire or license products or technologies; and
- finance our capital expenditures and general and administrative expenses.

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

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

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

In addition, we could be forced to discontinue product development and commercialization of one or more of our product candidates, curtail or forego sales and marketing efforts, and/or forego licensing attractive business opportunities.

Table of Contents

Our auditor has expressed substantial doubt about our ability to continue as a going concern and absent additional financing we may be unable to remain a going concern.

In light of our recurring losses, accumulated deficit and negative cash flow as described in our notes to our audited financial statements, the report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2015 contains an explanatory paragraph raising substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that may be necessary in the event we are unable to continue as a going concern. If we are unable to establish to the satisfaction of our independent registered public accounting firm that the net proceeds from our financing efforts will be sufficient to allow for the removal of this going concern qualification, we may need to significantly modify our operational plans for us to continue as a going concern. We believe we can continue our current level of operations with the cash we have on hand and current revenues without additional financing through June 2016. Absent sufficient additional financing, we may be unable to remain a going concern.

We recently received a non-compliance letter from the NYSE MKT LLC and we cannot assure you that our shares will continue to be listed on the NYSE MKT.

The listing of our common stock on the NYSE MKT is contingent on our compliance with the NYSE MKT's continued listing standards. On May 10, 2015, we were notified by the NYSE MKT that we were no longer in compliance with the NYSE MKT continued listing standards because our last reported stockholders' equity was below continued listing standards. Specifically, we are not in compliance with Section 1003(a)(iii) (requiring stockholders' equity of \$6.0 million or more if it has reported losses from continuing operations and/or net losses in its five most recent fiscal years). As of December 31, 2015, we had stockholders' equity of \$4.7 million. We are required to submit a plan to the NYSE MKT by June 10, 2016 advising of actions we have taken or will take to regain compliance with the continued listing standards by November 10, 2017. While we intend to submit a plan by the June 10, 2016 deadline, if we fail to submit a plan, or if our plan is not accepted or if we fail to regain compliance by the deadline, the NYSE MKT may commence delisting procedures. There can be no assurance that we will be able to submit an acceptable plan or otherwise regain compliance. A delisting of our common stock from the NYSE MKT could negatively affect the price and liquidity of our common stock and could impair our ability to raise capital in the future.

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.

[Table of Contents](#)

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 16th day of May, 2016.

ORAGENICS, INC.

BY: /s/ Michael Sullivan

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

[Table of Contents](#)

EXHIBIT INDEX

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

CERTIFICATION

I, Michael Sullivan., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Orogenics, 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 16th day of May, 2016

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 16th day of May, 2016

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, 2016 (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 16, 2016

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, 2016 (the "Report") of Orogenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Michael Sullivan, hereby certify, to the best of my knowledge, that:

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

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

/s/ Michael Sullivan

Name: Michael Sullivan
Chief Financial Officer
(Principal Financial Officer)
Date: May 16, 2016