

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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

For the quarterly period ended March 31, 2013.

OR

**TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE EXCHANGE ACT**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-32188

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**ORAGENICS, INC.**

(Exact name of registrant as specified in its charter)

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**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)

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

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

As of May 10, 2013, there were 27,489,080 shares of Common Stock, \$.001 par value, outstanding.

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**PART I – FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

**Orogenics, Inc.**

**Balance Sheets**

	<u>March 31,</u> <u>2013</u>	<u>December 31,</u> <u>2012</u>
	(Unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 8,350,325	\$ 9,925,967
Restricted cash	25,771	61,763
Accounts receivables, net	55,430	69,795
Inventory, net	117,266	124,178
Prepaid expenses and other current assets	<u>210,499</u>	<u>221,838</u>
Total current assets	8,759,291	10,403,541
Property and equipment, net	63,619	84,591
Total assets	<u>\$ 8,822,910</u>	<u>\$ 10,488,132</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,082,214	\$ 1,157,520
Short term notes payable	67,281	47,977
Deferred revenue	<u>24,114</u>	<u>50,989</u>
Total current liabilities	1,173,609	1,256,486
Shareholders' equity:		
Preferred stock, no par value; 20,000,000 shares authorized; none issued and outstanding	—	—
Common stock, \$0.001 par value; 50,000,000 shares authorized; 27,489,080 and 27,382,830 shares issued and outstanding at March 31, 2013 and December 31, 2012, respectively	27,489	27,383
Additional paid-in capital	63,298,134	63,290,625
Accumulated deficit	<u>(55,676,322)</u>	<u>(54,086,362)</u>
Total shareholders' equity	<u>7,649,301</u>	<u>9,231,646</u>
Total liabilities and shareholders' equity	<u>\$ 8,822,910</u>	<u>\$ 10,488,132</u>

*See accompanying notes.*

**Orogenics, Inc.**  
**Statements of Operations**  
**(Unaudited)**

	For the Three Months Ended March 31,	
	2013	2012
Revenue, net	\$ 176,407	\$ 380,527
Cost of sales	63,949	198,209
Gross profit	112,458	182,318
Operating expenses:		
Research and development	745,395	353,198
Selling, general and administrative	1,103,187	1,307,994
Total operating expenses	1,848,582	1,661,192
Loss from operations	(1,736,124)	(1,478,874)
Other income (expense):		
Interest income	6,410	383
Interest expense	(949)	(138,265)
Local business tax	(3,800)	(152)
Other income	144,503	—
Total other expense, net	146,164	(138,034)
Loss before income taxes	(1,589,960)	(1,616,908)
Income tax benefit	—	—
Net loss	\$ (1,589,960)	\$ (1,616,908)
Basic and diluted net loss per share	\$ (0.06)	\$ (0.25)
Shares used to compute basic and diluted net loss per share	27,452,483	6,449,342

*See accompanying notes.*

**Oragenics, Inc.**  
**Statements of Cash Flows**  
**(Unaudited)**

	For the Three Months Ended March 31,	
	2013	2012
<b>Cash flows from operating activities:</b>		
Net loss	\$(1,589,960)	\$(1,616,908)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion of discount on notes payable to shareholder	—	7,463
Depreciation and amortization	20,972	19,565
Stock-based compensation expense	7,615	261,403
Changes in operating assets and liabilities:		
Accounts receivable, net	14,365	29,330
Inventory, net	6,912	112,607
Prepaid expenses and other current assets	61,376	39,516
Accounts payable and accrued expenses	(75,306)	11,690
Deferred revenue	(26,875)	(7,766)
Net cash used in operating activities	(1,580,901)	(1,143,100)
<b>Cash flows from financing activities:</b>		
Borrowings under note payable to shareholder	—	1,250,000
Borrowings under convertible secured note payable to shareholder	—	750,000
Payments on short term notes payable	(30,733)	(31,551)
Restricted cash (receipts) released, net	35,992	(29,144)
Net cash provided by financing activities	5,259	1,939,305
Net increase (decrease) in cash and cash equivalents	(1,575,642)	796,205
Cash and cash equivalents at beginning of period	9,925,967	171,739
Cash and cash equivalents at end of period	\$ 8,350,325	\$ 967,944
<i>Supplemental disclosure of cash flow information:</i>		
Interest paid	\$ 982	\$ 447
<i>Non-cash investing and financing activities:</i>		
Borrowings under short term notes payable for prepaid expense	\$ 50,037	\$ 50,037
Par value of common stock issued for cashless exercise of warrants	\$ 106	\$ —
Conversion of convertible note payable and accrued interest to common stock	\$ —	\$ 8,737,011
Discount on note payable to shareholder for warrants	\$ —	\$ 483,559
Par value of forfeited stock	\$ —	\$ 5

*See accompanying notes.*

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**Oragenics, Inc.**  
**Notes to Financial Statements**  
**(Unaudited)**

**1. Organization**

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

**2. Basis of Presentation**

The accompanying unaudited interim financial statements as of March 31, 2013 and December 31, 2012 (audited) and for the three months ended March 31, 2013 and 2012 have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the financial condition, results of operations and cash flows for the periods presented. The results of operations for the interim period March 31, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013 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, 2012, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 26, 2013. 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 \$176,407, incurred a net loss of \$1,589,960 and used cash of \$1,580,901 in its operating activities during the three months ended March 31, 2013. As of March 31, 2013, the Company had an accumulated deficit of \$(55,676,322).

During 2012 and 2011, a significant source of debt and equity funding was provided to the Company by its largest shareholder, the Koski Family Limited Partnership (the “KFLP”). In addition, in 2012 the Company raised \$13,000,000 in gross proceeds through the private placement sale of its common stock. The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes the working capital at March 31, 2013 will be sufficient to meet the business objectives as presently structured through March 2014.

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.

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### **3. Significant Accounting Policies**

#### **Recently Issued Accounting Pronouncements**

There are no new accounting pronouncements issued or effective during the first quarter of 2013 that have had or are expected to have an impact on the Company's financial statements.

#### **Use of Estimates**

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. The principal areas of estimation reflected in the financial statements are stock based compensation, valuation of warrants, inventory obsolescence reserve, sales returns and allowances and the allowance for doubtful accounts.

#### **Fair Value of Financial Instruments**

The fair value of the Company's cash and cash equivalents, accounts payable and accrued expenses approximate their carrying values due to their short-term nature.

#### **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 the customer provides notification to the Company that the product has been sold to the end consumer. Once notification has been received and verified, the Company records revenue in that accounting period. The Company had \$23,671 and \$27,812 of revenue deferred under guaranteed rights of return arrangements included in deferred revenue in the balance sheets as of March 31, 2013 and December 31, 2012, respectively.

#### **Inventory**

Inventory is stated at the lower of cost or market. Cost, which includes material, labor and overhead, is determined on a first-in, first-out basis. On a quarterly basis, we analyze our inventory levels and reserve for inventory that is expected to expire prior to being sold, inventory that has a cost basis in excess of its expected net realizable value, inventory in excess of expected sales requirements, or inventory that fails to meet commercial sale specifications. Expired inventory is disposed of and the related costs are written off to the reserve for inventory obsolescence. The inventory reserve was approximately \$178,000 and \$253,000 as of March 31, 2013 and December 31, 2012, respectively.

#### **Stock-Based Payment Arrangements**

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

#### **Stock-Based Compensation**

GAAP requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values as of the grant date. Stock-based compensation expense is recorded over the requisite service period in which the grantee provides services to us, to the extent the options do not vest at the grant date and are subject to forfeiture.

## Warrants

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

## Net Loss Per Share

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

## Revenue Recognition

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

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

## Concentrations

The Company is dependent on key suppliers to provide probiotics, blending, warehousing and packaging of its EvoraPlus, EvoraKids, EvoraPro, and Teddy's Pride products. The Company had four key suppliers during the three months ended March 31, 2013 and 2012. The majority of the Company's cost of sales are from these key suppliers during the three months ended March 31, 2013 and 2012. Accounts payable and accrued expenses for these vendors totaled approximately \$2,000 and \$99,000 as of March 31, 2013 and December 31, 2012, respectively.

## 4. Stock-based Compensation

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

	Three Months Ended March 31, 2013	Three Months Ended March 31, 2012
Research and development	\$ (27,097)	\$ 22,716
Selling, general and administrative	34,712	238,687
Total Stock based compensation	<u>\$ 7,615</u>	<u>\$ 261,403</u>

The Company granted 10,000 stock options, with a weighted-average grant date fair value of \$3.52 per share, during the three months ended March 31, 2013. During the three months ended March 31, 2013, 0 stock options previously granted have vested and 26,050 stock options were forfeited.



## 5. Warrants

A summary of warrant activity for the year ended December 31, 2012 and the three months ended March 31, 2013 is as follows:

	<u>Warrants</u>	<u>Weighted Average Price</u>
Balance - December 31, 2011	306,388	\$ 19.14
Granted	2,942,094	1.87
Exercised	—	—
Expired	(12,500)	(6.00)
Balance - December 31, 2012	3,235,982	3.53
Granted	—	—
Exercised	(200,000)	1.50
Expired	—	—
Balance - March 31, 2013	<u>3,035,982</u>	<u>\$ 3.62</u>

On January 31, 2013 Griffin Securities Inc. exercised 200,000 of their previously issued warrants resulting in the issuance of 106,250 shares of our common stock.

The warrants outstanding as of March 31, 2013 are as follows:

<u>Exercise Price</u>	<u>Warrants Outstanding</u>	<u>Expiration Dates</u>
\$1.50	571,169	7/30/17
\$2.00	2,170,925	3/23/15
\$10.00	5,000	4/15/14
\$15.00	161,000	5/30/13
\$26.00	127,888	5/30/13
	<u>3,035,982</u>	

## 6. Short Term Notes Payable

As of March 31, 2013 and December 31, 2012, the Company had \$67,281 and \$47,977 respectively, in short-term notes payable for the financing of various insurance policies. On March 8, 2013, the Company entered into a short-term note payable for \$50,037 bearing interest at 6.57% to finance the product liability insurance. Principal and interest payments on this note began April 10, 2013 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on January 10, 2014.

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## 7. Commitments and Contingencies

### *The University of Florida Research Foundation Licenses*

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

*MU1140* – The Company has exclusively licensed the intellectual property for our MU1140 lantibiotic technology from the UFRF. The original license agreement was dated June 22, 2000 and was subsequently amended on September 15, 2000, July 10, 2002, September 25, 2002, March 17, 2003 and April 19, 2013. The amended license agreement provides the Company with an exclusive worldwide license to make, use and sell products and processes covered by Patent No. 5,932,469 entitled “Antimicrobial Polypeptide, Nucleic Acid and Methods of Use” and includes U.S. patent numbers 6,964,760; 7,067,125; 6,391,285; 6,475,771 and foreign patents. The Company’s license is for the period of the patents, which expire from 2017 through 2019, subject to the performance of terms and conditions contained therein.

*SMaRT Replacement Therapy*—The Company has exclusively licensed the intellectual property for its replacement therapy technology from the UFRF. The original license agreement was dated August 4, 1998 and was subsequently amended on September 15, 2000, July 10, 2002, September 25, 2002, March 17, 2003 and April 19, 2013. The amended license agreement provides the Company with an exclusive worldwide license to make, use and sell products and processes covered by Patent No. 5,607,672, entitled “Replacement Therapy for Dental Caries”, which was filed in the U.S. PTO on June 7, 1995 and made effective on March 4, 1997. The patent will expire on June 7, 2015. The Company’s license is for the period of the patent, subject to the performance of terms and conditions contained therein.

*Additional Terms of UFRF License Agreements*—In the amended license agreements for SMaRT Replacement Therapy and MU1140, the Company is obligated to pay 5% of the selling price of any products developed from the licensed technologies that the Company may sell as royalty to the UFRF. In addition, if the Company sublicenses any rights granted by the amended license agreements, the Company is obligated to pay the UFRF 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 May 1, 2013 and the month of the first anniversary of a commercial sale. The post-commercialization minimum royalty payments of \$50,000 annually would be due following payment of a commercialization fee. The one-time additional royalty payment would be due when total cumulative royalties paid to UFRF exceed \$2.0 million, upon which we would be obligated to make a one-time additional payment to UFRF of 10% of the total royalties due to UFRF in the calendar year in which cumulative royalties exceeded \$2.0 million.

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

### *The Exclusive Channel Collaboration (“ECC”) Agreement with Intrexon Corporation (“Intrexon”)*

On June 5, 2012, the Company entered into ECC Agreement with Intrexon that governs a “channel partnering” arrangement in which the Company will use Intrexon’s advanced transgene and cell engineering platforms for the development and production of lantibiotics, a class of peptide antibiotics that are naturally produced in Gram-positive bacteria and contain the characteristic polycyclic thioether amino acids lanthionine and methylanthionine (collectively, the “Lantibiotics Program”). The ECC Agreement establishes committees comprised of Company and Intrexon representatives that will govern activities related to the Lantibiotics Program in the areas of project establishment, chemistry, manufacturing and controls matters, clinical and regulatory matters, commercialization efforts and intellectual property matters.

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The ECC Agreement grants the Company an exclusive worldwide license to use patents and other intellectual property of Intrexon in connection with the research, development, use, importing, exporting, manufacture, sale, and offer for sale of drug products involving the direct administration to humans or companion animals of a lantibiotic for the prevention or treatment of infectious disease (“Oragenics Products”). Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of Oragenics Products, and otherwise is non-exclusive. Subject to limited exceptions, the Company may not sublicense the rights described without Intrexon’s written consent.

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

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

During the first 18 months of the agreement, neither the Company nor Intrexon may terminate the ECC Agreement, except under limited circumstances, including in the event of a material breach by the other party and Intrexon may terminate the ECC Agreement under certain circumstances if the Company assigns its rights under the ECC Agreement without Intrexon’s consent. Following the first 12 months of the agreement, Intrexon may also terminate the ECC Agreement if the Company fails to use diligent efforts to develop and commercialize Oragenics Products or if the Company elects not to pursue the development of a Lantibiotics Program identified by Intrexon that is a “Superior Therapy” as defined in the ECC Agreement. Following the first 18 months of the agreement, the Company may voluntarily terminate the ECC Agreement at any time upon 90 days written notice to Intrexon.

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

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

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

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

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Under the Stock Issuance Agreement and as part of the ECC Agreement, the Company has also agreed to make certain payments to Intrexon upon the Company's achievement of designated milestones in the form of shares of Company Common Stock or at the Company's option make a cash payment to Intrexon (based upon the fair market value of the shares otherwise required to be 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 Orogenics Product, that number of shares equal to the number of shares of Common Stock comprising 1.0% of the Base Shares;
- (ii) upon the dosing of the first patient in the first Phase 2 clinical study with an Orogenics 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 Orogenics Product, that number of shares equal to the number of shares of Common Stock comprising 2% of the Base Shares;
- (iv) upon the filing of the first New Drug Application ("NDA") or Biologics License Application ("BLA") with the U.S. Food and Drug Administration for an Orogenics 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 Orogenics 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 these milestones had been achieved as of March 31, 2013.

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

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

### Forward-Looking Statements

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

### Overview

We are a healthcare company focused primarily on developing novel antibiotics and oral health products. Within oral health we are marketing our oral health probiotics blend, ProBiora3 to consumers and to dental professionals. We also maintain a suite of other technologies stemming from several years of our research efforts in the oral health space.

#### *Our Antibiotics*

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

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

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

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

- In June 2012, we entered into a worldwide exclusive collaboration agreement (ECC) with Intrexon Corporation (Intrexon) for the development and commercialization of the native strain of MU1140 using Intrexon's advanced transgene and cell engineering platforms. We expect to pursue our research and development efforts with Intrexon in accordance with the terms of the ECC on the development of the MU1140 molecule and potential derivatives of the molecule.
- We also produced a synthetic version of MU1140 known as MU1140-S. We created MU1140-S using our patented, novel organic chemistry synthesis platform known as DPOLT (Differentially Protected Orthogonal Lanthionine Technology). We engaged Bachem Americas, Inc. ("Bachem"), a peptide synthesis manufacturing company to assist us with research on producing greater amounts of MU1140-S. While the work performed by Bachem generated improvements in the yield of components necessary to synthesize MU1140-S, further research was determined to be needed, which was beyond the scope of our initial agreement with Bachem. We continue to pursue this research internally through the use of existing grant funds.

We have previously performed preclinical testing on native MU1140 and such testing has demonstrated the molecule's novel mechanism of action. We expect to begin preclinical activities on either native MU1140, or an analog developed under the ECC with Intrexon, in the second half of 2013. These preclinical activities are expected to include toxicity results, pharmacokinetic studies, and efficacy studies in animals. This work will be done solely by us through the use of outside contractors. Pursuit of clinical trials toward the goal of ultimately obtaining regulatory approval will depend upon further successful advancements in our research collaboration efforts with Intrexon and our efforts to have additional product manufactured. Developments from these efforts will dictate our regulatory path. If our preclinical work is successful, we would expect to file an Investigational New Drug application with the FDA by the first quarter of 2015.

Through our work with Intrexon, we have been able to produce an exponential increase in the fermentation titer of the target compound MU1140 and the discovery of a new purification process for MU1140. We believe these developments represent progress toward our goal of commercial production of sufficient quantities of MU1140 and deliver a step in validating the lantibiotics platform targeting infectious diseases. Previously, the ability to manufacture MU1140 by fermentation was originally thought not to be commercially feasible due to low titers and difficulties in purification. In addition to the optimization of fermentation and purification strategies, we are working to leverage Intrexon's genetic and cell engineering expertise to produce analogs of MU1140 toward the goal of establishing a pipeline of new lantibiotics.

Manufacturing requirements and methods for producing MU1140, or an analog, will primarily be dependent upon the end results of our efforts under the ECC with Intrexon. We are actively seeking a third party manufacturer to produce additional quantities of MU1140, or a designated analog, based upon the developments achieved from our work with Intrexon. The additional quantities of MU1140, or a designated analog, are needed for the consummation and pursuit of our preclinical testing activities.

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### *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, or GRAS. We sell our ProBiora3 products through multiple distribution channels. We continue to seek improvement in the performance of our oral care probiotics business and consistent with these efforts:

- We are focusing our efforts on our direct-to-consumer channel, including internet, as well as on our Dental channel, which entails distribution to dentists throughout the United States.
- We initiated two, double blinded randomized, placebo controlled clinical studies one at the University of Washington and the other at Loma Linda University in California that we believe could allow us to enhance the claims we can make about our ProBiora3 products and assist us in registering the product for commercial sale in the European Union. While we have received preliminary data from the University of Washington study the results are inconclusive and we continue to analyze the data and study parameters. We are also supporting a two-year study in children in Scandinavia.
- To better serve our customers, we continue to evaluate new delivery systems which we believe will enable us to deliver ProBiora3 to new markets and end-users;
- *ProBiora3 Distribution Agreement.* On January 22, 2013, we announced that we entered into a three year distribution agreement with Organic Wave, Inc. Under the terms of the agreement, Organic Wave will be the exclusive distributor of our oral care probiotics for pets in Japan under the EvoraPet name as well as a private label brand. The pet product will contain ProBiora3; our patented proprietary blend of three probiotics specifically designed for improved oral health.
- *European Patent.* On March 12, 2013, we announced we had received our first patent approval in Europe for our ProBiora3. The approval provided additional protection for ProBiora3's proprietary blend of three probiotic bacteria, specifically designed to enhance oral health, whiten teeth and freshen breath. European Patent No. 1659885, entitled "Compositions and Methods for the Maintenance of Oral Health," affords protection for ProBiora3 for use in a broad spectrum of potential applications, including the prevention of tooth decay and periodontal diseases, halitosis, and other therapeutic and cosmetic applications. The claims further protect ProBiora3 in several delivery forms, such as food supplements, tablets, and mouth rinses.

In order to better understand and define our customer base, we conducted detailed market research utilizing outside consultants at the end of 2012. The goal of the research was to develop a plan to improve market awareness and sales of our oral probiotic product line. The effort has produced strategic marketing and sales plans that we have begun to implement. While our quarter over quarter sales of our probiotic product lines may fluctuate we believe that the successful execution of our marketing plans can lead to improved probiotic sales on a year over year sales basis.

### *Other Product Candidates and Technologies*

We also possess and have developed other product candidates and technologies that originated from the discoveries of our scientific team. These other product candidates and technologies include our SMaRT Replacement Therapy, our weight loss agent, LPT3-04, DPOLT which was specifically designed as a methodology for synthesizing lantibiotics using traditional organic chemistry techniques. We continue to consider and evaluate opportunities that could promote the advancement of our other product candidates and technologies. We believe our other product candidates and technologies could provide potential partnership opportunities for us. For our product candidates and technologies we expect to devote limited financial resources toward continued research and development while exploring the possibilities for outlicensing such product candidates or entering into partnerships or collaborative arrangements for the further development of such product candidates.

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

*Our Weight Loss Agent-LPT3-04.* LPT3-04 is a naturally occurring compound that is normally consumed in the human diet in small amounts. In the course of our SMaRT Replacement Therapy research, our scientific team also discovered that consumption of a significant amount of LPT3-04 resulted in dose-dependent weight loss in experimental animal models. We have filed a patent application for use of LPT3-04 for weight regulation with the United States Patent Office. We believe this product candidate is positioned for collaboration, particularly or outlicensing opportunities, which we expect to pursue.

#### *About Us*

We were incorporated in November 1996 and commenced operations in 1999. We consummated our initial public offering in June 2003. We have devoted substantially all of our available resources to the commercialization of our ProBiora3 products as well as our discovery efforts comprising research and development, clinical trials for our product candidates, protection of our intellectual property and the general and administrative support of these operations. We have generated limited revenues from grants and ProBiora3 product sales through December 31, 2012, and have principally funded our operations through the sale of debt and equity securities, including the exercise of warrants issued in connection with these financing transactions. Prior to 2008 our revenues were derived solely from research grants. Since 2008, our revenues have also included sales of our ProBiora3 products, which we initiated in late 2008. Our net revenues were \$176,407 and \$380,527 for the three months ended March 31, 2013 and 2012, respectively, and \$1,331,764 and \$1,444,447 for the years ended December 31, 2012 and 2011, respectively.

As of March 31, 2013, we had an accumulated deficit of \$55,676,322 and we have yet to achieve profitability. We incurred net losses of \$1,589,960 and \$1,616,908 for the three months ended March 31, 2013 and 2012, respectively, and \$13,090,446 and \$7,678,868 for the years ended December 31, 2012 and 2011, 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 are continuing our efforts to raise additional capital. Adequate additional funding may not be available to us on acceptable terms, or at all. We expect that research and development expenses will increase along with general and administrative costs, as we grow and operate our business. There can be no assurance that additional capital will be available to us on acceptable terms, if at all.

#### **Recent Developments**

##### **Exchange Listing**

On April 5, 2013, we were notified that the Company's common stock had been approved for listing on the NYSE: MKT and we began trading on the NYSE: MKT on Wednesday, April 10, 2013 under the ticker symbol OGEN.

##### **Our In-Licensed Technology Agreements**

###### *The University of Florida Research Foundation Licenses*

On April 19, 2013, we entered into amendments (the "Fifth Amendments") to each of our existing exclusive license agreements with the University of Florida Research Foundation, Inc. ("UFRF") for (i) the Antimicrobial Polypeptide, Nucleic Acid and Methods of Use patent (the "MU1140 License Agreement") and (ii) the Replacement Therapy for Dental Carries patent (the "SMaRT Replacement Therapy License Agreement").



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As a result of the Fifth Amendments, our annual payments to UFRF on the license agreements have decreased from \$100,000 to \$20,000 as we continue our efforts with respect to the intellectual property covered by the UFRF licenses. The Fifth Amendments: identified the patents covered; lowered the amount of current annual payments we are required to make to UFRF from \$50,000 to \$10,000; and removed the requirement for us to spend at least \$1.0 million annually on combined research and development. Our obligation to provide a development report to UFRF was revised from bi-annually to annually. In addition, the amount payable to UFRF on all revenue received from sublicensees was increased from 20% to 22%, and additional fees payable to UFRF were added as follows: a new one-time commercialization fee, post-commercialization minimum royalty payments, and a new 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 May 1, 2013 and 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.

## **Financial Overview**

### ***Net Revenues***

Our revenues prior to 2008 consisted exclusively of grant funding from government agencies under the National Science Foundation's, or NSF, and National Institutes of Health's, or NIH, Small Business Innovation Research, or SBIR, grants. Since the initial launch of our ProBiora3 products in late 2008, our net revenues for the year ended December 31, 2008 and thereafter, also included sales of our ProBiora3 products. Sales of our ProBiora3 products were \$1,194,878 and \$1,229,510 for the years ended December 31, 2012 and 2011, respectively. Because of our efforts to increase the distribution of our ProBiora3 products, we expect net revenues to increase in the future. However, our success will depend on a number of factors, including our ability to successfully engage in marketing efforts related to our ProBiora3 products.

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

### ***Cost of Goods Sold***

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

### ***Research and Development Expenses***

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

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

Our research and development expenses were \$745,395 and \$353,198 for the three months ended March 31, 2013 and 2012, respectively.

Our current strategy is to increase our research and development expenses in the future as we continue the advancement of our clinical trials and preclinical product development programs for our MU1140 product candidate and with respect to our probiotic projects. The lengthy process of completing clinical trials; seeking regulatory approval for our product candidates; and expanding the claims we are able to make, requires expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenues and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Our current MU1140 product development candidate is not expected to be commercially available before 2014.

For our other product candidates and technologies, our plan is to reduce expenditures in research and development. We expect to license or partner with larger pharmaceutical companies with respect to our other product candidates, and technologies while committing limited research and development expenditures.

### ***Selling, General and Administrative Expenses***

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

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

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

### ***Other Income and (Expense)***

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

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### **Income Taxes**

As of December 31, 2012 and 2011, we have net operating loss carryforwards of approximately \$48,822,000 and \$36,480,000, respectively, to offset future federal and state income taxes. We also have research and development and investment tax credit carryforwards of approximately \$881,000 and \$551,000 as of December 31, 2012 and 2011, respectively, to offset future federal and state income taxes. Our net operating loss and research and development tax credit carryforwards will expire if not used by 2033 and 2023, respectively. Our ability to utilize our net operating loss and tax credit carryforwards may be limited in the event a change in ownership, as defined in Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, has occurred or may occur in the future. The private placement transaction with the KFLP in June 2009 (the "June 2009 Private Placement") constituted such an event and our historical loss carryforwards were limited. See "Tax Loss Carryforwards." In each period since our inception, we have recorded a 100% valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal tax benefit in our statements of operations.

### **Results of Operations for the Three Months Ended March 31, 2013 and 2012**

**Net Revenues.** We generated net revenues of \$176,407 for the three months ended March 31, 2013 compared to \$380,527 for the three months ended March 31, 2012. Our ProBiora3 revenues decreased from Q1 2012 due primarily to a decline in revenues from sales to our international clients.

**Cost of Goods Sold.** Cost of goods sold was \$63,949 for the three months ended March 31, 2013 compared to \$198,209 for the three months ended March 31, 2012, a decrease of \$134,260. This decrease was primarily attributable to a decrease in revenues from the sales of ProBiora3 to our international clients.

**Research and Development.** Research and development expenses were \$745,395 for the three months ended March 31, 2013 compared to \$353,198 for the three months ended March 31, 2012, an increase of \$392,197 or 111.04%. This increase in research and development expenses was primarily due to increases in consulting costs relating to our ECC with Intrexon and clinical trial costs of \$427,696 and \$78,216, respectively. These increases were offset by decreases in salary and salary related costs, and stock based compensation costs of \$51,897 and \$49,812, respectively.

**Selling, General and Administrative.** Selling, general and administrative expenses were \$1,103,187 for the three months ended March 31, 2013 compared to \$1,307,994 for the three months ended March 31, 2012; a decrease of \$204,807 or 15.65%. This decrease was due to decreases in salary and salary related costs, stock based compensation costs, legal and accounting costs of \$154,215, \$203,482, \$63,500, and \$46,024, respectively. These decreases were offset by increases in consulting and advertising and marketing costs of \$97,719 and \$141,825, respectively.

**Other Income (Expense).** Other income (expense) was \$146,164 for the three months ended March 31, 2013 compared to \$(138,034) for the three months ended March 31, 2012, resulting in a net change of \$284,198. The net change was primarily attributable to an increase in other income of \$144,655 due to the receipt of cash relating to the purchase of our membership interest in our mutual insurer by an unrelated third party. In addition there was a decrease in interest expense of \$137,316 due to the conversion of the note payable with warrants to common stock and the write off of the remaining discount to interest expense.

### **Liquidity and Capital Resources**

Since our inception, we have funded our operations primarily through the sale of equity securities in our initial public offering, the sale of equity securities and warrants in private placements, debt financing and grants. During the three months ended March 31, 2013 and 2012, our operating activities used cash of \$1,580,901 and \$1,143,100, 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 \$7,585,682 and \$9,147,055 at March 31, 2013 and December 31, 2012, respectively.

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During the three months ended March 31, 2013 and 2012, our financing activities provided cash of \$5,259 and \$1,939,305, respectively. The cash provided by financing activities during the three months ended March 31, 2013 was primarily due to the release of restrictions on cash offset by reductions in short term notes payable. The cash provided by financing activities during the three months ended March 31, 2012 was primarily due to the release of restrictions on cash, borrowings under a convertible revolving note payable from a shareholder, offset by reductions in short term notes payable.

## **Financing**

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

On July 30, 2010, we entered into an unsecured revolving credit agreement (the "Credit Facility") with the Koski Family Limited Partnership ("KFLP") an accredited investor and our largest shareholder. Pursuant to the Credit Facility, we were able to borrow up to \$2,000,000 from the KFLP at LIBOR plus 6.0%. The term of the Credit Facility was initially for 12 months commencing August 1, 2010.

On January 24, 2011, we entered into a First Amendment to the Credit Facility (the "First Amendment") to increase the available borrowing from \$2,000,000 to \$2,500,000 and simultaneously therewith we drew on the Credit Facility as amended by the First Amendment to borrow the additional \$500,000 in available funds and executed another revolving unsecured promissory note (the "January 2011 Promissory Note") initially due on July 30, 2011.

On February 4, 2011, we entered into a Second Amendment (the "Second Amendment") to the Credit Facility. As a result of the Second Amendment, we are able to borrow up to an additional \$2,500,000 from the KFLP. Future draws under the Credit Facility, as amended, were limited to \$500,000 per month commencing no earlier than March 2011. Under the Second Amendment, the due date of the amounts then outstanding under the Credit Facility, (the September 2010 Promissory Note, November 2010 Promissory Note and January 2011 Promissory Note) were extended by one year from July 30, 2011 to July 30, 2012. The interest rate remained at LIBOR plus 6.0%. The Second Amendment further provided for the automatic conversion of any amounts borrowed and outstanding under the Credit Facility into securities that we may issue in subsequent securities offerings. Any automatic conversion of amounts outstanding under the Credit Facility would be on the same terms of any such offering. In addition, the Second Amendment provided the KFLP with the right to put any undrawn available amounts under the Credit Facility, as amended, to us and thereby have a note issued to the KFLP.

On each of March 15, 2011, April 5, 2011, May 5, 2011, June 3, 2011, and July 8, 2011 we borrowed an additional \$500,000 under the Credit Facility, as amended, and executed a revolving unsecured promissory note in such amounts that each matured on July 30, 2012.

On June 29, 2011, we entered into a Third Amendment (the "Third Amendment") to the Credit Facility. As a result of the Third Amendment, we increased our availability under the Credit Facility by \$2,000,000 from \$5,000,000 to \$7,000,000. Future draws of the \$2,000,000 in increased availability provided by the Third Amendment to the Credit Facility are limited to \$1,000,000 increments beginning no earlier than August 2011 and October 2011, respectively. All other terms of the Credit Facility remained the same.

On each of August 1, 2011 and October 5, 2011, the Company borrowed an additional \$1,000,000 under the Credit Facility, as amended by the Third Amendment, and executed a revolving unsecured promissory note in such amounts that matured on July 30, 2012.

On December 9, 2011, we entered into a Fourth Amendment (the "Fourth Amendment") to the Credit Facility. The Fourth Amendment increased the available borrowing under the Credit Facility by \$500,000 from \$7,000,000 to \$7,500,000. On December 9, 2011, the Company drew down on the Credit Facility, as amended, to borrow \$500,000 in the newly available funds. All other terms of the Credit Facility remained the same.

On January 23, 2012, we entered into a Fifth Amendment (the "Fifth Amendment") to the Credit Facility. The Fifth Amendment increased the available borrowing under the Credit Facility by \$750,000 from \$7,500,000 to \$8,250,000. On January 23, 2012, we drew down on the Credit Facility, as amended, to borrow \$750,000. All other terms of the Credit Facility remained the same.

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On March 23, 2012, we entered into an Exchange of Notes for Equity Agreement (the “Debt Exchange Agreement”) with the KFLP. Pursuant to the terms of the Debt Exchange Agreement, we issued 6,285,619 shares of common stock and warrants to acquire 1,571,405 shares of common stock to the KFLP in exchange for the cancellation of an aggregate of \$8,737,011 of indebtedness owed to the KFLP under our existing unsecured revolving credit facility (the “Credit Facility”) with the KFLP. The outstanding indebtedness consisted of \$8,250,000 in principal owed on twelve separate promissory notes previously issued by us to the KFLP under the Credit Facility and accrued interest through March 23, 2012 (the closing date) of \$487,011. The Credit Facility was terminated and the previously issued promissory notes thereunder were cancelled. The warrants are exercisable immediately at a price per share of \$2.00 and expire three (3) years from the date of issuance.

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

### *The July 2012 Private Placement*

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

Griffin Securities, Inc. (the “Placement Agent”) served as the placement agent for the Offering. In consideration for services rendered as the Placement Agent in the Offering, we agreed to (i) pay to the Placement Agent cash commissions equal to \$899,698, or 7.0% of the gross proceeds received in the Offering, less certain excluded proceeds, (ii) issue to the Placement Agent, or its designee, a five-year warrant to purchase up to 771,169 shares of our Common Stock (representing 9% of the Common Shares sold in the Offering) with an exercise price of \$1.50 per share (the “Agent Warrants”); and (iii) reimburse the Placement Agent for its reasonable actual out-of-pocket expenses, incurred in connection with the Offering, including reasonable legal fees and disbursements up to a maximum aggregate amount of \$50,000. The determination of the Placement Agent’s fees did not include any shares issued to the KFLP, (in connection with the automatic conversion of its secured debt with us described below) or shares acquired by any officers or directors participating in the Offering. The warrants were valued at \$2.40 per share.

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

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### ***Other Financings***

On March 3, 2011, we entered into a short-term notes payable for \$48,988 bearing interest at 5.48% to finance product liability insurance. Payments on this note are made evenly based on a straight line amortization over a ten-month period with the final payment due on January 10, 2012.

On July 12, 2011, we entered into a short-term note payable for \$77,751 bearing interest at 4.75% to finance a portion of the directors' and officers' liability insurance. Principal and interest payments on this note begin August 24, 2011 and are made evenly based on a straight line amortization over an 11-month period with the final payment due on June 24, 2012.

On March 10, 2012, we entered into a short-term note payable for \$50,037 bearing interest at 6.17% to finance the product liability insurance. Principal and interest payments on this note begin April 10, 2012 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on January 10, 2013.

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

### ***Grants***

On June 10, 2010, we were awarded the matching \$500,000 grant from the NSF to support an SBIR Phase II grant previously awarded in 2008 for further development of our DPOLT platform. On each of June 17, 2010, February 28, 2011, September 29, 2011 and March 29, 2012, we received \$125,000 related to this NSF awarded SBIR II Phase II grant for our DPOLT platform. Proceeds from the financing are to be allocated to further the development of our DPOLT platform, essential to the production of our lead antibiotic, MU1140, subject to the goals set forth by the NSF SBIR Phase II grant received by us.

### ***Future Capital Requirements***

Our capital requirements for 2013 will depend on numerous factors, including the success of our commercialization efforts and of our research and development, the resources we devote to develop and support our technologies and our success in pursuing strategic licensing and funded product development relationships with external partners. Subject to our ability to generate revenues and cash flow from our ProBiora3 products and our ability to raise additional capital including through possible joint ventures and/or partnerships, we expect to incur substantial expenditures to further commercialize or develop our technologies including continued increases in costs related to research, preclinical testing and clinical studies, as well as costs associated with our capital raising efforts and being a public company. We will require substantial funds to conduct research and development and preclinical and Phase 1 clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase 2 and 3 clinical testing and manufacture and marketing of any products that are approved for commercial sale. Our plans include seeking both equity and debt financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to ensure continuation of our operations and research and development programs.

Our current available cash and cash equivalents are sufficient to satisfy our liquidity requirements. We believe our existing cash and cash equivalents will allow us to fund our operating plan through March 2014. We will continue to seek the additional funding for our operations. The sale of additional equity or debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We also will likely require additional capital beyond our currently forecasted amounts, for example, as we continue to work with Intrexon under the ECC for the development of MU1140. 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.

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Because of the numerous risks and uncertainties associated with sales of our ProBiora3 products as well as research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the cash flow generated from our ProBiora3 product sales;
- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical and clinical trials including the research and development expenditures we expect to make in connection with our collaboration with Intrexon Corporation;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities for our ProBiora3 products and, if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing our ProBiora3 products and product candidates and any products we successfully commercialize;
- our ability to 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 licensing arrangements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our products and future products, if any.

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

#### **Critical Accounting Estimates and Policies**

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”). The preparation of financial statements in accordance with GAAP requires us to make estimates and assumptions that affect reported amounts and related disclosures. We consider an accounting estimate to be critical if it requires assumptions to be made that were uncertain at the time the estimate was made; and changes in the estimate or different estimates that could have been made could have a material impact on our results of operations or financial condition. The principal areas of estimation reflected in the financial statements are stock-based compensation, valuation of warrants, sales returns and allowances, inventory obsolescence and allowance for doubtful accounts. For a detailed discussion of our critical accounting estimates, see our Annual Report on Form 10-K for the year ended December 31, 2012. There have been no material changes to our critical accounting estimates during the three months ended March 31, 2013.

#### **Recently Issued Accounting Pronouncements**

There are no new accounting pronouncements issued or effective during the first quarter of 2013 have had or are expected to have an impact on our financial statements.

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**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

**ITEM 4. CONTROLS AND PROCEDURES****Evaluation of Disclosure Controls and Procedures**

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

During 2011, we disclosed and identified several material weaknesses in our internal controls. Since that time we have been working on remediation of the identified material weaknesses and have provided updates in our periodic reports. Management believes progress has been made during the year ended December 31, 2012 and thereafter to remediate material weaknesses in the internal control over financial reporting. Although the control environment has significantly improved during the year ended December 31, 2012 and thereafter when compared to prior periods, a material weakness still remains. Nevertheless, based on a number of factors, including the performance of additional procedures by management designed to ensure the reliability of our financial reporting, management believes that the financial statements in our Quarterly Report of Form-10Q on March 31, 2013 fairly present, in all material respects, our financial position, results of operations, and cash flows for the periods presented in conformity with GAAP.

As previously disclosed and referenced above, the matters involving internal controls and procedures that our management identified and considered to be material weaknesses that have not yet been satisfactorily remediated is insufficient personnel to employ segregation of duties. This risk is expected to remain until such time as the Company is able to expand its personnel in a sufficient manner to satisfactorily address control weaknesses.

**Management's Remediation Initiatives**

Although management has not fully remediated the material weakness mentioned above, management believes progress is being made as we continue the engagement with a consulting firm specializing in Sarbanes-Oxley Section 404 compliance to assist us in the implementation of internal controls for financial reporting and disclosure and our remediation efforts. During 2012, the consulting firm completed an analysis to identify the most critical controls in our environment and a design and operating effectiveness evaluation of those controls was performed. Reasonable remediation activities were identified based on cost and reduction of risk. All planned remediation was completed prior to year-end. Management will continue to monitor and evaluate risk factors affecting our internal controls as our resources and available liquidity permit. Management is responsible for and is committed to achieving and maintaining a strong control environment, high ethical standards, and financial reporting integrity. This commitment continues to be communicated to, and reinforced with, our employees.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Because of the inherent limitations of internal control, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.



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## Changes in Internal Controls over Financial Reporting

Except as indicated in the preceding paragraphs about management's evaluation of disclosure controls and procedures and internal controls, our management, with the participation of our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), has concluded there were no other significant changes in our internal controls over financial reporting that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### Limitations on the Effectiveness of Controls

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

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

## PART II – OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

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

### ITEM 1A. RISK FACTORS

*In addition to the other information set forth in this Form 10-Q, you should carefully consider the factors discussed in Part I, Item 1A, subsection "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 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, 2012 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, 2012 filed on March 26, 2013.*

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

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***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 \$1.6 million for the three months ended March 31, 2013 and 2012, and approximately \$13.1 million and \$7.7 million for the years ended December 31, 2012, and 2011, respectively. As of March 31, 2013 our accumulated deficit was approximately \$55.7 million. We have devoted a significant amount of our financial resources to research and development, including our preclinical development activities and clinical trials, and currently we only have our ProBiora3 products available for commercial sale which to date has not generated significant revenue. We expect that the costs associated with our exclusive channel partnership with Intrexon Corporation and the development and commercialization of our MU1140 product candidates and lantibiotics using Intrexon's advanced transgene and cell engineering platforms, as well as our expected increased marketing and sales efforts for our ProBiora3 products will increase the level of our overall expenses significantly going forward. As a result, we expect to continue to incur substantial net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' equity and working capital. Because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to accurately predict the timing or amount of substantial expenses or when, or if, we will be able to achieve or maintain profitability. The size of our future net losses will depend, in part, on the rate of growth of our expenses and the rate of growth of our revenues. If we are unable to develop and commercialize our other product candidates or if sales revenue from ProBiora3 products is insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

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

Developing and commercializing biopharmaceutical products, including conducting preclinical studies and clinical trials and establishing manufacturing capabilities, is expensive. As a result of the approximately \$12.0 million in net proceeds from our private placement of common stock in July 2012, we anticipate that our cash resources as of March 31, 2013 will be sufficient to fund our operations for at least the next 12 months. However, changes may occur that would consume our existing capital prior to that time, including the scope and progress of our efforts to develop and commercialize our product candidates. Because we currently expect to devote a significant portion of our resources to develop and commercialize our antibiotic product candidates and for ProBiora3 sales and marketing efforts, further progress with the development of our other product candidates including our SMaRT Replacement Therapy, and LPT3-04 product candidates may be significantly delayed and may depend on the success of our development efforts involving our antibiotic 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. If our current cash, cash equivalents and short-term investments are not sufficient to fully implement our business strategy and sustain our operations, we will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development and commercialization of one or more of our product candidates, curtail or forego sales and marketing efforts, and/or forego licensing attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

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

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

***Our success will also depend on our ability to significantly increase sales of our ProBiora3 products which is currently our only source of product revenue and has not generated substantial revenues to date.***

Currently our sole source of product revenues is from sales of our ProBiora3 products, which began in late 2008 and have generated only modest revenues to date. Sales of our ProBiora3 products were \$156,673, \$342,849, and \$299,065 for the three months ended March 31, 2013, 2012, and 2011, and \$1,194,878, \$1,229,510 and \$1,128,895 for the years ended December 31, 2012, 2011 and 2010, respectively. Achieving significant and sustained growth in the Company's ProBiora3 product sales has been a challenge. In order to better understand and define our customer base, in 2012, we conducted detailed market research utilizing outside consultants. The goal of the research was to develop a plan to improve market awareness and sales of our oral ProBiora3 product line. The effort has produced strategic plans that we believe can lead to improved ProBiora3 product sales. While we plan to significantly increase the amount we spend on sales and marketing efforts for our ProBiora3 products, there can be no assurance that it will result in a significant and sustained increase in sales. If we are unable to generate significant revenues from our ProBiora3 products our business, financial condition and results of operations will be materially adversely affected.

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

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

In January 2013, we issued 106,250 shares to Griffin Securities, Inc. ("Griffin") pursuant to Griffin's partial cashless exercise of 200,000 warrant shares issued to Griffin in connection with our July 2012 Private Financing.

## **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

## **ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable.

## **ITEM 5. OTHER INFORMATION**

None.

## **ITEM 6. EXHIBITS**

Incorporated by reference to Exhibits filed after signature page.

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**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 14th day of May, 2013.

**ORAGENICS, INC.**

BY: /s/ John N. Bonfiglio Ph.D.

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

BY: /s/ Michael Sullivan

Michael Sullivan, Chief Financial Officer  
and Principal Accounting Officer

## EXHIBIT INDEX

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
10.1	Exclusive License Agreement between the Company and the University of Florida Research Foundation, Inc. effective August 4, 1998 for Replacement Therapy for Dental Caries (the "Replacement Therapy License Agreement")	SB-2	333-100568	10.1	10/16/02	
10.2	First Amendment to Replacement Therapy License Agreement dated September 15, 2000	SB-2	333-100568	10.2	10/16/02	
10.3	Second Amendment to Replacement Therapy License Agreement dated June 2002	SB-2	333-100568	10.3	10/16/02	
10.4	Third Amendment to Replacement Therapy License Agreement dated September 25, 2002	SB-2	333-100568	10.4	10/16/02	
10.5	Fourth Amendment to Replacement Therapy License Agreement dated March 2003	SB-2/A-3	333-100568	10.36	4/9/03	
10.6	Standard Exclusive License Agreement with Sublicensing Terms between the Company and the University of Florida Research Foundation, Inc. effective June 22, 2000 (the "MU1140 License Agreement")	SB-2	333-100568	10.5	10/16/02	
10.7	First Amendment to the MU1140 License Agreement dated September 15, 2000	SB-2	333-100568	10.6	10/16/02	
10.8	Second Amendment to the MU1140 License Agreement dated June 10, 2002	SB-2	333-100568	10.7	10/16/02	
10.9	Third Amendment to the MU1140 License Agreement dated September 25, 2002	SB-2	333-100568	10.4	10/16/02	
10.10	Fourth Amendment to the Antimicrobial Polypeptide License Agreement dated March 2003	SB-2/A-3	333-100568	10.36	4/9/03	
10.11	Fifth Amendment to Replacement Therapy License Agreement dated April 2013	8-K	001-32188	10.2	4/23/13	
10.12	Fifth Amendment to the MU1140 License Agreement dated April 2013	8-K	001-32188	10.1	4/23/13	
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).					X
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).					X

<u>Exhibit number</u>	<u>Exhibit description</u>	<u>Incorporated by Reference</u>			<u>Filed herewith</u>
		<u>Form</u>	<u>File no.</u>	<u>Exhibit</u>	
101.INS*	XBRL Instance Document				
101.SCH*	XBRL Taxonomy Extension Schema				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase				
101.LAB*	XBRL Taxonomy Extension Label Linkbase				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase				

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

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**

I, John N. Bonfiglio Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Oragenics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying 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 14<sup>th</sup> day of May, 2013

By: /s/ John N. Bonfiglio Ph.D.

John N. Bonfiglio Ph.D.  
Chief Executive Officer

**CERTIFICATION OF CHIEF FINANCIAL OFFICER**

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 14<sup>th</sup> day of May, 2013

By: /s/ Michael Sullivan  
Michael Sullivan  
Chief Financial Officer



**Certification of Chief Executive Officer**  
**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, 2013 (the "Report") of Orogenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, John N. Bonfiglio Ph.D., the Chief Executive Officer of the Registrant, 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/ John N. Bonfiglio Ph.D.

Name: John N. Bonfiglio Ph.D.

Date: May 14, 2013

**Certification of Chief Financial Officer**  
**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, 2013 (the "Report") of Orogenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Michael Sullivan, the Chief Financial Officer of the Registrant, 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

Date: May 14, 2013