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

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**FORM 10-Q**

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

For the quarterly period ended June 30, 2015.

OR

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

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

Commission File Number: 001-32188

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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 August 7, 2015, there were 36,477,536 shares of Common Stock, \$.001 par value, outstanding.



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**PART I - FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

**Oragenics, Inc.**

**Balance Sheets**

|   | <b>June 30,<br/>2015</b> | <b>December 31,<br/>2014</b> |
|---|--------------------------|------------------------------|
|   | (Unaudited)              |                              |
| <b>Assets</b>   |                          |                              |
| Current assets:   |                          |                              |
| Cash and cash equivalents   | \$ 8,043,503             | \$ 10,448,921                |
| Accounts receivables, net   | 26,798                   | 15,608                       |
| Inventory, net  | 364,074                  | 439,189                      |
| Prepaid expenses and other current assets   | 90,389                   | 119,410                      |
| Total current assets  | <u>8,524,764</u>         | <u>11,023,128</u>            |
| Property and equipment, net   | 170,724                  | 109,292                      |
| Total assets  | <u>\$ 8,695,488</u>      | <u>\$ 11,132,420</u>         |
| <b>Liabilities and Shareholders' Equity</b>   |                          |                              |
| Current liabilities:  |                          |                              |
| Accounts payable and accrued expenses   | \$ 548,686               | \$ 710,210                   |
| Short-term notes payable  | 34,767                   | 64,840                       |
| Convertible note payable to shareholder   | 5,000,000                | —                            |
| Deferred revenue  | 17,855                   | 21,222                       |
| Total current liabilities   | <u>5,601,308</u>         | <u>796,272</u>               |
| Shareholders' equity:   |                          |                              |
| Preferred stock, no par value; 20,000,000 shares authorized; none issued and outstanding  | —                        | —                            |
| Common stock, \$0.001 par value; 100,000,000 shares authorized 36,378,944 and 36,178,944 shares issued and outstanding at June 30, 2015 and December 31, 2014 | 36,379                   | 36,179                       |
| Additional paid-in capital  | 86,630,684               | 86,244,604                   |
| Accumulated deficit   | <u>(83,572,883)</u>      | <u>(75,944,635)</u>          |
| Total shareholders' equity  | <u>3,094,180</u>         | <u>10,336,148</u>            |
| Total liabilities and shareholders' equity  | <u>\$ 8,695,488</u>      | <u>\$ 11,132,420</u>         |

*See accompanying notes.*

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## Oragenics, Inc.

Statements of Operations  
(Unaudited)

|   | For the Three Months<br>Ended June 30, |                       | For the Six Months<br>Ended June 30, |                       |
|---|--|-----------------------|--------------------------------------|-----------------------|
|   | 2015                                   | 2014                  | 2015                                 | 2014                  |
| Revenue, net  | \$ 242,038                             | \$ 303,752            | \$ 605,812                           | \$ 518,412            |
| Cost of sales   | 86,782                                 | 125,605               | 254,779                              | 205,365               |
| Gross profit  | 155,256                                | 178,147               | 351,033                              | 313,047               |
| Operating expenses:   |  |                       |                                      |                       |
| Research and development                                    | 5,611,921                              | 903,328               | 6,288,516                            | 1,919,792             |
| Selling, general and administrative                         | 873,630                                | 1,177,335             | 1,689,095                            | 1,944,729             |
| Total operating expenses                                    | 6,485,551                              | 2,080,663             | 7,977,611                            | 3,864,521             |
| Loss from operations  | (6,330,295)                            | (1,902,516)           | (7,626,578)                          | (3,551,474)           |
| Other income (expense):                                     |  |                       |                                      |                       |
| Interest income   | 5,755                                  | 9,680                 | 12,371                               | 20,519                |
| Interest expense  | (10,031)                               | (980)                 | (10,637)                             | (1,551)               |
| Local business tax  | (900)                                  | (1,500)               | (2,900)                              | (3,694)               |
| Other income (expense):                                     | —                                      | (203)                 | (504)                                | (203)                 |
| Total other income (expense), net                           | (5,176)                                | 6,997                 | (1,670)                              | 15,071                |
| Loss before income taxes                                    | (6,335,471)                            | (1,895,519)           | (7,628,248)                          | (3,536,403)           |
| Income tax benefit  | —                                      | —                     | —                                    | —                     |
| Net loss  | <u>\$ (6,335,471)</u>                  | <u>\$ (1,895,519)</u> | <u>\$ (7,628,248)</u>                | <u>\$ (3,536,403)</u> |
| Basic and diluted net loss per share                        | <u>\$ (0.17)</u>                       | <u>\$ (0.05)</u>      | <u>\$ (0.21)</u>                     | <u>\$ (0.10)</u>      |
| Shares used to compute basic and diluted net loss per share | <u>36,378,944</u>                      | <u>36,145,977</u>     | <u>36,295,428</u>                    | <u>36,127,076</u>     |

See accompanying notes.

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## Oragenics, Inc.

Statements of Cash Flows  
(Unaudited)

|   | For the Six Months Ended June 30, |                |
|---|-----------------------------------|----------------|
|   | 2015                              | 2014           |
| <b>Cash flows from operating activities:</b>                                |                                   |                |
| Net loss  | \$ (7,628,248)                    | \$ (3,536,403) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                   |                |
| Technology access fee paid in convertible note payable to shareholder       | 5,000,000                         | —              |
| Depreciation and amortization   | 32,457                            | 13,299         |
| Loss on sale of fixed assets  | —                                 | 203            |
| Stock issued as compensation to non-employee directors                      | 132,000                           | 102,500        |
| Stock-based compensation expense  | 254,280                           | 154,221        |
| Changes in operating assets and liabilities:                                |                                   |                |
| Accounts receivable, net  | (11,190)                          | 41,609         |
| Inventory, net  | 75,115                            | 49,408         |
| Prepaid expenses and other current assets                                   | 78,416                            | 81,367         |
| Accounts payable and accrued expenses                                       | (161,524)                         | (206,743)      |
| Deferred revenue  | (3,367)                           | 20,037         |
| Net cash used in operating activities                                       | (2,232,061)                       | (3,280,502)    |
| <b>Cash flows from investing activities:</b>                                |                                   |                |
| Proceeds from sale of fixed asset   | —                                 | 424            |
| Purchase of property and equipment  | (93,889)                          | (18,889)       |
| Net cash used in investing activities                                       | (93,889)                          | (18,465)       |
| <b>Cash flows from financing activities:</b>                                |                                   |                |
| Payments on short-term notes payable  | (79,468)                          | (78,970)       |
| Net cash used by financing activities                                       | (79,468)                          | (78,970)       |
| Net decrease in cash and cash equivalents                                   | (2,405,418)                       | (3,377,937)    |
| Cash and cash equivalents at beginning of period                            | 10,448,921                        | 16,276,510     |
| Cash and cash equivalents at end of period                                  | \$ 8,043,503                      | \$ 12,898,573  |
| <i>Supplemental disclosure of cash flow information:</i>                    |                                   |                |
| Interest paid   | \$ 1,471                          | \$ 1,579       |
| <i>Non-cash investing and financing activities:</i>                         |                                   |                |
| Borrowings under short-term notes payable for prepaid expense               | \$ 49,395                         | \$ 50,694      |
| Par value of common stock issued for cashless exercise of warrants          | \$ —                              | \$ 135         |
| Par value of restricted shares issued                                       | \$ 200                            | \$ —           |

See accompanying notes.

**Oragenics, Inc.**

**Notes to Financial Statements  
(Unaudited)**

**1. Organization**

Oragenics, Inc. (formerly known as Oragen, Inc.) (the “Company” or “we”) was incorporated in November 1996; however, operating activity did not commence until 1999. We are focused on becoming the world leader in novel antibiotics against infectious disease. We also develop, market and sell proprietary probiotics specifically designed to enhance oral health for humans and pets.

**2. Basis of Presentation**

The accompanying unaudited interim financial statements as of June 30, 2015 and December 31, 2014 (audited) and for the three and six months ended June 30, 2015 and 2014 have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the accompanying financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the financial condition, results of operations and cash flows for the periods presented. The results of operations for the interim period June 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015 or any future period.

These financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2014, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2015. The Company has incurred recurring losses and negative cash flows from operations since inception. To date the Company has not generated significant revenues from operations. The Company generated revenues of \$605,812, incurred a net loss of \$7,628,248, and used cash of \$2,232,061 in its operating activities during the six months ended June 30, 2015. As of June 30, 2015, the Company had an accumulated deficit of \$83,572,883.

In 2013 the Company raised \$3,900,000 in gross proceeds through a private placement sale of its common stock and \$9,904,996 in net proceeds through an underwritten public offering. The Company expects to incur substantial expenditures to further develop each of its technologies. In June of 2015, the Company issued a convertible note payable to Intrexon Corporation (“Intrexon”) as consideration for the Technology Access Fee associated with the Oral Mucositis Exclusive Channel Collaboration agreement (See Note 8). The Company currently intends to issue its common stock as payment of the convertible note payable and any accrued interest. Assuming the Company is able to issue its common stock as payment of its convertible note payable and accrued interest, the Company believes that its cash position as of June 30, 2015 will be sufficient to meet the business objectives as presently structured over the next nine months.

The Company’s ability to continue operations after its current cash resources are exhausted depends on its ability to obtain additional financing or achieve profitable operations, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in the Company’s focus and direction of its research and development programs, competitive and technical advances, limitation of financial resources, or other developments. Additional financing will be required for the Company to fund our further work under the Lantibiotic ECC and our normal operating costs; inclusive of selling, general, and administrative costs through March 2016. We will need to raise additional capital to begin work under the Oral Macostas ECC. There can be no assurance that any such financing can be realized by the Company, or if realized, what the terms thereof may be, or that any amount that the Company is able to raise will be adequate to support the Company’s working capital requirements until it achieves profitable operations.

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

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

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

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

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

#### **Use of Estimates**

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

#### **Guaranteed Rights of Return**

The Company has granted guaranteed rights of return to two dental distributors. The Company defers recognition of revenue on these accounts until either the distributor provides notification to the Company that the product has been sold to the end consumer or the guaranteed right of return period expires. Once notification has been received and verified, the Company records revenue in that accounting period. The Company had \$17,855 and \$21,222 of revenue deferred under guaranteed rights of return arrangements included in deferred revenue in the balance sheets as of June 30, 2015 and December 31, 2014, respectively.

#### **Inventory**

Inventory is stated at the lower of cost or market. Cost, which includes material, labor and overhead, is determined on a first-in, first-out basis. On a quarterly basis, we analyze our inventory levels and reserve for inventory that is expected to expire prior to being sold, inventory that has a cost basis in excess of its expected net realizable value, inventory in excess of expected sales requirements, or inventory that fails to meet commercial sale specifications. Expired inventory is disposed of and the related costs are written off to the reserve for inventory obsolescence. The inventory reserve was approximately \$68,200 and \$50,100 as of June 30, 2015 and December 31, 2014, respectively.

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

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

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

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

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



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### **Warrants**

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

### **Net Loss Per Share**

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

### **Revenue Recognition**

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

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

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

### **Concentrations**

The Company is dependent on key suppliers to provide probiotics, blending, warehousing and packaging of its EvoraPlus, EvoraKids, EvoraPro, EvoraPet, and Teddy's Pride products. The Company had four key suppliers during the three and six months ended June 30, 2015. The majority of the Company's cost of revenues is from these key suppliers during the three and six months ended June 30, 2015 and 2014. Accounts payable and accrued expenses for these vendors totaled approximately \$60,643 and \$189,120 as of June 30, 2015 and December 31, 2014, respectively.

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains cash accounts in commercial banks, which may, at times, exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash and cash equivalents. As of June 30, 2015, the uninsured portion of this balance was \$7,793,503. As of December 31, 2014, the uninsured portion of this balance was \$10,198,921.

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### 4. Stock-based Compensation

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

|                                     | Three Months Ended<br>June 30, 2015 | Three Months Ended<br>June 30, 2014 | Six Months Ended<br>June 30, 2015 | Six Months Ended<br>June 30, 2014 |
|-------------------------------------|-------------------------------------|-------------------------------------|-----------------------------------|-----------------------------------|
| Research and development            | \$ 82,953                           | \$ 127,730                          | \$ 103,870                        | \$ 137,767                        |
| Selling, general and administrative | 191,187                             | 123,446                             | 282,410                           | 118,954                           |
| Total Stock based compensation      | <u>\$ 274,140</u>                   | <u>\$ 251,176</u>                   | <u>\$ 386,280</u>                 | <u>\$ 256,721</u>                 |

The Company granted 10,000 and 910,000 stock options, with a weighted-average grant date fair value of \$0.77 and \$1.29 per share, during the three and six months ended June 30, 2015, respectively. The Company granted 100,000 stock options, with a weighted-average grant date fair value of \$2.81 per share, during the three and six months ended June 30, 2014.

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

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

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

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

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

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### 5. Warrants

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

|                             | Warrants    | Weighted<br>Average<br>Price |
|-----------------------------|-------------|------------------------------|
| Balance - December 31, 2013 | 2,747,094   | \$ 1.91                      |
| Granted                     | —           | —                            |
| Exercised                   | (210,000)   | 1.50                         |
| Expired                     | (5,000)     | (10.00)                      |
| Balance - December 31, 2014 | 2,532,094   | 1.93                         |
| Granted                     | —           | —                            |
| Exercised                   | —           | —                            |
| Expired                     | (2,170,925) | (2.00)                       |
| Balance – June 30, 2015     | 361,169     | \$ 1.50                      |

On March 23, 2015, warrants to acquire 2,170,925 shares of the Company's common stock at a price of \$2.00 per share expired.

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

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

### 6. Short-Term Notes Payable

As of June 30, 2015 and December 31, 2014, the Company had \$34,767 and \$64,840, respectively, in short-term notes payable for the financing of various insurance policies. On March 10, 2014, the Company entered into a short-term note payable for \$50,694 bearing interest at 6.57% to finance the product liability insurance. Principal and interest payments on this note began April 10, 2014 and are made evenly based on a straight line amortization over a 10-month period with the final payment being made on January 10, 2015. On March 16, 2015, we entered into a short-term note payable for \$49,395 bearing interest at 5.68% per annum to finance the product liability insurance. Principal and interest payments on this note began April 16, 2015 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on January 16, 2016. On July 24, 2014, the Company entered into a short-term note payable for \$108,306 bearing interest at 4.647% to finance a portion of the directors' and officers' liability insurance and employment practices liability insurance premiums. Principal and interest payments on this note began August 24, 2014 and are made evenly based on a straight line amortization over an 11-month period with the final payment made on June 22, 2015.

### 7. Convertible Note Payable To Shareholder

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

### 8. Commitments and Contingencies

#### *The University of Florida Research Foundation (UFRF) Licenses*

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

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royalty payments of \$50,000 annually would be due following payment of a commercialization fee. The one-time additional royalty payment would be due when total cumulative royalties paid to UFRF exceed \$2.0 million, upon which we would be obligated to make a one-time additional payment to UFRF of 10% of the total royalties due to UFRF in the calendar year in which cumulative royalties exceeded \$2.0 million.

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

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

The patent the Company exclusively licensed from UFRF for its Replacement Therapy expired in June 2015. The Company is currently evaluating its options with respect to the SMaRT Replacement Therapy technology.

### *Texas A&M License Agreement*

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

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

Pursuant to the Texas A&M license agreement, the Company is obligated to meet the following milestones and make milestone payments: (i) enrollment of first patient in a Phase I clinical trial using the licensed technology, to occur on or before June 1, 2015, with a milestone achievement payment of \$50,000, (ii) completion of Phase II clinical trial using the licensed technology to occur on or before June 1, 2019, with a milestone achievement payment of \$100,000, (iii) completion of Phase III clinical trial of the licensed technology to occur on or before June 1, 2022, with a milestone achievement payment of \$150,000, and (iv) first sale of the licensed technology to occur on or before June 1, 2025 with a milestone achievement payment of \$400,000. If we fail to accomplish the milestones or fail to achieve net sales of products including the licensed technology for two consecutive calendar years, Texas A&M at its sole option may waive the requirement, negotiate the missed milestones or terminate the license agreement. None of the Texas A&M milestones had been achieved as of June 30, 2015. The Company plans to seek an extension of the first enrollment of a patient milestone referred to above prior to the due date.

On July 11, 2012 the Texas A&M license agreement was amended to add references to replacement therapy in the defined terms "Licensed Technology" and "Patent Rights". All other terms of the Texas A&M license agreement remain unchanged.

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

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

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### *The Lantibiotic ECC*

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

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

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

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

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

None of the Lantibiotic ECC milestones had been achieved as of June 30, 2015.

Intrexon may terminate the Lantibiotic ECC if we fail to use diligent efforts to develop and commercialize Oragenics Products or if we elect not to pursue the development of a Lantibiotics Program identified by Intrexon that is a "Superior Therapy" as defined in the Lantibiotic ECC. We may voluntarily terminate the Lantibiotic ECC at any time upon 90 days written notice to Intrexon.

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

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

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

### *The Live Biotherapeutic Products ("LBPs") ECC*

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

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

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

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

None of the LBPs ECC milestones had been achieved as of June 30, 2015.

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

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

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

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### *The Oral Mucositis ECC*

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

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

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

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

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

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

- (i) the particular Company Product is being sold by the Company triggering profit sharing payments under the ECC to Intrexon;
- (ii) the particular Company Product has received regulatory approval;
- (iii) the particular Company Product is a subject of an application for regulatory approval in the Field covered by the ECC that is pending before the applicable regulatory authority;
- (iv) the particular Company Product is AG013, and such Company Product has been the subject of at least one completed phase II clinical trial (as such is defined by relevant FDA guidelines) during the Term; or
- (v) the particular Company Product other than AG013 and such Orogenics Product is the subject of at least an ongoing Phase 1, Phase 2 or Phase 3 clinical trial in the Field.

### **9. Related Party Transactions**

During the three and six months ended June 30, 2015 and 2014, we paid \$31,927 and \$361,294; \$45,755 and \$901,319, respectively, to Intrexon under the ECC agreements (See Note 8). Included in accounts payable and accrued expenses at June 30, 2015 and 2014 was \$38,932 and \$7,605, respectively, related to unpaid invoices received from Intrexon relating to work performed under the ECC Agreements. As of June 30, 2015 and 2014 Intrexon owned approximately 24% of our outstanding common stock.

### **10. Common Stock**

On March 16, 2015, in connection with and in furtherance of the new equity based award program (see Note 4), the Board approved the award of 40,000 restricted shares of Company common stock to each of the Company’s non-employee directors, Frederick Telling, Charles Pope, Alan Dunton, Christine Koski and Robert Koski under the Company’s 2012 Plan of which a total of 20,000 restricted shares have vested on June 30, 2015 for each non-employee director and the remainder will vest at the end of each calendar quarter in 2015 provided the recipient remains a director through the vesting date. The awards are considered issued and outstanding as of the date of the grant and are eligible to be voted by the recipient. The Company has \$132,000 in unrecognized compensation expense relating to these awards that will be recognized pro-rata through the remainder of 2015.

### **11. Subsequent Event**

On August 3, 2015, Griffin Securities Inc. exercised 185,585 of their previously issued warrants resulting in the issuance of 98,592 shares of our common stock

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

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

### **Forward-Looking Statements**

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



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### Overview

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

#### *Our Antibiotics*

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

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

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

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

We are working with third party manufacturers to produce additional quantities of designated homologs, based upon the developments achieved from our work with Intrexon and outside contractors. The additional quantities of designated homologs that are needed for the consummation and pursuit of our nonclinical testing activities including the pre-IND meeting, technology transfer to a GLP manufacturing facility and the drug product necessary for completing all pre-IND studies are underway. In support of a pre Investigational New Drug ("IND") filing with the FDA to study lantibiotics for the treatment of a *c. diff* infection, a specific animal model is traditionally utilized as part of the IND submission to show efficacy against the infection. The Syrian Golden Hamster model has been accepted by the FDA as the model to show efficacy of any investigational product. In July 2015 we announced that we had obtained positive results from this model and that, as a result, we had selected a lead lantibiotic candidate.

We tested a total of six homologs based on important compound characteristics including but not limited to: drug activity (based on minimum inhibitory concentration or "MIC") equal or better than "standard of care" drugs against certain drug-resistant bacteria, safety, toxicity, stability, and manufacturability. The study specifically evaluated homolog efficacy in relation to survival, measurable amounts of *c. diff* colony forming units, and toxin levels. Overall, three homologs demonstrated promising results with one homolog achieving a 100% survival rate throughout the entire study in contrast to an approximately 30% survival rate for the vancomycin positive control. Multiple test compounds demonstrated clear efficacy signals over vancomycin. Oragenics' current lead compound provided 100% protection and survival to all animals throughout the course of the 24 day study, meeting the primary study endpoint and exceeding that of the vancomycin positive control.

We intend to move forward with our lead lantibiotic candidate with the goal of having a pre IND meeting with the FDA in the fourth quarter of 2015. Thereafter we would expect to be in a position to file the IND for a first-in-human clinical study in 2016.

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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 (“GRAS”). We have historically sold our ProBiora3 products through multiple distribution channels. We continue to seek improvement in the performance of our oral care probiotics products, to better serve our customers, and as appropriate, we continue to evaluate new delivery systems, which we believe will enable us to deliver ProBiora3 to new markets and end-users.

Since initial commercialization of our ProBiora3 products we have attempted to improve market awareness and sales of our oral probiotic product line with limited success to date and we have reduced our marketing expenditures accordingly to focus more on antibiotics. The allocation of limited financial resources between research and development of antibiotics for our other product candidates and sale and marketing efforts for our ProBiora3 products, among other factors, resulted in our December 2014 announcement that we would seek to explore strategic alternatives for the probiotic business. These alternatives could include joint ventures, strategic partnerships or alliances, a sale of the probiotic products business or other possible transactions. There can be no assurance that a transaction or agreement will be consummated with terms favorable to us. While exploring strategic alternatives we expect to continue to operate the consumer probiotic business, but we do not expect any significant increase in sales in the near future due to the limited amount of marketing resources we are committing to this product at this time.

### *Live Biotherapeutic Products (LBPs)*

On September 30, 2013, we entered into a second worldwide exclusive channel collaboration agreement with Intrexon that governs a “channel collaboration” arrangement in which we will use Intrexon’s proprietary technology relating to the identification, design, culturing and/or production of genetically modified cells, DNA vectors and in vivo control of expression for the development and commercialization of LBPs, specifically the direct administration to humans of genetically modified bacterial LBPs for the treatment of diseases of the oral cavity, throat, sinus and esophagus, including, but not limited to, aphthous stomatitis and Behcet’s disease (the “LBPs ECC”). Our initial planned focus was to develop a genetically engineered bacterial strain designed to deliver and release a therapeutic locally at the oral disease sites to target pain management, reduce inflammation, and improve patient outcomes in Behcets Disease (and/or Aphthous Stomatitis). In reviewing and considering the potential opportunities, we concluded that other therapeutic indications may be more commercially viable, and as such, we are exploring other options for the planned focus areas with respect to this collaboration. Under the terms of LBP ECC the joint steering committee is meeting to determine a plan to move forward with developing LBPs taking into consideration an allocation of limited financial resources.

### *Other Product Candidates and Technologies*

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

*Our SMaRT Replacement Therapy.* Our SMaRT Replacement Therapy is based on the creation of a genetically modified strain of bacteria that colonizes in the oral cavity and replaces native bacteria that cause tooth decay. Our SMaRT Replacement Therapy product candidate is designed to be a painless, one-time, five-minute topical treatment applied to the teeth that has the potential to offer lifelong protection against dental caries, or tooth decay. While we commenced a Phase 1b clinical trial for SMaRT Replacement Therapy during the first quarter of 2011, the very restrictive study enrollment criteria required by the FDA made the enrollment of candidates meeting the restrictive criteria difficult. This enrollment difficulty was also present in our Phase 1a clinical trial. Due to the enrollment difficulties we encountered with our initial Phase 1a clinical trial and with our phase 1b clinical trial, we determined to discontinue pursuit of our Phase 1b clinical trial. Our focus for the SMaRT Replacement Therapy technology is on possible partnering opportunities that may exist or for consideration in our LBP program. The patent we exclusively licensed from the University of Florida Research Foundation for our Replacement Therapy expired this quarter. We expect to evaluate the continued pursuit of this technology going forward.

*Our Weight Loss Agent-LPT3-04.* LPT3-04 is a natural occurring dietary substance with an excellent safety and tolerance profile that is believed to support weight loss in overweight men and women. LPT3-04 is normally consumed in the human diet in small amounts, in the course of our SMaRT Replacement Therapy research; our scientific team also discovered that consumption of a significant amount of LPT3-04, resulted in dose-dependent weight loss in experimental animal models. In December 2013 we entered into an exclusive licensing agreement for our LPT3-04 weight-loss product candidate with LPThera LLC for further development of this technology. On March 26, 2014 we amended this license agreement to extend the time for achievement of the milestones.

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### Recent Developments

#### *Our Oral Mucositis License (OM)*

On June 9, 2015, the Company entered into a worldwide Exclusive Channel Collaboration Agreement (the “Oral Mucositis ECC”) with Intrexon and Intrexon Actobiotics NV (“Actobiotics”), a wholly-owned subsidiary of Intrexon, through which the Company intends to research, develop and commercialize products, including the continued development and commercialization of AG013, for use in the treatment of oral mucositis in humans and/or the administration to humans of a trefoil factor via genetically modified bacteria (including *L. lactis*) for the treatment of diseases and conditions of the oral cavity, throat, and esophagus, but, in any case, excluding the delivery of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer (collectively, the “Program”). The Oral Mucositis ECC provides for the establishment of committees comprised of Company and Intrexon representatives that will govern activities in the areas of project establishment, chemistry, manufacturing and controls, clinical and regulatory matters, commercialization efforts, and intellectual property. Under the terms of the Oral Mucositis ECC we expect that a newly formed joint steering committee will meet to determine a development plan for the Program.

Contemporaneously with the Oral Mucositis ECC, the Company and Intrexon also entered into a Stock Issuance Agreement (the “SIA”) which authorized the issuance of the Technology Access Fee (as defined below) and the future stock issuance of Company’s Common Stock to Intrexon upon the achievement of designated milestones.

The Oral Mucositis ECC grants the Company an exclusive worldwide license to utilize Intrexon’s and Actobiotics’ intellectual property to develop and commercialize products, including the continued development and commercialization of AG013, for use in the treatment of oral mucositis in humans and/or the administration to humans of a trefoil factor via genetically modified bacteria (including *L. lactis*) for the treatment of diseases and conditions of the oral cavity, throat, and esophagus, but, in any case, excluding the delivery of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer (the “Field”). It also grants the Company an exclusive license in the Field under all Information Controlled by Actobiotics (or otherwise by Intrexon) and existing as of the Effective Date relating to the regulatory approval of AG013, including regulatory filings, data, clinical trial reports, and rights thereunder.

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

The Company will pay Intrexon 12% of the net sales derived from the sale of products developed from the exclusive channel collaboration.

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

- two million United States dollars (\$2,000,000) within thirty (30) days of the first instance of the achievement of the Phase II Milestone Event meaning the first dosing of a patient by or on behalf of Orogenics, or an Affiliate or permitted sublicensee of Orogenics, in a phase II clinical trial, whether such occurs in the United States of America under the jurisdiction of the FDA or elsewhere under the jurisdiction of a foreign regulatory agency, for each different Orogenics Product;
- five million United States dollars (\$5,000,000) within thirty (30) days of the first instance of the achievement of the Phase IIb/III Milestone Event meaning meeting of the primary endpoint by or on behalf of Orogenics, or an Affiliate or permitted sublicensee of Orogenics, in a phase III clinical trial, whether such occurs in the United States of America under the jurisdiction of the FDA or elsewhere under the jurisdiction of a foreign regulatory agency, for each different Orogenics Product;
- five million United States dollars (\$5,000,000) within thirty (30) days of the first instance of the achievement of the Regulatory Approval Application Milestone Event for each different Orogenics Product which Regulatory Approval Application Milestone Event meaning for a given Orogenics Product, the first to occur of (a) the filing by Orogenics, an Affiliate thereof, or a permitted sublicensee thereof, of a FDA New Drug Application or a Biologics License Application with the FDA seeking approval of such Orogenics Product, or (b) the filing of an equivalent approval or marketing application for such Orogenics Product with an equivalent regulatory authority in a foreign jurisdiction;

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- ten million United States dollars (\$10,000,000) within thirty (30) days of the first instance of the achievement of the Approval Milestone Event for each different Oragenics Product which Approval Milestone Event meaning the first to occur of (a) the First Commercial Sale of an Oragenics Product anywhere in the Territory, or (b) 90th day after the approval of a FDA New Drug Application for an Oragenics Product by the FDA or equivalent regulatory action in a foreign jurisdiction;
- Oragenics shall pay Intrexon a milestone payment of five million United States dollars (\$5,000,000) within thirty (30) days of the first instance of the achievement of the New Indication Milestone Event meaning the filing by or on behalf of Oragenics, an Affiliate of Oragenics, or a permitted sublicensee of Oragenics a Supplemental FDA Application with the FDA or with another equivalent regulatory agency seeking approval of an indication for use of the product AG013 other than the current regulatory-approved indication; and
- Oragenics shall pay Intrexon a milestone payment of five million United States dollars (\$5,000,000) within thirty (30) days of the first instance of the achievement of the New Product Milestone Event meaning the filing of a regulatory package filed with the FDA or with another equivalent regulatory agency by or on behalf of Oragenics, an Affiliate of Oragenics, or a permitted sublicensee of Oragenics, that is deemed (according to relevant FDA guideline) to be a different drug product than AG013.

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

The Company may voluntarily terminate the Oral Mucositis ECC upon 90 days written notice to Intrexon. Intrexon may also terminate the Oral Mucositis ECC if the Company breaches and fails to cure the breach within 60 days or the Company does not pursue development of the Superior Therapy under the probiotics identified by Intrexon that is a "Superior Therapy" as defined in the Oral Mucositis ECC.

Upon termination of the Oral Mucositis ECC, the Company may continue to develop and commercialize any Company Product that, at the time of termination that satisfies at least one of the following criteria:

- the particular Company Product is being sold by the Company triggering profit sharing payments under the ECC to Intrexon;
- the particular Company Product has received regulatory approval;
- the particular Company Product is a subject of an application for regulatory approval in the Field covered by the ECC that is pending before the applicable regulatory authority;
- the particular Company Product is AG013, and such Company Product has been the subject of at least one completed phase II clinical trial (as such is defined by relevant FDA guidelines) during the Term; or
- the particular Company Product other than AG013 and such Oragenics Product is the subject of at least an ongoing Phase 1, Phase 2 or Phase 3 clinical trial in the Field.

Pursuant to the SIA, the Company paid a technology access fee (the "Technology Access Fee") to Intrexon in the form of a convertible promissory note to Intrexon in the principal amount of \$5,000,000 (the "Convertible Note"). The SIA also provides for payments of any milestones (described above) triggered under the ECC in Oragenics' Common Stock.

The Convertible Note is payable, at the Company's option, in cash or shares of Company Common Stock. The Convertible Note matures on December 31, 2015. In order to repay the Convertible Note in shares of common stock the Company will be required to obtain shareholder approval prior to any conversion into Common Stock pursuant to applicable rules of the New York Stock Exchange. The conversion price would be equal to the closing price of the Company's Common Stock on the last trading day immediately prior to the date of conversion.

### *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 June 30, 2015, and have principally funded our operations through the sale of debt and equity securities, including the exercise of warrants issued in connection with these financing transactions. Prior to 2008 our revenues were derived solely from research grants. Since 2008, our revenues have also included sales of our ProBiora3 products, which we initiated in late 2008. Our net revenues were \$605,812 and \$518,412 for the six months ended June 30, 2015 and 2014, respectively, and our net revenues were \$939,926 and \$1,032,233, for the years ended December 31, 2014 and 2013, respectively.

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As of June 30, 2015, we had an accumulated deficit of \$83,572,883 and we have yet to achieve profitability. We incurred net losses of \$7,628,248 and \$3,536,403 for the six months ended June 30, 2015 and 2014, respectively, and \$5,789,519 and \$16,068,754 for the years ended December 31, 2014 and 2013, respectively. We expect to incur significant and increasing operating losses for the foreseeable future as we seek to advance our product candidates through preclinical testing and clinical trials to ultimately obtain regulatory approval and eventual commercialization. We will need to raise additional capital. Adequate additional funding may not be available to us on acceptable terms, or at all. We expect that research and development expenses will increase along with general and administrative costs, as we seek to grow and continue to operate our business. There can be no assurance that additional capital will be available to us on acceptable terms, if at all.

### **Financial Overview**

#### ***Net Revenues***

Our revenues prior to 2008 consisted exclusively of grant funding from government agencies under the National Science Foundation's, or NSF, and National Institutes of Health's, or NIH, Small Business Innovation Research, or SBIR, grants. Since the initial launch of our ProBiora3 products in late 2008, our net revenues for the year ended December 31, 2008 and thereafter, also included sales of our ProBiora3 products. Sales of our ProBiora3 products were \$939,926 and \$949,593 for the years ended December 31, 2014 and 2013, respectively and \$605,812 and \$518,412 for the six months ended June 30, 2015 and 2014, respectively. Future increases in net revenue for our ProBiora3 products will depend on a number of factors, including our ability to successfully engage in marketing efforts related to our ProBiora3 products, which we have substantially scaled back. Our marketing efforts for our ProBiora3 products have had limited success to date as revenues have not significantly increased from period to period. We continue to consider options for marketing our ProBiora3 Products that can be cost-effective as we seek to manage the use of our cash resources relative to the research and development we are conducting for our other product candidates while we explore and consider strategic alternatives for our consumer probiotic business.

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

#### ***Cost of Revenues***

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

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

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

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

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Our research and development expenses were \$6,288,516 and \$1,919,792 for the six months ended June 30, 2015 and 2014, respectively.

Our current strategy is to manage our research and development expenses in the future as we continue the advancement of our clinical trials and nonclinical product development programs for our MU1140 product candidate, our oral mucositis product candidate, and with respect to our LBP project. The lengthy process of completing clinical trials; seeking regulatory approval for our product candidates; and expanding the claims we are able to make, requires expenditure of substantial resources. Any failure or delay in completing nonclinical or clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenues and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Certain of our current product development candidates are not expected to be commercially available until we are able to obtain regulatory approval from the FDA, which is not expected before 2017.

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

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

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

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

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

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

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

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

### ***Income Taxes***

As of December 31, 2014, we have net operating loss carryforwards of approximately \$69,735,000 to offset future federal and state income taxes. We also have research and development tax credit carryforwards of approximately \$1,355,000 as of December 31, 2014 to offset future federal and state income taxes. Our net operating loss and research and development tax credit carryforwards will expire if not used by 2034 and 2024, respectively. Our ability to utilize our net operating loss and tax credit carryforwards may be limited in the event a change in ownership, as defined in Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, has occurred or may occur in the future. The private placement transaction with the Koski Family Limited Partnership ("KFLP") in June 2009 (the "June 2009 Private Placement") constituted such an event and the ability to use our historical loss carryforwards in the

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future to offset income after that point in time were limited. Furthermore, our transactions with Intrexon during 2013 constituted a second such event, and the ability to use our historical loss carryforwards up to December 2013 were further limited. In each period, we have recorded a 100% valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal tax benefit in our statements of operations.

### **Results of Operations for the Three Months Ended June 30, 2015 and 2014**

**Net Revenues.** We generated net revenues of \$242,038 for the three months ended June 30, 2015 compared to \$303,752 for the three months ended June 30, 2014 a decrease of \$61,714. Our ProBiora3 revenues decreased from June 30, 2014 due primarily to a decrease in private label sales.

**Cost of Sales.** Cost of sales was \$86,782 for the three months ended June 30, 2015 compared to \$125,605 for the three months ended June 30, 2014, a decrease of \$38,823. This decrease was due primarily to a decrease in revenues during the period. Gross margin for the three months ended June 30, 2015 was 64.1% versus 58.6% for the same period in 2014

**Research and Development.** Research and development expenses were \$5,611,921 for the three months ended June 30, 2015 compared to \$903,328 for the three months ended June 30, 2014, an increase of \$4,708,593. This increase was primarily due to the payment of a \$5.0 million technology access fee through the issuance of a Convertible Note payable to Intrexon pursuant to the terms of the our new Oral Mucositis ECC during the three months ended June 30, 2015. There was no such payment of a Technology Access Fee to Intrexon during the three month period ending June 30, 2014. This increase was partially offset by decreases in costs associated with third party lantibiotic research of \$284,458.

**Selling, General and Administrative.** Selling, general and administrative expenses were \$873,630 for the three months ended June 30, 2015 compared to \$1,177,335 for the three months ended June 30, 2014, a decrease of \$303,705 or 25.8%. This decrease was primarily due to decreases in salary and salary related costs, consulting costs, legal costs, filing fees and registrations, and conferences and tradeshow costs of \$104,512, \$127,591, \$131,426, \$15,106, and \$13,007, respectively. These decreases were partially offset by an increase in board costs and non-employee stock based compensation of \$43,250 and \$42,945 respectively.

**Other Income (Expense).** Other income (expense), net was \$(5,176) for the three months ended June 30, 2015 compared to \$6,997 for the three months ended June 30, 2014, resulting in a net change of \$12,173. The net change was primarily attributable to a decrease in interest income of \$3,925 due to decreased cash balances during 2015 and an increase in interest expense of \$9,051 due to increased levels of borrowing in 2015.

### **Results of Operations for the Six Months Ended June 30, 2015 and 2014**

**Net Revenues.** We generated net revenues of \$605,812 for the six months ended June 30, 2015 compared to \$518,412 for the six months ended June 30, 2014 an increase of \$87,400. Our ProBiora3 revenues increased from June 30, 2014 due primarily to sales to our international distributor.

**Cost of Sales.** Cost of sales was \$254,779 for the six months ended June 30, 2015 compared to \$205,365 for the six months ended June 30, 2014, an increase of \$49,414. This increase was due primarily to an increase in revenues during the period and an increase in scrap expense. Gross margin for the six months ended June 30, 2015 was 57.9% versus 60.4% for the same period in 2014.

**Research and Development.** Research and development expenses were \$6,288,516 for the six months ended June 30, 2015 compared to \$1,919,792 for the six months ended June 30, 2014, an increase of \$4,368,724. This increase was primarily due to the payment of a \$5.0 million technology access fee through the issuance of a Convertible Note payable to Intrexon pursuant to the terms of the our new Oral Mucositis ECC during the six months ended June 30, 2015. There was no such payment of a Technology Access Fee to Intrexon during the six month period ending June 30, 2014. In addition, there was an increase in salary and salary related costs of \$172,696. These increases were partially offset by decreases in costs associated with third party lantibiotic and live biotherapeutic product research and patent costs of \$768,262 and \$39,068, respectively.

**Selling, General and Administrative.** Selling, general and administrative expenses were \$1,689,095 for the six months ended June 30, 2015 compared to \$1,944,729 for the six months ended June 30, 2014, a decrease of \$255,634 or 13.1%. This decrease was primarily due to decreases in salary and salary related costs, consulting costs, and legal costs of \$203,904, \$144,874, and \$117,855 respectively which were partially offset by an increase in board costs, non-employee stock based compensation, and depreciation costs of \$81,500, \$116,094 and \$19,158, respectively.

**Other Income (Expense).** Other income (expense), net was \$(1,670) for the six months ended June 30, 2015 compared to \$15,071 for the six months ended June 30, 2014, resulting in a net change of \$16,741. The net change was primarily attributable to a decrease in interest income of \$8,148 due to decreased cash balance during 2015 and an increase in interest expense of \$9,086 due to increased levels of borrowing in 2015.

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### **Liquidity and Capital Resources**

Since our inception, we have funded our operations primarily through the sale of equity securities in our initial public offering, the sale of equity securities and warrants in private placements, debt financing, warrant exercises, public offerings, and grants. During the six months ended June 30, 2015 and 2014, our operating activities used cash of \$2,232,061 and \$3,280,502, respectively. The use of cash in all periods primarily resulted from our net losses adjusted for non-cash items and changes in operating assets and liabilities. We had a working capital surplus of \$2,923,456 and \$10,226,856 at June 30, 2015 and December 31, 2014, respectively.

During the six months ended June 30, 2015 and 2014, our investing activities used cash of \$93,889 and \$18,465 respectively.

During the six months ended June 30, 2015 and 2014, our financing activities used cash of \$79,468 and \$78,970, respectively. The cash used by financing activities during the six months ended June 30, 2015 and 2014 was primarily due to the reductions in short term notes payable.

### **Financing**

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

#### ***The September 2013 Private Placement and Convertible Note Payable to Shareholder***

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

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

#### ***The November 2013 Underwritten Public Offering***

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

#### ***The June 2015 Convertible Note Payable To Shareholder***

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

### ***Other Financings***

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

On June 20, 2013, we entered into a short-term note payable for \$106,994 bearing interest at 4.64% per annum to finance a portion of the directors' and officers' liability insurance and employment practices liability insurance premiums. Principal and interest payments on this note begin August 24, 2013 and are made evenly based on a straight line amortization over an 11-month period with the final payment being made on June 16, 2014.

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



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

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

### **Future Capital Requirements**

Our capital requirements for 2015 and 2016 will depend on numerous factors, including the success of our commercialization efforts and of our research and development, the resources we devote to develop and support our technologies and our success in pursuing strategic licensing and funded product development relationships with external partners. Subject to our ability to generate revenues and cash flow from our ProBiora3 products and our ability to raise additional capital including through possible joint ventures and/or partnerships, we expect to incur substantial expenditures to further commercialize or develop our technologies including continued increases in costs related to research, nonclinical testing and clinical studies, as well as costs associated with our capital raising efforts and being a public company. We will require substantial funds to conduct research and development and nonclinical and Phase 1 clinical testing of our licensed, patented technologies and to conduct or develop sublicensing relationships for the Phase 2 and 3 clinical testing and manufacture and marketing of any products that are approved for commercial sale. Our plans include seeking both equity and debt financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to ensure continuation of our operations and research and development programs.

We believe that our existing cash and cash equivalents will allow us to fund our further work under the Lantibiotics ECC and our normal operating costs inclusive of selling, general, and administrative costs through March 2016. We will need to raise additional capital to begin work under the Oral Mucositis ECC. We expect to continue to seek additional funding for our operations. The sale of additional equity or debt securities will result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We also will require additional capital beyond our currently forecasted amounts, for example, as we continue to work with Intrexon under the Lantibiotic ECC for the development of our lead lantibiotic candidate and other homologs, our LBPs ECC, and our new Oral Mucositis ECC. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned clinical testing, research and development and commercialization activities, which could harm our business.

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

- the cash flow, if any, generated from our ProBiora3 product sales;
- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting nonclinical and clinical trials including the research and development expenditures we expect to make in connection with our collaboration agreements with Intrexon;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities for our ProBiora3 products and, if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- our ability to maintain current research and development licensing agreements and to establish new strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- our ability to achieve our milestones under our ECC agreements and licensing arrangements and the payment obligations we may have under such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our products and future products, if any.

We have based our estimates on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our shares or debt and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional

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funding will be available when we need it on terms that will be acceptable to us or when market conditions are favorable, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed.

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

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”). The preparation of financial statements in accordance with GAAP requires us to make estimates and assumptions that affect reported amounts and related disclosures. We consider an accounting estimate to be critical if it requires assumptions to be made that were uncertain at the time the estimate was made; and changes in the estimate or different estimates that could have been made could have a material impact on our results of operations or financial condition. The principal areas of estimation reflected in the financial statements are anticipated milestone payments, stock based compensation, valuation of warrants, income tax valuation allowance, inventory obsolescence reserve, sales returns and allowances and allowance for doubtful accounts. For a detailed discussion of our critical accounting estimates, see our Annual Report on Form 10-K for the year ended December 31, 2014. There have been no material changes to our critical accounting estimates during the six months ended June 30, 2015.

### **Recently Issued Accounting Pronouncements**

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

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

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

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

### **ITEM 4. CONTROLS AND PROCEDURES**

#### **Evaluation of Disclosure Controls and Procedures**

Management’s evaluation of the effectiveness of the Company’s disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act was performed under the supervision and participation of our Interim Principal Executive Officer/Chief Financial Officer. The purpose of disclosure controls and procedures is to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to management, including our Interim Principal Executive Officer/Chief Financial Officer, to allow timely decisions regarding required disclosures. Based upon that evaluation, our Interim Principal Executive Officer/Chief Financial Officer concluded that, as of the end of such period, our disclosure controls and procedures were effective as of June 30, 2015 in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported with the time periods specified in the Securities and Exchange Commission’s rules and forms.

We have identified a material weakness in our internal controls over financial reporting relating to a lack of adequate segregation of duties. This material weakness has existed at the Company for some time and is expected to continue to exist for the foreseeable future. The material weakness is due to our small number of employees. Nevertheless, based on a number of factors, including the performance of additional procedures by management designed to ensure the reliability of our financial reporting, management believes that the financial statements in our Quarterly Report on Form 10-Q on June 30, 2015 fairly present, in all material respects, our financial position, results of operations, and cash flows for the periods presented in conformity with GAAP.

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

### **Changes in Internal Controls over Financial Reporting**

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

### **Limitations on the Effectiveness of Controls**

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

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

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### **PART II – OTHER INFORMATION**

#### **ITEM 1. LEGAL PROCEEDINGS**

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

#### **ITEM 1A. RISK FACTORS**

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

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

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

We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of approximately and \$7.6 million and \$3.5 million for the six months ended June 30, 2015 and 2014, respectively, and approximately \$5.8 million and \$16.1 million for the years ended December 31, 2014, and 2013, respectively. As of June 30, 2015 our accumulated deficit was approximately \$83.6 million. We have devoted a significant amount of our financial resources to research and development, including our nonclinical development activities and clinical trials, and currently we only have our ProBiora3 products available for commercial sale which to date have not generated significant revenue. We expect that the costs associated with our exclusive channel collaborations with Intrexon in the areas of lantibiotics (“Lantibiotics Program”), probiotics (“Probiotics Program”) and Oral Mucositis (Oral Mucositis Program) and the development and commercialization of our product candidates under the Lantibiotics Program (which includes MU1140), Probiotics Program and Oral Mucositis Program using Intrexon’s advanced transgene and cell engineering platforms will continue to increase the level of our overall expenses significantly going forward. As a result, we expect to continue to incur substantial net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders’ equity and working capital. Because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to accurately predict the timing or amount of substantial expenses or when, or if, we will be able to generate the revenue necessary to achieve or maintain profitability.

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

Developing and commercializing biopharmaceutical products, including conducting nonclinical studies and clinical trials and establishing manufacturing capabilities, is expensive. We anticipate that our cash resources as of June 30, 2015 will be sufficient to fund our operations as presently structured over the next nine months. However, changes may occur that would consume our existing capital prior to that time, including the scope and progress of our efforts to develop and commercialize our product candidates. Our actual costs, as well as the actual revenues from sales of our ProBiora3 products, may ultimately vary from our current expectations, which could materially impact our use of capital and our forecast of the period of time through which our financial resources will be adequate to support our operations. Our current cash, cash equivalents and short-term investments are not sufficient to fully implement our business strategy and sustain our operations over a longer period of time. Accordingly, we will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete existing nonclinical and planned clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure, and research and development activities. Specifically, we may need to raise additional capital to, among other things:

- expand our clinical laboratory operations;

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

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

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

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

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

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

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

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

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

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

Currently our sole source of product revenues is from sales of our ProBiora3 products, which have generated only modest revenues to date. Sales of our ProBiora3 products were \$595,988, \$517,139, and \$319,481 for the six months ended June 30, 2015, 2014, and 2013, respectively, and \$921,075, \$949,593, and \$1,194,878, for the years ended December 31, 2014, 2013 and 2012, respectively. There can be no assurance our ProBiora3 product sales will ever generate significant revenue and cash flow for us.

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

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

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

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

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

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

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

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

Under our ECCs with Intrexon we are responsible for, among other things, funding the further anticipated development of lantibiotics, LBPs and AG013 toward the goal of commercialization, conducting nonclinical and clinical development of product candidates, as well as for other aspects of manufacturing and the commercialization of the product(s). During the first 18 months of each ECC, neither we nor Intrexon may terminate such ECC's, except under limited circumstances. Intrexon may terminate such agreements if we do not perform certain specified requirements, including developing therapies identified to us and considered superior by Intrexon. There can be no assurance that we will be able to successfully perform under the ECC's and if the ECC's are terminated it would prevent us from achieving our business objectives.

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

As of June 30, 2015, the Koski Family Limited Partnership (“KFLP”), together with members of the Koski family, beneficially owns approximately 30.7% of our outstanding shares of common stock. Additionally, Christine L. Koski and Robert C. Koski, serve on our Board of Directors. Intrexon, together with its CEO, beneficially owns approximately 27.0% of our outstanding shares of common stock. As a result, our principal shareholders have the ability to affect the outcome of all matters requiring shareholder approval, including the election and removal of directors, amending our charter or by-laws, and agreeing to or preventing mergers, consolidations or the sale of all or substantially all our assets. In particular, this concentration of ownership of our common stock could have the effect of delaying or preventing a change of control of us or otherwise discouraging or preventing a potential acquirer from attempting to obtain control of us. This, in turn, could have a negative effect on the market price of our common stock. It could also prevent our shareholders from realizing a premium over the market price for their shares of common stock. Moreover, the interests of this concentration of ownership may not always coincide with our interests or the interests of other shareholders, and, accordingly, our majority shareholders could cause us to enter into transactions or agreements that we would not otherwise consider. The significant concentration of stock ownership may also adversely affect the trading price of our common stock due to investors’ perception that conflicts of interest may exist or arise. However with respect to Intrexon, the Stock Issuance Agreement we entered into with Intrexon on June 9, 2015, contains a standstill provision pursuant to which, among other things, Intrexon has agreed that until June 9, 2018, subject to certain exceptions and unless invited in writing by the Company to do so, neither Intrexon nor its affiliates will, directly or indirectly: (i) effect or seek, initiate, offer or propose to effect, or cause or participate in any acquisition of securities or assets of the Company; any tender or exchange offer, merger, consolidation or other business combination involving the Company; any recapitalization, restructuring, liquidation, dissolution or other extraordinary transaction with respect to the Company; or any “solicitation” of “proxies” or consents to vote any voting securities of the Company, or in any way advise or, assist any other person in doing so; (ii) form, join or in any way participate in a “group” with respect to any securities of the Company; (iii) otherwise act to seek to control or influence the management, Board of Directors or policies of the Company; (iv) take any action reasonably expected to force the Company to make a public announcement regarding any such matters; or (v) enter into any agreements, discussions or arrangements with any third party with respect to any of the foregoing. This standstill provision could also have the effect of delaying, deferring or preventing a change in control that our shareholders might consider to be in their best interests.

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

Our board of directors has authority, without action or vote of our shareholders, to issue all or a part of our authorized but unissued shares, except where shareholder approval is required by law. Any issuance of additional equity securities by us in the future could result in dilution to our existing shareholders. Such issuances could be made at a price that reflects a discount or a premium to the then-current trading price of our common stock. In addition, our business strategy may include expansion through internal growth by acquiring complementary businesses, acquiring or licensing additional products or brands, or establishing strategic relationships with targeted customers and suppliers. In order to do so, or to finance the cost of our other activities, we may issue additional equity securities that could result in further dilution to our existing shareholders. These issuances would dilute your percentage ownership interest, which would have the effect of reducing your influence on matters on which our shareholders vote, and might dilute the book value of our common stock. For example, we have recently issued a significant number of shares of our common stock in connection with financings and establishing strategic relationships and as a result our outstanding shares have increased from 27,382,830 shares as of December 31, 2012 to 36,178,944 shares as of December 30, 2014.

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

In connection with the new LBPs ECC we entered into on September 30, 2013, we will be required, at our option, to pay up to \$17.0 million cash to Intrexon or issue up to \$17.0 million of additional shares of our common stock to Intrexon upon meeting certain commercialization milestones. We also issued the Convertible Note in the amount of \$1,956,000 which is payable, at our option, in cash or shares of our common stock. On December 18, 2013, we issued to Intrexon 698,241 shares of our common stock in connection with the conversion of the Convertible Note.

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

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You may also incur additional dilution if performance awards are made pursuant to any long term incentive programs for executives and non-employee directors we may put into place or holders of stock options, whether currently outstanding or subsequently granted, exercise their options, or if warrant holders exercise their warrants to purchase shares of our common stock. For example, during the year ended December 31, 2013 we issued an aggregate of 727,090 shares of our common stock to our executive officers and non-employee directors pursuant to performance awards under our long term incentive which expired on December 31, 2014. During the year ended December 31, 2014, as part of our non-employee director compensation program we issued an aggregate of 50,000 shares of our common stock to our non-employee directors under the Company's 2012 Equity Incentive Plan.

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

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

Incorporated by reference to Exhibits filed after signature page.



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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 7th day of August, 2015.

**ORAGENICS, INC.**

BY: /s/ Michael Sullivan

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

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| <u>Exhibit number</u> | <u>Exhibit description</u>  | <u>Incorporated by Reference</u> |                 |                | <u>Filing date</u> | <u>Filed herewith</u> |
|-----------------------|---|----------------------------------|-----------------|----------------|--------------------|-----------------------|
|                       |   | <u>Form</u>                      | <u>File no.</u> | <u>Exhibit</u> |                    |                       |
| 10.1                  | Exclusive Channel Collaboration Agreement by and between Intrexon Corporation, Intrexon Actobiotics NV and Oragenics, Inc. dated as of June 9, 2015.**          | 8-K                              | 001-32188       | 10.1           | 6/11/15            |                       |
| 10.2                  | Stock Issuance Agreement by and between Oragenics, Inc. and Intrexon Corporation dated as of June 9, 2015.  | 8-K                              | 001-32188       | 10.2           | 6/11/15            |                       |
| 10.3                  | Convertible Promissory Note dated June 9, 2015.   | 8-K                              | 001-32188       | 10.3           | 6/11/15            |                       |
| 10.4                  | License Agreement by and between Oragenics Inc. and Texas A&M University System dated December 20, 2011.  | 10-K                             | 001-32188       | 10.28          | 4/6/12             |                       |
| 10.5                  | Amendment No. 1 to the License Agreement between Oragenics, Inc. and the Texas A&M University System dated July 11, 2012.                                       |                                  |                 |                |                    | X                     |
| 10.6                  | Second Amendment to License Agreement between Oragenics, Inc. and the Texas A&M University System dated May 18, 2015.   |                                  |                 |                |                    | X                     |
| 31.1                  | Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended. |                                  |                 |                |                    | X                     |
| 31.2                  | Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended. |                                  |                 |                |                    | X                     |
| 32.1                  | Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Principal Executive Officer).           |                                  |                 |                |                    | X                     |
| 32.2                  | Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).               |                                  |                 |                |                    | X                     |
| 101.INS               | XBRL Instance Document  |                                  |                 |                |                    |                       |
| 101.SCH               | XBRL Taxonomy Extension Schema  |                                  |                 |                |                    | X                     |
| 101.CAL               | XBRL Taxonomy Extension Calculation Linkbase  |                                  |                 |                |                    | X                     |
| 101.DEF               | XBRL Taxonomy Extension Definition Linkbase   |                                  |                 |                |                    | X                     |
| 101.LAB               | XBRL Taxonomy Extension Label Linkbase  |                                  |                 |                |                    | X                     |
| 101.PRE               | XBRL Taxonomy Extension Presentation Linkbase   |                                  |                 |                |                    | X                     |

\*\* Confidential treatment has been requested for the redacted portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

AMENDMENT NO. 1  
TO THE LICENSE AGREEMENT  
between  
Oragenics, Inc.  
and  
The Texas A&M University System

This Amendment No. 1 is made and entered into by and between Oragenics, Inc. a corporation with principal offices in Tampa, Florida ("ORAGENICS") and The Texas A&M University System ("SYSTEM"), with principal offices in College Station, Texas; both Parties to the License Agreement dated December 20, 2011.

WITNESSETH:

WHEREAS, the Parties have entered into a license agreement for commercial rights in certain intellectual property related to "new antibiotic variants of Mutacin 1140" (the "License Agreement"); and

WHEREAS, SYSTEM and ORAGENICS have further developed related intellectual property directed toward "improved replacement therapy for dental caries;" and

WHEREAS, the Parties now desire to add such intellectual property to the scope of the License Agreement; and

WHEREAS, in consideration for inclusion of the intellectual property in the License Agreement, ORAGENICS agrees to commercialize the intellectual property under the terms and conditions of this Agreement.

NOW THEREFORE, the Parties agree that the License Agreement of December 20, 2011 is hereby amended as follows:

1. DELETE paragraph 1.01 in its entirety.
2. ADD new paragraph 1.01 as follows:
  - 1.01 "LICENSED TECHNOLOGY" means the Parties' rights in their jointly owned proprietary technology relating to SYSTEM Disclosure of Invention Number TAMUS 3447 entitled "Site Directed Mutagenesis of Mutacin 1140 and Its Effect on Bactericidal Activity," and TAMUS 3657 entitled "Replacement Therapy for *Dental Caries*." For the purposes of this Agreement, LICENSED TECHNOLOGY shall also include MATERIALS.
3. DELETE paragraph 1.02 in its entirety.
4. ADD new paragraph 1.02 as follows:
  - 1.02 "PATENT RIGHTS" means the Parties' rights in:
    - (a) Each United States patent application filed for protection of LICENSED TECHNOLOGY, including United States provisional patent applications 61/603,661 entitled "Variants of the "antibiotic MU1140 and Other Lantibiotics with Improved Pharmacological Properties and Structural Features," and 61/603,693 entitled "Replacement Therapy for Dental Caries," both filed February 27, 2012;

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- (b) Each divisional, continuation, or continuation-in-part application of the patent applications described in (a) above to the extent the claims are directed to subject matter specifically described in such patent applications;
  - (c) Equivalent patent application in each country other than the United States which claims priority under the applications described in (a) or (b) above; and
  - (d) Patent issuing from the applications described above and each extension or reissue of such patents.

Except as amended her above; all other terms and conditions of the License Agreement between the Parties dated December 20, 2011 remain unchanged and in full force and effect. This Amendment No. 1 is entered into as of the date last executed below.

ORAGENICS,

THE TEXAS A&M UNIVERSITY-SYSTEM

/s/ John Bonfiglio

/s/ Brett Cornwell

John Bonfiglio  
CEO, Oragenics Inc.  
Date: July 2, 2012

Brett Cornwell  
Associate Vice Chancellor for Commercialization  
Date: July 11, 2012

**SECOND AMENDMENT TO  
LICENSE AGREEMENT**

This SECOND AMENDMENT TO LICENSE AGREEMENT (“Second Amendment”) is entered into as of May 18, 2015, by and between ORAGENICS, INC., a Florida corporation located at 4902 Eisenhower Blvd., Ste. 125, Tampa, FL 33634 (“Oragenics”), and THE TEXAS A&M UNIVERSITY SYSTEM, an agency of the State of Texas, with principal offices in College Station, Texas (“System”), herein collectively referred to as the Parties.

**RECITALS:**

**WHEREAS**, the Parties entered into the license agreement on December 20, 2011, as subsequently amended on July 11, 2012 (“License Agreement”); and

**WHEREAS**, Oragenics has shown good faith in attempts to meet all obligations set forth in the License Agreement, however, implementation of a necessary model system has required unforeseen, additional time in developing a Product; and

**WHEREAS**, the Parties desire to amend the License Agreement to reflect the new timeline for achievement of the milestone related to the enrollment of the first patient in a Phase I clinical trial of a Product.

**NOW, THEREFORE, IN CONSIDERATION** of the agreements contained in this Second Amendment, and for other good and valuable consideration the receipt and adequacy of which are hereby acknowledged, the Parties agree as follows:

1. DELETE the table in paragraph 5.01 in its entirety, and REPLACE it with the following new table:

| <u>Milestone</u>   | <u>Due Date for First Occurrence</u> | <u>Milestone Achievement Payment</u> |
|--|--------------------------------------|--------------------------------------|
| Enrollment of the first patient in a Phase I clinical trial of a Product   | June 1, 2016                         | \$ 50,000                            |
| Successful completion of a Phase II clinical trial of a Product, where “successful completion” means enrollment of the first patient in a Phase III clinical trial of a Product                          | June 1, 2019                         | \$ 100,000                           |
| Successful completion of a Phase III clinical trial of a Product, where “successful completion” means receipt of an approved New Drug Application (NDA) from the FDA or foreign equivalent for a Product | June 1, 2022                         | \$ 150,000                           |
| First sale of a Product  | June 1, 2025                         | \$ 400,000                           |

2. Delete paragraph 10.01 in its entirety, and REPLACE it with the following new paragraph 10.01:

10.01 Notices. Payments, notices, or other communications required by this Agreement will be sufficiently made or given if mailed by certified First Class United States mail, postage pre-paid, or by commercial carrier (e.g., FedEx, UPS, etc.) when the carrier maintains receipt or record of delivery, addressed to the address stated below, or to the last address specified in writing by the intended recipient.

If to SYSTEM:

Associate Vice Chancellor for Commercialization  
Texas A&M System Technology Commercialization  
800 Raymond Stotzer Pkwy. Ste. 2020

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Mail Stop 3369 TAMU  
College Station, Texas, USA 77845  
Phone: (979) 847-8682  
FAX: (979) 845-1402

If to ORAGENICS:

CEO Oragenics, Inc.  
4902 Eisenhower Blvd., Ste. 125,  
Tampa, FL 33634  
Phone: (813) 286-7900  
Facsimile: (813) 286-7904

3. Except as amended hereinabove, all other terms and conditions of the License Agreement remain unchanged and in full force and effect.
4. This Second Amendment may be executed by the Parties hereto in separate counterparts, each of which when so executed and delivered shall be an original, by all such counterparts shall together constitute one and the same instrument. Each counterpart may consist of a number of copies hereof each signed by less than all, but together signed by the Parties. The Parties hereto agree that facsimile and electronically transmitted portable document format (pdf) signatures shall be deemed originals.

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**IN WITNESS WHEREOF**, the Parties have executed this SECOND AMENDMENT on the date first indicated above.

ORAGENICS, INC.

By: /s/ Michael Sullivan

Name: Michael Sullivan

Interim Principal Executive Officer and  
Chief Financial Officer

THE TEXAS A&M UNIVERSITY SYSTEM

By: /s/ Brett Cornwell

Name: Brett Cornwell

Associate Vice Chancellor for  
Commercialization

## CERTIFICATION

I, Michael Sullivan., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Oragenics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Dated this 7th day of August, 2015

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



## CERTIFICATION

I, Michael Sullivan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Oragenics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Dated this 7th day of August, 2015

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

**Certification**

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

In connection with the Quarterly Report on Form 10-Q for the quarter ended June 30, 2015 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Michael Sullivan, hereby certify, to the best of my knowledge, that:

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

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

/s/ Michael Sullivan

Name: Michael Sullivan  
Interim Principal Executive Officer  
(Principal Executive Officer)  
Date: August 7, 2015

**Certification**

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

In connection with the Quarterly Report on Form 10-Q for the quarter ended June 30, 2015 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Michael Sullivan, hereby certify, to the best of my knowledge, that:

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

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

/s/ Michael Sullivan

Name: Michael Sullivan  
Chief Financial Officer  
(Principal Financial Officer)  
Date: August 7, 2015