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

FORM 10-Q

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

For the quarterly period ended September 30, 2017.

OR

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

For the transition period from _____ to _____
Commission File Number: 001-32188

ORAGENICS, INC.

(Exact name of registrant as specified in its charter)

FLORIDA
(State or other jurisdiction of incorporation or organization)

59-3410522
(IRS Employer Identification No.)

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

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

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if smaller reporting company)	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

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

As of October 31, 2017, there were 49,274,219 shares of Common Stock, \$.001 par value, outstanding.

[Table of Contents](#)

Table of Contents

	<u>Page</u>
<u>PART I – FINANCIAL INFORMATION</u>	3
Item 1. Financial Statements	3
Balance Sheets as of September 30, 2017 (unaudited) and December 31, 2016	3
Statements of Operations for the Three and Nine Months Ended September 30, 2017 and 2016 (unaudited)	4
Statements of Cash Flows for the Nine Months Ended September 30, 2017 and 2016 (unaudited)	5
Notes to Financial Statements (unaudited)	6
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3. Quantitative and Qualitative Disclosures About Market Risk.	23
Item 4. Controls and Procedures	23
<u>PART II – OTHER INFORMATION</u>	24
Item 1. Legal Proceedings	24
Item 1A. Risk Factors	25
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	27
Item 3. Defaults Upon Senior Securities	27
Item 4. Mine Safety Disclosures	28
Item 5. Other Information	28
Item 6. Exhibits	28
Signatures	30

[Table of Contents](#)

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Oragenics, Inc.

Balance Sheets

	September 30, 2017	December 31, 2016
	<u>(Unaudited)</u>	<u></u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,923,454	\$ 4,080,618
Restricted cash	1,408,115	—
Prepaid expenses and other current assets	<u>769,629</u>	<u>141,086</u>
Total current assets	5,101,198	4,221,704
Property and equipment, net	<u>34,120</u>	<u>87,462</u>
Total assets	<u>\$ 5,135,318</u>	<u>\$ 4,309,166</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,594,245	\$ 1,277,066
Short-term notes payable	<u>128,070</u>	<u>66,377</u>
Total current liabilities	1,722,315	1,343,443
Long-term liabilities:		
Note payable to shareholder	<u>2,400,000</u>	<u>—</u>
Total long-term liabilities	2,400,000	—
Shareholders' equity:		
Preferred stock, no par value; 20,000,000 shares authorized; 12,000,000 and -0- Series A shares issued and outstanding at September 30, 2017 and December 31, 2016	1,245,508	—
Common stock, \$0.001 par value; 250,000,000 shares authorized 49,274,219 and 49,114,219 shares issued and outstanding at September 30, 2017 and December 31, 2016	49,274	49,114
Stock subscription receivable	—	(30,563)
Additional paid-in capital	99,658,285	97,616,444
Accumulated deficit	<u>(99,940,064)</u>	<u>(94,669,272)</u>
Total shareholders' equity	<u>1,013,003</u>	<u>2,965,723</u>
Total liabilities and shareholders' equity	<u>\$ 5,135,318</u>	<u>\$ 4,309,166</u>

See accompanying notes.

[Table of Contents](#)

Orogenics, Inc.
Statements of Operations
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	\$ 996,477	\$ 924,800	\$ 2,724,349	\$ 2,978,775
General and administrative	925,043	1,101,870	2,581,586	2,855,822
Total operating expenses	<u>1,921,520</u>	<u>2,026,670</u>	<u>5,305,935</u>	<u>5,834,597</u>
Loss from continuing operations	(1,921,520)	(2,026,670)	(5,305,935)	(5,834,597)
Other income (expense):				
Interest income	3,004	18,526	6,771	22,554
Interest expense	(105,894)	(1,291)	(164,560)	(2,947)
Change in value of derivative liability	(42,918)	—	188,726	—
Local business tax	(588)	(1,200)	(2,988)	(3,578)
Other income	686	5,062	7,194	5,435
Total other income (expense), net	<u>(145,710)</u>	<u>21,097</u>	<u>35,143</u>	<u>21,464</u>
Loss from continuing operations before income taxes	<u>(2,067,230)</u>	<u>(2,005,573)</u>	<u>(5,270,792)</u>	<u>(5,813,133)</u>
Income tax benefit	—	—	—	—
Net loss from continuing operations	<u>\$ (2,067,230)</u>	<u>\$ (2,005,573)</u>	<u>\$ (5,270,792)</u>	<u>\$ (5,813,133)</u>
Basic and diluted net loss per share from continuing operations	<u>\$ (0.04)</u>	<u>\$ (0.04)</u>	<u>\$ (0.11)</u>	<u>\$ (0.13)</u>
Shares used to compute basic and diluted net loss per share from continuing operations	<u>49,274,219</u>	<u>49,114,219</u>	<u>49,246,673</u>	<u>43,078,989</u>
Discontinued operations				
Profit from operations of discontinued component	—	42,566	—	20,882
Gain on sale of discontinued operations	—	—	—	1,453,744
Income tax benefit	—	—	—	—
Profit from discontinued operations	<u>—</u>	<u>42,566</u>	<u>—</u>	<u>1,474,626</u>
Basic and diluted net profit per share from discontinued operations	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 0.03</u>
Shares used to compute basic and diluted net loss per share from discontinued operations	<u>49,274,219</u>	<u>49,114,219</u>	<u>49,246,673</u>	<u>43,078,989</u>
Net Loss	<u>\$ (2,067,230)</u>	<u>\$ (1,963,007)</u>	<u>\$ (5,270,792)</u>	<u>\$ (4,338,507)</u>
Basic and diluted net loss per share	<u>\$ (0.04)</u>	<u>\$ (0.04)</u>	<u>\$ (0.11)</u>	<u>\$ (0.10)</u>
Shares used to compute basic and diluted net loss per share	<u>49,274,219</u>	<u>49,114,219</u>	<u>49,246,673</u>	<u>43,078,989</u>

See accompanying notes.

[Table of Contents](#)

Oragenics, Inc.
Statements of Cash Flows
(Unaudited)

	For the Nine Months Ended September 30,	
	2017	2016
Cash flows from operating activities:		
Net loss	\$(5,270,792)	\$(4,338,507)
Adjustments to reconcile net loss to net cash used in operating activities:		
Technology access fee paid in convertible note payable to shareholder	—	3,126
Depreciation and amortization	53,342	55,402
Stock issued as compensation to non-employee directors	114,576	84,000
Stock-based compensation expense	307,630	384,992
Warrant issued in exchange for services	118,237	—
Gain on sale of discontinued operations	—	(1,453,744)
Decrease in fair value of derivative liability	(188,726)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(456,496)	198,557
Accounts payable and accrued expenses	317,179	(44,850)
Net cash used in operating activities	(5,005,050)	(5,111,024)
Cash flows from investing activities:		
Proceeds from sale of property and equipment	—	2,198
Purchase of property and equipment	—	(27,179)
Proceeds from payment of note receivable	—	450,000
Proceeds from sale of discontinued operations	—	1,250,000
Net cash provided by investing activities	—	1,675,019
Cash flows from financing activities:		
Payments on short-term notes payable	(110,354)	(112,770)
Net proceeds from issuance of convertible preferred stock and warrants	2,935,792	—
Net proceeds from issuance of common stock	—	2,640,146
Proceeds from issuance of note payable to shareholder	2,400,000	—
Proceeds from payment of stock subscription receivable	30,563	984,666
Restricted cash receipts, net	(1,408,115)	—
Net cash provided by financing activities	3,847,886	3,512,042
Net increase (decrease) in cash and cash equivalents	(1,157,164)	76,037
Operating cash flows from discontinued operations	—	(42,761)
Cash and cash equivalents at beginning of period	4,080,618	5,083,355
Cash and cash equivalents at end of period	\$ 2,923,454	\$ 5,116,631
Supplemental disclosure of cash flow information:		
Interest paid	\$ 3,040	\$ 2,769
Non-cash investing and financing activities:		
Borrowings under short term notes payable for prepaid expense	\$ 172,047	\$ 161,125
Short-term note receivable from stockholder in exchange for the issuance of common stock	\$ —	\$ (2,000,000)
Par value of restricted shares issued	\$ 160	\$ 230
Par value of restricted shares forfeited	\$ —	\$ (20)
Fair market value of 483,870 warrants issued for financial advisory services	\$ 118,237	\$ —

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 a leader in developing novel antibiotics against infectious disease and on developing effective treatments for oral mucositis.

2. Basis of Presentation

The accompanying unaudited interim financial statements as of September 30, 2017 and December 31, 2016 (audited) and for the three and nine months ended September 30, 2017 and 2016 have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by US GAAP for complete financial statements. In the opinion of management, the accompanying financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the financial condition, results of operations and cash flows for the periods presented. The results of operations for the interim period ending September 30, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017 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, 2016, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2017. 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 sold its consumer probiotics business in 2016 and, as a result, has generated \$-0- revenues, incurred a net loss of \$5,270,292, and used cash of \$5,005,050 in its operating activities during the nine months ended September 30, 2017. As of September 30, 2017, the Company had an accumulated deficit of \$99,940,064.

The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes the working capital at September 30, 2017, will be sufficient to meet the business objectives, as presently structured, through December of 2017. As such, there is substantial doubt that we can continue as a going concern beyond that date.

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

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

3. Significant Accounting Policies

Recently Issued Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board issued guidance on Compensation—Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting, to simplify the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of

[Table of Contents](#)

cash flows. Some of the areas for simplification apply only to nonpublic entities. The guidance is effective for annual and interim periods beginning after December 15, 2016. This guidance has not had a material impact on its results of operations, financial position or disclosures.

There are no other accounting pronouncements issued or effective during the three or nine months ended September 30, 2017 that have had, or are expected to have, an impact on our financial statements.

Use of Estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of 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, and income tax valuation allowance. Inventory obsolescence reserve, sales returns and allowances and the allowance for doubtful accounts were the principal areas of estimation that had been reflected in the financial statements related to discontinued operations.

Restricted Cash

The Company has cash that is restricted pursuant to the terms of the Note Purchase Agreement with Intrexon Corporation (“Intrexon”). Proceeds from the note are to be used to fund the Company’s AG013 research and clinical trials.

Stock-Based Payment Arrangements

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

Stock-Based Compensation

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

Warrants

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

Derivative Liabilities

In accordance with ASC 480-10-25 Liabilities-Distinguishing from Equity, warrants are accounted for as liabilities at their fair value during periods where they can be net cash settled in case of a change in control transaction.

The warrants are accounted for as a liability at their fair value at each reporting period. The value of the derivative warrant liability will be re-measured at each reporting period with changes in fair value recorded as a change in the value of derivative liability. To derive an estimate of the fair value of these warrants, a Black Scholes Option Pricing Model is utilized.

[Table of Contents](#)

Net Loss Per Share

During all periods presented, the Company had securities outstanding that could potentially dilute basic earnings per share in the future, but were excluded from the computation of diluted net loss per share, as their effect would have been antidilutive because the Company reported a net loss for all periods presented. Basic and diluted net loss per share amounts are the same for the periods presented. Net loss per share is computed using the weighted average number of shares of common stock outstanding.

Revenue Recognition

During the quarter ended June 30, 2016, the Company sold its consumer probiotic business, from which it had historically generated revenues. As a result of this sale, the Company is no longer generating revenues.

Concentrations

In June of 2016, the Company sold its consumer probiotics business, as such the Company is no longer dependent on key suppliers to continue to operate the consumer probiotics business.

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains cash accounts in commercial banks, which may, at times, exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash and cash equivalents. As of September 30, 2017, the uninsured portion of this balance was \$4,081,569. As of December 31, 2016, the uninsured portion of this balance was \$3,830,618.

4. Stock-based Compensation

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

	Three Months Ended September 30, 2017	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2017	Nine Months Ended September 30, 2016
Research and development	\$ (15,593)	\$ 3,697	\$ (3,336)	\$ (92,354)
General and administrative	143,033	243,315	425,542	582,664
Discontinued operations	—	(21,585)	—	(21,318)
Total Stock based compensation	\$ 127,440	\$ 225,427	\$ 422,206	\$ 468,992

At our annual meeting on May 4, 2017, our shareholders approved an amendment to our 2012 Equity Incentive Plan to increase the shares available for awards thereunder by 1,500,000 shares.

The Company granted -0- and 1,056,000 stock options, with a weighted-average grant date fair value of -0- and \$0.37 per share, during the three and nine months ended September 30, 2017, respectively. The Company granted -0- and 700,000 stock options, with a weighted-average grant date fair value of -0- and \$0.72 per share, during the three and nine months ended September 30, 2016, respectively.

During the nine months ended September 30, 2017, 386,666 stock options previously granted have vested and 71,200 stock options were forfeited and no stock options were exercised.

On June 22, 2017, in connection with, and in furtherance of, the non-employee director compensation program, the Board approved stock option awards in the amount of 140,000 to each of the Company's non-employee directors, Frederick Telling, Charles Pope, Alan Dunton, and Robert Koski under the Company's 2012 Equity Incentive Plan at an exercise price of \$0.37 per share, the closing price on June 22, 2017, the date of the grant.

In addition, on June 22, 2017, in connection with, and in furtherance of, the new equity based award program, the Board approved stock option awards in the amount of 455,000 to management and 41,000 to staff under the Company's 2012 Equity Incentive Plan at an exercise price of \$0.37 per share, the closing price on June 22, 2017, the date of the grant.

On February 9, 2017, in connection with, and in furtherance of, the non-employee director compensation program, the Board approved the award of 40,000 restricted shares of the Company's common stock to each of the Company's non-employee directors, Frederick Telling, Charles Pope, Alan Dunton, and Robert Koski under the Company's 2012 Equity Incentive Plan, of which, 10,000 restricted shares vest at the end of each calendar quarter in 2017, provided the recipient remains a director through the vesting date.

Table of Contents

On February 15, 2016, in connection with, and in furtherance of, the new, the non-employee director compensation 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, Robert Koski and former director Christine Koski under the Company's 2012 Equity Incentive Plan at an exercise price of \$0.84 per share, the closing price on the February 16, 2016, the date of grant. Dr. Telling, Mr. Pope, Dr. Dunton, Robert Koski and former director Christine Koski were each also awarded 40,000 restricted shares of the Company's common stock under the Company's 2012 Plan, of which 10,000 restricted shares vested at the end of each calendar quarter in 2016. Dr. Telling, Mr. Pope, Dr. Dunton, Robert Koski vested fully in the restricted shares awarded to them in 2016. Former director Christine Koski vested in 20,000 restricted shares due to her resignation as a director in June of 2016.

Each executive officer and non-employee director receiving equity based awards is 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 Equity Incentive Plan which requirements are intended to align the ability to sell shares with the performance of the Company's stock price. The executive officer recipients 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 Equity Incentive Plan. Also, the non-employee directors are each 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 Equity Incentive Plan.

5. Warrants

In connection with the Preferred Stock financing (See Note 11), the Company has issued warrants to purchase 10,645,161 shares of the Company's Common stock. The warrants have a term of seven years from the date of issuance and are non-exercisable until six months after issuance, and have an exercise price of \$0.31 per share. In addition, the Company issued a warrant to purchase 483,870 shares of the Company's Common stock pursuant to the terms of a financial advisory services agreement. The warrant has a term of five years from the date of issuance and is non-exercisable until six months after issuance, and has an exercise price of \$0.31 per share. A summary of warrant activity for the year ended December 31, 2016 and the nine months ended September 30, 2017 is as follows:

	<u>Warrants</u>	<u>Weighted Average Price</u>
Balance – December 31, 2015	175,584	\$ 1.50
Granted	—	—
Exercised	—	—
Expired	—	—
Balance – December 31, 2016	175,584	1.50
Granted	11,129,031	0.31
Exercised	—	—
Expired	(175,584)	1.50
Balance – September 30, 2017	<u>11,129,031</u>	<u>\$ 0.31</u>

The warrants outstanding as of September 30, 2017 are as follows:

<u>Exercise Price</u>	<u>Warrants Outstanding</u>	<u>Expiration Dates</u>
\$ 0.31	4,621,037	5/10/24
\$ 0.31	6,024,124	7/25/24
\$ 0.31	483,870	9/19/22
	<u>11,129,031</u>	

6. Short-Term Notes Payable

As of September 30, 2017 and December 31, 2016, the Company had \$128,070 and \$66,377, respectively, in short-term notes payable for the financing of various insurance policies.

On March 1, 2016, the Company entered into a short-term note payable for \$49,395 bearing interest at 5.93% per annum to finance the product liability insurance. Principal and interest payments on this note began April 10, 2016 and were made evenly based on a straight line amortization over a 10-month period with the final payment being made on January 4, 2017.

Table of Contents

On March 10, 2017, the Company entered into a short-term note payable for \$31,985 bearing interest at 6.18% per annum to finance the product liability insurance. Principal and interest payments on this note began April 10, 2017 and are made evenly based on a straight line amortization over a 10-month period with the final payment due on January 10, 2018.

On July 24, 2016, the Company entered into a short-term note payable for \$111,730 bearing interest at 4.89% 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, 2016 and were made evenly based on a straight line amortization over an 11-month period with the final payment being made on June 21, 2017.

On July 21, 2017, the Company entered into a short-term note payable for \$140,062 bearing interest at 5.09% 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, 2017 and are made evenly based on a straight line amortization over an 11-month period with the final payment being due on June 24, 2018.

7. Note Payable to Stockholder

On May 10, 2017 the Company entered into a Note Purchase Agreement with Intrexon pursuant to which the Company issued a \$2,400,000 unsecured non-convertible promissory note to Intrexon and amended the first milestone in its oral mucositis Exclusive Channel Collaboration Agreement ("Oral Mucositis ECC") with Intrexon. The note matures in two (2) years and has a simple interest rate of 12% per annum. Proceeds from the note are to be used to fund the Company's AG013 research and clinical trials.

8. Commitments and Contingencies

The University of Florida Research Foundation Licenses

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

The Company is required to make minimum annual maintenance payments to the UFRF for the term of the amended license agreement in the amount of \$10,000 for the license agreement. The aggregate minimum annual payments are required to be paid in advance on a quarterly basis (i.e. \$2,500 per quarter) for the license. The Company must also pay all patent costs and expenses incurred by the UFRF for the preparation, filing, prosecution, issuance and maintenance of the patents.

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

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 was to pay Texas A&M \$15,000 as minimum annual consideration for the continuation of the license agreement. In October of 2016 the Texas A&M license agreement was amended to provide for a payment of \$25,000 commencing in 2017 and each year thereafter prior to the calendar year of the first sale of products using the licensed technology, as minimum annual 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

Table of Contents

Texas A&M and every year thereafter through the expiration of the Agreement. However, once sales begin, any royalty payments the Company makes on net sales will be credited against the \$100,000 required maintenance payment.

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

Pursuant to the amended Texas A&M license agreement, the Company is obligated to meet the following milestones and make milestone payments: (i) enrollment of first patient in a Phase 1 clinical trial using the licensed technology, to occur on or before June 1, 2019, with a milestone achievement payment of \$50,000, (ii) completion of Phase 2 clinical trial using the licensed technology to occur on or before June 1, 2022, with a milestone achievement payment of \$100,000, (iii) completion of Phase 3 clinical trial of the licensed technology to occur on or before June 1, 2025, with a milestone achievement payment of \$150,000, and (iv) first sale of the licensed technology to occur on or before June 1, 2026 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 September 30, 2017.

The Lantibiotic ECC

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

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

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

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

Base Shares is defined in the Stock Issuance Agreement to mean (i) the number of shares of Company common stock together with any securities or instruments convertible or exercisable for shares of common stock issued and outstanding at the time of the applicable milestone event, (ii) minus any shares issuable upon conversion of Capital Inducement Securities. Capital Inducement Securities is defined in the Stock Issuance Agreement to mean warrants or other convertible securities of the Company issued to investors in connection with a debt or equity investment in the Company that are issued in addition to the primary investment

Table of Contents

securities and in an amount not to exceed 10% of the overall number of shares issued in the investment (on an as-converted to common stock basis).

None of the Lantibiotic ECC milestones had been achieved as of September 30, 2017.

The Oral Mucositis ECC

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

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

- (i) two million United States dollars (\$2,000,000) within thirty (30) days of the first instance of the achievement of the Phase 2 Milestone Event meaning the first dosing of a patient by or on behalf of Oragenics, or an Affiliate or permitted sublicensee of Oragenics, in a Phase 2 clinical trial, whether such occurs in the United States of America under the jurisdiction of the FDA or elsewhere under the jurisdiction of a foreign regulatory agency, for each different Oragenics Product. On May 10, 2017, the Company and Intrexon agreed to amend this milestone payment from a \$2,000,000 payment upon first dosing of a patient to a \$3,000,000 million payment upon the earlier of (a) dosing of the last patient, in a Phase 2 clinical trial, and (b) the twenty four (24) month anniversary of the dosing of the first patient in the Phase 2 clinical trial.
- (ii) five million United States dollars (\$5,000,000) within thirty (30) days of the first instance of the achievement of the Phase 2b/3 Milestone Event meaning meeting of the primary endpoint by or on behalf of Oragenics, or an Affiliate or permitted sublicensee of Oragenics, in a Phase 3 clinical trial, whether such occurs in the United States of America under the jurisdiction of the FDA or elsewhere under the jurisdiction of a foreign regulatory agency, for each different Oragenics Product;
- (iii) five million United States dollars (\$5,000,000) within thirty (30) days of the first instance of the achievement of the Regulatory Approval Application Milestone Event for each different Oragenics Product which Regulatory Approval Application Milestone Event meaning for a given Oragenics Product, the first to occur of (a) the filing by Oragenics, an Affiliate thereof, or a permitted sublicensee thereof, of a FDA New Drug Application or a Biologics License Application with the FDA seeking approval of such Oragenics Product, or (b) the filing of an equivalent approval or marketing application for such Oragenics Product with an equivalent regulatory authority in a foreign jurisdiction;
- (iv) ten million United States dollars (\$10,000,000) within thirty (30) days of the first instance of the achievement of the Approval Milestone Event for each different Oragenics Product which Approval Milestone Event meaning the first to occur of (a) the First Commercial Sale of an Oragenics Product anywhere in the Territory, or (b) 90th day after the approval of a FDA New Drug Application for an Oragenics Product by the FDA or equivalent regulatory action in a foreign jurisdiction;
- (v) Oragenics shall pay Intrexon a milestone payment of five million United States dollars (\$5,000,000) within thirty (30) days of the first instance of the achievement of the New Indication Milestone Event meaning the filing by or on behalf of Oragenics, an Affiliate of Oragenics, or a permitted sublicensee of Oragenics a Supplemental FDA Application with the FDA or with another equivalent regulatory agency seeking approval of an indication for use of the product AG013 other than the current regulatory-approved indication; and
- (vi) Oragenics shall pay Intrexon a milestone payment of five million United States dollars (\$5,000,000) within thirty (30) days of the first instance of the achievement of the New Product Milestone Event meaning the filing of a regulatory package filed with the FDA or with another equivalent regulatory agency by or on behalf of Oragenics, an Affiliate of Oragenics, or a permitted sublicensee of Oragenics, that is deemed (according to relevant FDA guideline) to be a different drug product than AG013.

Table of Contents

None of the Oral Mucositis ECC milestones had been achieved as of September 30, 2017.

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

9. Related Party Transactions

On May 10, 2017 the Company entered into a Note Purchase Agreement with Intrexon pursuant to which the Company issued a \$2.4 million unsecured non-convertible promissory note to Intrexon and amended the first milestone in its Oral Mucositis ECC with Intrexon. The note matures in two (2) years and has a simple interest rate of 12% per annum. Proceeds from the note will be used to fund the Company's AG013 research and clinical trials.

During the three and nine months ended September 30, 2017, we paid \$-0- and \$524,620 respectively; and during the three and nine months ended September 30, 2016 we paid \$253,646 and \$1,187,021 respectively, to Intrexon under the Oral Mucositis and Lantibiotic ECC agreements (See Note 8). Included in accounts payable and accrued expenses at September 30, 2017 and December 31, 2016 was \$894,922 and \$524,620, respectively, related to unpaid invoices received from Intrexon relating to work performed under the ECC Agreements and accrued interest relating to unpaid invoices and the unsecured non-convertible promissory note. As of September 30, 2017 and 2016 Intrexon beneficially owned approximately 31.4% and 31.5% of our outstanding common stock.

On June 27, 2016, the Company completed the sale of its consumer probiotics business to ProBiora Health, LLC, ("ProBiora Health") an entity owned by Ms. Christine L. Koski, a director at the time of the transaction. The purchase price was \$1,700,000 in cash of which \$1,250,000 was paid at closing and \$450,000 was payable on or before July 31, 2016. The note accrued interest at the rate of 1% per annum and was paid in full on July 29, 2016. In connection with the sale, ProBiora Health assumed certain liabilities. ProBiora Health is obligated to pay the Company contingent consideration annually over a 10 year period based on a percentage of sales of products using the Purchased Assets, in excess of \$2,000,000 annually over the contingent contribution period, with a maximum obligation to the Company of \$2,000,000. No payments were made by or due from ProBiora Health for post-closing sales in 2016.

The activities related to the consumer probiotic business are reflected as part of "Discontinued Operations" for the periods presented.

10. Common Stock

On February 9, 2017, in connection with and in furtherance of the non-employee director compensation program (See Note 4), the Board approved the award of 40,000 restricted shares of the Company's common stock to each of the Company's non-employee directors, Frederick Telling, Charles Pope, Alan Dunton, and Robert Koski under the Company's 2012 Equity Incentive Plan of which a total of 30,000 restricted shares vested on September 30, 2017 for each non-employee director and the remainder will vest at the end of each calendar quarter in 2017 provided the recipient remains a director through the vesting date. The awards are considered issued and outstanding as of the date of the grant and are eligible to be voted by the recipient. At September 30, 2017, the Company has \$8,624 in unrecognized compensation expense relating to these awards that will be recognized through the remainder of 2017.

11. Convertible Preferred Stock

On May 10, 2017 the Company entered into a securities purchase agreement with three accredited investors, to purchase up to \$3,000,000 of Series A Convertible Preferred Stock (the "Preferred Stock Financing"). The sale of the preferred stock took place in two separate closings. At the first closing which occurred on May 10, 2017, the Company received gross proceeds of approximately \$1.302 million. At the second closing, which occurred on July 25, 2017, the Company received \$1.698 million. The full \$3,000,000 of preferred stock is convertible into twelve million shares of the Company's common stock, based on a fixed conversion price of \$0.25 per share on an as-converted basis. In addition, the Company issued warrants to purchase an aggregate of 4,621,037 shares of common stock at the first closing and an aggregate of 6,024,124 shares of common stock at the second closing. The warrants have a term of seven years from the date of issuance, are non-exercisable until 6 months after issuance, and have an exercise price of \$0.31 per share.

On July 27, 2017, the Company entered into an agreement to amend the warrants issued in connection with the Preferred Stock Financing to provide notification and objection requirements with respect to the change of control provisions. The change of control provisions in the warrants had previously caused the warrants to be treated as a derivative liability as opposed to being treated as equity on the Company's balance sheet. The warrants have been replaced by amended and restated warrants containing such notification and objection requirements (the "Amended and Restated Common Stock Purchase Warrants") so that the Amended and Restated Common Stock Purchase Warrants are now treated as equity on the Company's balance sheet. All other terms of the original warrants remain unchanged by the Amended and Restated Common Stock Purchase Warrants.

Table of Contents

In connection with the Preferred Financing, the Company filed a Certificate of Designations of Preferences, Rights and Limitations of Series A Preferred Stock with the Secretary of State of the State of Florida, to be effective May 10, 2017. The number of shares of Preferred Stock designated as Series A Preferred Stock is 12,000,000.

In connection with the issuance and sale of the Preferred Stock and Warrants, the Company granted certain demand registration rights and piggyback registration rights with respect to the shares of the Company's Common Stock issuable upon conversion of the Preferred Stock and exercise of the Warrants, pursuant to a Registration Rights Agreement.

Except as otherwise required by law, the Series A Preferred Stock has no voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, the Company shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Certificate of Designation, (b) amend its articles of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series A Preferred Stock, (c) increase the number of authorized shares of Series A Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary that is not a Fundamental Transaction (as defined in the Certificate of Designation), the holders of Series A Preferred Stock shall be entitled to receive out of the assets, the greater of (i) the product of the number of shares of Series A Preferred Stock then held by such holder, multiplied by the Original Issue Price; and (ii) the amount that would be payable to such holder in the Liquidation in respect of Common Stock issuable upon conversion of such shares of Series A Preferred Stock if all outstanding shares of Series A Preferred Stock were converted into Common Stock immediately prior to the Liquidation. The preferred stock is classified as permanent equity.

[Table of Contents](#)

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

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

Forward-Looking Statements

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

Overview

We are focused on becoming a leader in novel antibiotics against infectious disease and on developing effective treatments for oral mucositis.

Our Oral Mucositis Product Candidate-Clinical

In June of 2015, we entered into a worldwide Exclusive Channel Collaboration Agreement ("Oral Mucositis ECC") with Intrexon Corporation ("Intrexon") and Intrexon Actobiotics NV, a wholly-owned subsidiary of Intrexon, pursuant to which we obtained certain exclusive rights to AG013 as a potential treatment of oral mucositis, or OM for cancer patients, which we intend to continue to develop. AG013, is an oral rinsing solution designed to deliver human Trefoil Factor 1 (hTFF1) to protect and regenerate damaged mucosal lining of the oral cavity.

OM results in a painful inflammation and mucosal ulceration in the lining of the oral cavity, throat and esophagus and is one of the most commonly reported adverse events associated with cancer chemotherapy affecting up to 500,000 patients annually. OM has a negative effect on patient well-being and if severe, negatively affects a patient's cancer treatment regimen. At present, we are not aware of any drug that is approved to prevent the condition broadly and current therapies are primarily palliative in nature, only addressing symptom relief but not treating the underlying causes of the condition.

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

We have developed a Phase 2 protocol for AG013 with the FDA and it has received fast track designation. The study will be a double blind, placebo controlled, evaluation of daily AG013, administered three times a day, oral rinse for the duration of the cancer treatment. The study is expected to enroll between 160-180 patients receiving chemoradiation over 7 to 9 weeks. The primary endpoint is a reduction, compared to the placebo, in the number of days of severe oral mucositis. In addition, a number of secondary endpoints will also be evaluated.

[Table of Contents](#)

In August of 2016, we received feedback from the FDA in response to our Type C meeting and the pursuit of a Phase 2 trial on AG013 for the treatment of oral mucositis in head and neck cancer patients. We filed an Investigational New Drug (“IND”) update in March 2017 and plan to initiate a Phase 2 study with AG013 in the United States and Europe in 2017. We previously announced that the first patient has been dosed in its Phase 2 clinical trial of AG013 for the treatment of oral mucositis (OM). The Phase 2 clinical trial of AG013 is a double-blind, placebo-controlled study that will be conducted at approximately 30 sites across the United States and Europe, and is expected to enroll up to 200 patients. The purpose of the study is to evaluate the efficacy, safety and tolerability of administered AG013 compared to placebo for reducing OM in patients undergoing chemo-radiation for the treatment of head and neck cancer, as measured by the duration, time to development, and overall incidence of OM. Presently, the Phase 2 clinical study is enrolling patients in the United States.

Our Antibiotic Product Candidate-Preclinical

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

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

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

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

In our pre-clinical studies to support a potential IND filing with the FDA, we tested a total of six homologs of MU1140 for certain compound characteristics, including but not limited to: drug activity (based on minimum inhibitory concentration or “MIC”) equal or better than “standard of care” drugs against certain drug-resistant bacteria, safety, toxicity, stability, and manufacturability. The study specifically evaluated homolog efficacy in relation to survival, measurable amounts of *Clostridium difficile* (“*C. diff*”) colony forming units, and toxin levels. Three homologs demonstrated promising results with one homolog, OG253 achieving a 100% survival rate throughout the entire study in contrast to an approximately 30% survival rate for the vancomycin positive control.

We selected a lead candidate, OG253, and we had a pre IND meeting with the FDA in November of 2015 regarding the pursuit of an IND on OG253. Following additional research and development on second generation lantibiotics, in August of 2016, we opted to select a second generation lantibiotic, OG716, for treatment of *C. diff* as our new lead candidate. OG716 is a new, orally-active homolog, that has exhibited positive results in an animal model for potential treatment of *C. diff*. Generated from our MU1140 platform, this new lantibiotic showed promising efficacy in reducing clinically relevant *C. diff* infections as measured by increased animal survival and decreased relapse as well as reduced production of *C. diff* spores when compared to a vancomycin positive control.

The timing of the filing of an IND regarding OG716 is subject to our having sufficient available capital given all of our anticipated needs and expected requirements in connection with our ongoing research and development initiatives. While we were able to raise additional capital during the quarter ended June 30, 2017, we currently expect the IND for a first-in-human clinical study of OG716 by year end 2018 as we continue to seek additional capital to advance the program.

Other Product Candidates and Technologies.

In addition to our lantibiotics and oral mucositis product candidates, we also have other candidates and technologies in the oral care and weight loss areas. We do not intend to continue to develop these potential product candidates and technologies without partnering with a third party. We out-licensed the continued research and development of our weight loss product candidate in December 2013 to, LPThera LLC, and LPThera LLC continues to work to develop a product for commercial use. Our oral care product candidate SMaRT Replacement Therapy is positioned for out-licensing opportunities.

Table of Contents

Recent Developments

The Preferred Stock Financing –Second Closing

On May 10, 2017 we entered into a securities purchase agreement with three accredited investors, to purchase up to \$3.0 million of Series A Convertible Preferred Stock (the “Preferred Stock Financing”). The sale of the Preferred Stock took place in two separate closings and at the first closing which occurred on May 10, 2017, we received gross proceeds of approximately \$1,302,000. The second closing occurred on July 25, 2017 and we received gross proceeds of approximately \$1,698,000, which was the balance of the Preferred Stock Financing. The full \$3,000,000 of Preferred Stock is convertible into twelve million shares of our Common Stock, based on a fixed conversion price of \$0.25 per share on an as-converted basis. In addition, we issued warrants to purchase an aggregate of 4,621,037 shares of Common Stock at the first closing and we issued an aggregate of 6,024,124 shares of Common Stock at the second closing. The Warrants have a term of seven years from the date of issuance are non-exercisable until 6 months after issuance, and have an exercise price of \$0.31 per share.

Proceeds from the Preferred Stock Financing (including the exercise of any warrants for cash) will be used for general corporate purposes, including working capital.

In connection with the Preferred Financing, we filed a Certificate of Designations of Preferences, Rights and Limitations of Series A Preferred Stock with the Secretary of State of the State of Florida, to be effective May 10, 2017. The number of shares of Preferred Stock designated as Series A Preferred Stock is 12,000,000.

In connection with the issuance and sale of the Preferred Stock and Warrants, we granted certain demand registration rights and piggyback registration rights with respect to the shares of our Common Stock issuable upon conversion of the Preferred Stock and exercise of the Warrants, pursuant to a Registration Rights Agreement.

Except as otherwise required by law, the Series A Preferred Stock shall have no voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Certificate of Designation, (b) amend its articles of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series A Preferred Stock, (c) increase the number of authorized shares of Series A Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing. Upon any liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary that is not a Fundamental Transaction (as defined in the Certificate of Designation), the holders of Series A Preferred Stock shall be entitled to receive out of the assets, the greater of (i) the product of the number of shares of Series A Preferred Stock then held by such holder, multiplied by the Original Issue Price; and (ii) the amount that would be payable to such holder in the Liquidation in respect of Common Stock issuable upon conversion of such shares of Series A Preferred Stock if all outstanding shares of Series A Preferred Stock were converted into Common Stock immediately prior to the Liquidation.

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 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 as well as to the commercialization of our previously owned consumer probiotic products. We have generated limited revenues from grants and from our discontinued consumer product business through June 30, 2016, and have principally funded our operations through the sale of debt and equity securities, issued in connection with these financing transactions. Our net revenues were \$464,048 and \$1,175,841, for the years ended December 31, 2016 and 2015, respectively. In June of 2016, we completed the sale of our consumer probiotics business to ProBiora Health, LLC and as a result, we will no longer generate revenue from sales of consumer probiotic products.

As of September 30, 2017, we had an accumulated deficit of \$99,940,064 and we have yet to achieve profitability. We incurred net losses of \$5,270,792 and \$4,338,507 for the nine months ended September 30, 2017 and 2016, respectively, and \$7,013,304 and \$11,711,333 for the years ended December 31, 2016 and 2015, 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.

[Table of Contents](#)

Financial Overview

Research and Development Expenses

Research and development consists of expenses incurred in connection with the discovery and development of our product candidates. These expenses consist primarily of employee-related expenses, which include salaries and benefits and attending science conferences; expenses incurred under our ECC agreements with Intrexon and under other 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, stock-based compensation and research expenses we incur associated with our ECC agreements with Intrexon. Nonclinical research and development costs consist of our research activities, nonclinical studies, related personnel costs and laboratory supplies, and other costs such as rent, utilities, depreciation and stock-based compensation and research expenses we incur associated with our ECC agreements with Intrexon. While we are currently focused on advancing our product development programs, our future research and development expenses will depend on the clinical success of our product candidates, as well as ongoing assessments of each product candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans, research expenses and capital requirements.

Our research and development expenses were \$2,724,349 and \$2,978,775 for the nine months ended September 30, 2017 and 2016, respectively.

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

Our plan is to budget and manage expenditures in research and development such that they are undertaken in a cost-effective manner yet still advance the research and development efforts. While we have some control under our Lantibiotic ECC and Oral Mucositis ECC as to the planning and timing of the research and development and therefore the timing of when expenditures may be incurred for various phases of agreed upon projects, actual expenditures can vary from period to period. Subject to available capital, we expect overall research and development expenses to increase as a result of the expected initiation of our Phase 2b clinical trial on our oral mucositis product candidate 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.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, and administrative 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 will remain relatively flat from period to period as we manage our available capital. Subject to available capital our general and administrative expenses may increase for, among others, the following reasons:

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

[Table of Contents](#)

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, and interest earned on the stock subscription receivable. The primary objective of our investment policy is capital preservation. Interest expense consists primarily of interest and costs associated with our indebtedness.

Income Taxes

As of December 31, 2016, we have net operating loss carryforwards of approximately \$87,663,000 to offset future federal and state income taxes. We also have research and development tax credit carryforwards of approximately \$1,875,000 as of December 31, 2016 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 2036 and 2026, respectively. Our ability to utilize our net operating loss and tax credit carryforwards may be limited in the event a change in ownership, as defined in Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, has occurred or may occur in the future. The private placement transaction with the KFLP in June 2009 (the "June 2009 Private Placement") constituted such an event and our historical loss carryforwards up to such point in time were limited. Furthermore, our transactions with Intrexon during 2013 constituted a second such event, and our historical loss carryforwards up to December 2013 were further limited. See "Tax Loss Carryforwards." In each period since our inception, we have recorded a 100% valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal tax benefit in our statements of operations.

Results of Operations for the Three Months Ended September 30, 2017 and 2016

Research and Development. Research and development expenses were \$996,477 for the three months ended September 30, 2017 compared to \$924,800 for the three months ended September 30, 2016, an increase of \$71,677. This increase was primarily due to increases in costs associated with work under our Oral Mucositis ECC and patent costs of \$391,822 and \$37,321 respectively. This increase was partially offset by decreases costs associated with salary and salary related costs, work under our Lantibiotic ECC, insurance, travel and entertainment, repairs and maintenance, and postage and delivery of \$191,355, \$154,322, \$5,047, \$3,405, \$1,687, and \$1,403 respectively.

General and Administrative. General and administrative expenses were \$925,043 for the three months ended September 30, 2017 compared to \$1,101,870 for the three months ended September 30, 2016, a decrease of \$176,827 or 16.0%. This decrease was primarily due to decreases in costs associated with stock based compensation costs, salary and salary related costs, patents, filing fees, travel and entertainment, legal costs, board fees, supplies and equipment, and outside accountant costs of \$92,240, \$89,543, \$36,476, \$31,354, \$28,926, \$22,661, \$15,750, \$11,866, and \$9,824 respectively which was partially offset by an increase in consulting costs of \$166,669.

Other Income (Expense). Other income (expense), net was \$(145,710) for the three months ended September 30, 2017 compared to \$21,097 for the three months ended September 30, 2016, resulting in a net change of \$166,807. The net change was primarily attributable to an increase in interest expense of \$104,603 due to increased levels of borrowing in 2017, changes in the fair value of derivative liabilities of \$42,918, and a decrease in interest income of \$15,522.

Discontinued Operations. Net Profit from discontinued operations was \$-0- for the three months ended September 30, 2017 compared to \$42,566 for the three months ended September 30, 2016, resulting in a net change of \$(42,566). The net change was primarily attributable to decreases in salary and salary related costs of \$42,493.

Results of Operations for the Nine Months Ended September 30, 2017 and 2016

Research and Development. Research and development expenses were \$2,724,349 for the nine months ended September 30, 2017 compared to \$2,978,775 for the nine months ended September 30, 2016, a decrease of \$254,426. This decrease was primarily due to decreases in costs associated with work under our Lantibiotic ECC, salary and salary related costs, patents, and insurance of \$822,521, \$151,139, \$18,686, and \$10,302 respectively. This decrease was partially offset by an increase in costs associated with work under our Oral Mucositis ECC of \$749,885.

General and Administrative. General and administrative expenses were \$2,581,586 for the nine months ended September 30, 2017 compared to \$2,855,822 for the nine months ended September 30, 2016, a decrease of \$274,236 or 9.6%. This decrease was primarily due to decreases in costs associated with stock based compensation costs, legal, board fees, filing fees, rent and utilities, outside accountants, travel and entertainment, and supplies and equipment costs of \$188,965, \$170,438, \$77,624, \$41,438, \$20,596, \$19,175, \$17,413, and \$15,084 respectively which were partially offset by increases in consulting costs and salary and salary related costs, of \$183,345 and \$90,600 respectively.

Table of Contents

Other Income (Expense). Other income, net was \$35,143 for the nine months ended September 30, 2017 compared to \$21,464 for the nine months ended September 30, 2016, resulting in a net change of \$13,679. The net change was primarily attributable to increases in the fair value of derivative liabilities of \$188,726, interest expense of \$161,613 due to increased levels of borrowing in 2017 and a decrease in interest income of \$15,783.

Discontinued Operations. Net Profit from discontinued operations was \$-0- for the nine months ended September 30, 2017 compared to \$1,474,626 for the nine months ended September 30, 2016, resulting in a net change of \$1,474,5626. The net change was primarily attributable to decreases in the gain on sale of discontinued operations of \$1,453,744. There was no such gain recorded during the nine months ended September 30, 2017.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through the sale of equity securities and warrants in private placements, debt financing, public offerings, and grants. During the nine months ended September 30, 2017 and 2016, our operating activities used cash of \$5,005,050 and \$5,111,024, 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 \$3,378,883 and \$2,878,261 at September 30, 2017 and December 31, 2016, respectively.

During the nine months ended September 30, 2017 and 2016, our investing activities provided cash of \$-0- and \$1,675,019, respectively.

During the nine months ended September 30, 2017 and 2016, our financing activities provided cash of \$3,847,886 and \$3,512,042, respectively. The cash provided by financing activities during the nine months ended September 30, 2017 and 2016 was primarily due to the sales of our common and convertible preferred stock with warrants, and the receipt of proceeds under a note payable to shareholder.

Financings

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

The Preferred Stock Financing

On May 10, 2017 we entered into a securities purchase agreement with three accredited investors, to purchase up to \$3,000,000 of Series A Convertible Preferred Stock (the "Preferred Stock Financing"). The sale of the Preferred Stock took place in two separate closings and at the first closing which occurred on May 10, 2017, we received gross proceeds of approximately \$1,302,000. The second closing occurred on July 25, 2017 and we received gross proceeds of approximately \$1,698,000, which was the balance of the Preferred Stock Financing. The full \$3,000,000 of Preferred Stock is convertible into twelve million shares of our Common Stock, based on a fixed conversion price of \$0.25 per share on an as-converted basis. In addition, we issued warrants to purchase an aggregate of 4,621,037 shares of Common Stock at the first closing and we issued an aggregate of 6,024,124 shares of Common Stock at the second closing. The Warrants have a term of seven years from the date of issuance are non-exercisable until 6 months after issuance, and have an exercise price of \$0.31 per share. Proceeds from the Preferred Stock Financing (including the exercise of any warrants for cash) will be used for general corporate purposes, including working capital.

In connection with the Preferred Financing, we filed a Certificate of Designations of Preferences, Rights and Limitations of Series A Preferred Stock with the Secretary of State of the State of Florida, to be effective May 10, 2017. The number of shares of Preferred Stock designated as Series A Preferred Stock is 12,000,000.

In connection with the issuance and sale of the Preferred Stock and Warrants, we granted certain demand registration rights and piggyback registration rights with respect to the shares of our Common Stock issuable upon conversion of the Preferred Stock and exercise of the Warrants, pursuant to a Registration Rights Agreement.

Except as otherwise required by law, the Series A Preferred Stock shall have no voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Certificate of Designation, (b) amend its articles of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series A Preferred Stock, (c) increase the number of authorized shares of Series A Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing. Upon any liquidation, dissolution or winding-up by us, whether voluntary or involuntary that is not a Fundamental Transaction (as defined in the Certificate of Designation), the holders of Series A Preferred Stock shall be entitled to receive out of the assets, the greater of (i) the product of the number of shares of Series A Preferred Stock then held by such holder, multiplied by the Original Issue Price; and (ii) the amount that

Table of Contents

would be payable to such holder in the Liquidation in respect of Common Stock issuable upon conversion of such shares of Series A Preferred Stock if all outstanding shares of Series A Preferred Stock were converted into Common Stock immediately prior to the Liquidation.

The May 2017 Intrexon Debt Financing and ECC Amendment

On May 10, 2017, concurrently with the above referenced Preferred Stock Financing, we entered into Note Purchase Agreement with Intrexon pursuant to which the Company issued a \$2,400,000 unsecured non-convertible promissory note to Intrexon (the "Intrexon Note") and amended the first milestone in our Oral Mucositis exclusive channel collaboration agreement (the "Oral Mucositis ECC") with Intrexon.

The Intrexon Note matures in two (2) years and has a simple interest rate of 12% per annum. Proceeds from the Intrexon Note will be used to fund our AG013 research and clinical trials. In addition to, and as part of the Intrexon note, we amended the first milestone payment on the Oral Mucositis ECC from a \$2,000,000 payment upon first dosing of a patient to a \$3,000,000 payment upon the earlier of (a) dosing of the last patient, in a Phase 2 clinical trial, and (b) the twenty four (24) month anniversary of the dosing of the first patient in the Phase 2 clinical trial. Simultaneously with the amendment to the Oral Mucositis ECC a similar amendment was put in place with respect to our Stock Issuance Agreement with Intrexon reflecting the milestone amendment.

The June 2016 Private Placement

On June 30, 2016, we closed on a private placement of 9,045,679 shares of our common stock to three accredited investors. The investors in the private placement included some of our current shareholders, the Koski Family Limited Partnership ("KFLP"), Intrexon Corporation, as well as our Chairman, Dr. Frederick Telling. Approximately \$4.667 million was raised of which \$2 million was payable under a note payable by the KFLP which was due on or before September 30, 2016. The note accrued interest at 3% per annum. The purchase price per share of the common stock sold in the private placement was \$0.5159, which was the midpoint of the closing quote on the Company's primary exchange, NYSE MKT, on June 29, 2016 as required by NYSE listing standards. We will use the net proceeds, after payment of offering expenses, for the funding of research and development activities related to the Intrexon Exclusive Channel Collaborations and for general corporate purposes.

On September 15, 2016, the note payable with the KFLP was amended. Under the terms of the amendment, the KFLP paid \$1,000,000 on September 30, 2016 which was first applied to accrued interest and then to the outstanding principal balance. The amendment extended the maturity date on the remaining balance of the note payable to, on or before, December 31, 2016 and increased the interest rate on the note payable from 3% per annum to 6% per annum commencing on the date of the amendment. On December 29, 2016, the KFLP made a payment of \$1,000,000 which was applied to accrued interest and then to the outstanding principal balance. The remaining balance of the Note was paid in full in January of 2017.

Other Financings

We enter into short term financing arrangements for the payment of our annual insurance premiums for our products liability insurance and directors and officers and employment practices insurance. On March 1, 2016, the Company entered into a short-term note payable for \$49,395 bearing interest at 5.93% per annum to finance the product liability insurance. Principal and interest payments on this note began April 10, 2016 and were made evenly based on a straight line amortization over a 10-month period with the final payment being made on January 4, 2017.

On March 10, 2017, the Company entered into a short-term note payable for \$31,985 bearing interest at 6.18% per annum to finance the product liability insurance. Principal and interest payments on this note began April 10, 2017 and such payments are to be made evenly based on a straight line amortization over a 10-month period with the final payment due on January 10, 2018.

On July 24, 2016, the Company entered into a short-term note payable for \$111,730 bearing interest at 4.89% 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, 2016 and were made evenly based on a straight line amortization over an 11-month period with the final payment being made on June 21, 2017.

On July 24, 2017, the Company entered into a short-term note payable for \$104,062 bearing interest at 5.09% 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, 2017 and such payments are to be made evenly based on a straight line amortization over an 11-month period with the final payment being due on June 24, 2018.

[Table of Contents](#)

Future Capital Requirements

Our capital requirements for the remainder of 2017 and thereafter will depend on numerous factors, including the success 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 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 additional funds to conduct research and development and nonclinical and Phase 1 and Phase 2 clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase 2 and 3 clinical testing and manufacture and marketing of any products that are approved for commercial sale. Our plans include seeking both equity and debt financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to ensure continuation of our operations and research and development programs.

We believe our current available cash and cash equivalents together with the recently completed second closing of the Preferred Stock financing will allow us to fund our operating plan as currently structured through December 2017. We expect to continue to seek additional funding for our operations. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned clinical trial and clinical testing and, research and development activities, which could harm our business. The sale of additional equity or debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of equity or debt securities, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We also will require additional capital beyond our currently forecasted amounts. For example, as we continue to work with Intrexon under the Lantibiotic ECC for the development of MU1140 homologs and in our Oral Mucositis ECC, we will require additional capital.

Because of the numerous risks and uncertainties associated with 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 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;
- 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 to meet the payment obligations we may have thereunder;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our products and future products, if any.

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

Critical Accounting Estimates and Policies

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP"). The preparation of financial statements in accordance with US GAAP requires us to make estimates and assumptions that affect reported amounts and related disclosures. We consider an accounting estimate to be critical if it requires assumptions to be made that were uncertain at the time the estimate was made; and changes in the estimate or different estimates that could have been made could have a material impact on our results of operations or financial condition. The principal areas of estimation reflected in the financial statements are anticipated milestone payments, stock based compensation, valuation of warrants, and income tax valuation allowance.

[Table of Contents](#)

Inventory obsolescence reserve, sales returns and allowances and allowance for doubtful accounts were the principal areas of estimation that had been reflected in the financial statements related to discontinued operations. For a detailed discussion of our critical accounting estimates, see our Annual Report on Form 10-K for the year ended December 31, 2016. There have been no material changes to our critical accounting estimates during the nine months ended September 30, 2017.

Recently Issued Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board issued guidance on Compensation—Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting, to simplify the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. Some of the areas for simplification apply only to nonpublic entities. The guidance is effective for annual and interim periods beginning after December 15, 2016. This guidance has not had a material impact on the results of operations, financial position or disclosures.

There are no other accounting pronouncements issued or effective during the three or nine months ended September 30, 2017 that have had, or are expected to have, an impact on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Management's evaluation of the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act was performed under the supervision and participation of our senior management, including our Chief Executive Officer and Chief Financial Officer. The purpose of disclosure controls and procedures is to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of such period, our disclosure controls and procedures were effective as of September 30, 2017 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.

Changes in Internal Controls over Financial Reporting

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

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

[Table of Contents](#)

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.

[Table of Contents](#)

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, 2016 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, 2016 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, 2016 filed on February 27 2017. Except as set forth below, there have been no material changes to the risk factors previously disclosed under the caption "Risk Factors" in our Annual Report on Form 10-K.

Risks Related to Our Business

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

We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of approximately and \$5.3 million and \$4.3 million for the nine months ended September 30, 2017 and 2016, respectively, and approximately \$7.0 million and \$11.7 million for the years ended December 31, 2016, and 2015, respectively. As of September 30, 2017 our accumulated deficit was approximately \$99.9 million. We have devoted a significant amount of our financial resources to research and development, including our nonclinical development activities and clinical trials. We expect that the expenses associated with our anticipated clinical trial for our oral mucositis product candidate to increase. We expect the costs associated with our exclusive channel partnerships with Intrexon in the areas of lantibiotics ("Lantibiotics Program") and Oral Mucositis ("Oral Mucositis Program") and the development and commercialization of our product candidates under the Lantibiotics Program (which includes MU1140 homologs) using Intrexon's advanced transgene and cell engineering platforms will also continue to increase and as such the level of our overall expenses will increase significantly going forward. As a result, we expect to continue to incur substantial net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' equity and working capital. Because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to accurately predict the timing or amount of substantial expenses or when, or if, we will be able to generate the revenue necessary to achieve or maintain profitability.

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

Developing and commercializing biopharmaceutical products, including conducting nonclinical studies and clinical trials and establishing manufacturing capabilities, is expensive. We anticipate that our cash resources as of September 30, 2017, together with the recently completed second closing of the Preferred Stock financing will be sufficient to fund our operations as presently structured through December 2017. 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 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 will need to raise additional capital to, among other things:

- continue to conduct our Phase 2 clinical trial on our AG013 product candidate;
- expand our clinical laboratory operations;
- fund our clinical activities;
- expand our research and development activities;
- acquire or license products or technologies; and
- finance our capital expenditures and general and administrative expenses.

[Table of Contents](#)

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, which could in turn, impact our ability to maintain our existing license agreements.

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

In light of our recurring losses, accumulated deficit and negative cash flow as described in our notes to our audited financial statements, the report of our independent registered public accounting firm on our financial statements for the year ended December 31, 2016 contains an explanatory paragraph raising substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that may be necessary in the event we are unable to continue as a going concern. If we are unable to establish to the satisfaction of our independent registered public accounting firm that the net proceeds from our financing efforts will be sufficient to allow for the removal of this going concern qualification, we may need to significantly modify our operational plans for us to continue as a going concern. While we believe we can continue our current level of operations with the cash we have on hand coupled with the recently announced debt and equity financing arrangements through December 2017, we will need to arrange additional financing to remain a going concern.

We recently incurred significant debt and we will need to obtain additional financing to repay such debt.

On May 10, 2017 we issued a \$2,400,000 unsecured promissory note to Intrexon Corporation. The note matures in 24 months. We will need to obtain additional financing in order to meet our repayment obligations and there can be no assurance that financing will be available in amounts or on terms commercially acceptable to us, if at all.

Risks Related to Our Common Stock

All of our debt obligations and our Series A preferred stock will have priority over our common stock with respect to payment in the event of a liquidation, dissolution or winding up.

On May 10, 2017 we issued a \$2,400,000 unsecured promissory note to Intrexon Corporation and issued 5,209,169 shares of Series A preferred stock to three accredited investors. On July 25, 2017 we sold an additional 6,790,831 shares of Series A preferred stock. In any liquidation, dissolution or winding up, our common stock would rank below all debt claims against us and all of our outstanding shares of Series A preferred stock. As a result, holders of our common stock will not be entitled to receive any payment or other distribution of assets upon the liquidation or dissolution until after our obligations to our debt holders and holders of Series A preferred stock have been satisfied.

Table of Contents

As our warrant holders exercise their warrants into shares of our Common Stock, our shareholders will be diluted.

On May 10, 2017 we issued Common Stock Purchase Warrants to purchase 4,621,037 shares of common stock and on July 25, 2017 we issued an additional 6,024,124 Common Stock Purchase Warrants in connection with the sale of Series A preferred stock. The exercise of some or all of our Common Stock Purchase Warrants results in issuance of common shares that dilute the ownership interests of existing shareholders. Any sales of the Common Stock issuable upon exercise of the warrants could adversely affect prevailing market prices of our Common Stock and the potential for such downward pressure on the price of our Common Stock may encourage short selling of our Common Stock.

Under certain circumstances we may be required to settle the value of the Common Stock Purchase Warrants in cash.

If, at any time while the Common Stock Purchase Warrants are outstanding, we enter into a “Change of Control” (as defined in the Common Stock Purchase Warrants), which includes, but is not limited to, a merger or sale of substantially all of our assets, then each holder of outstanding Common Stock Purchase Warrants at any time prior to the consummation of the Change of Control, may elect and require us to purchase the Common Stock Purchase Warrants held by such person immediately prior to the consummation of such Change of Control by making a cash payment in an amount equal to the Black Scholes Value of the remaining unexercised portion of such holder’s Common Stock Purchase Warrants.

If our common stock is delisted for failure to regain compliance with the NYSE MKT’s continued listing standards, it could have negative consequences including reduced trading liquidity, lower share prices, impairment of our ability to raise needed additional capital and other consequences.

The listing of our common stock on the NYSE MKT is contingent on our compliance with the NYSE MKT’s continued listing standards. On May 10, 2015, we were notified by the NYSE MKT that we were no longer in compliance with the NYSE MKT continued listing standards because our last reported stockholders’ equity was below continued listing standards. Specifically, we are not in compliance with Section 1003(a)(iii) (requiring stockholders’ equity of \$6.0 million or more if it has reported losses from continuing operations and/or net losses in its five most recent fiscal years). As of December 31, 2015, we had stockholders’ equity of \$4.7 million. We were required to submit a plan to the NYSE MKT by June 10, 2016 advising of actions we have taken or will take to regain compliance with the continued listing standards by November 10, 2017. We submitted a plan by the June 10, 2016 deadline and were notified that NYSE Regulation has accepted the Company’s plan to regain compliance with the NYSE MKT exchange’s continued listing standards set forth in Sections 1003(a)(ii) and 1003(a)(iii) of the NYSE MKT Company Guide (the “Company Guide”) by November 10, 2017, subject to periodic review by the NYSE MKT for compliance with the initiatives set forth in the plan. If the Company is not in compliance with the continued listing standards by November 10, 2017, or if it does not make progress consistent with the plan during the plan period, the NYSE Regulation staff may initiate delisting proceedings as appropriate. There can be no assurance that we will be able to timely regain compliance with the NYSE MKT’s continued listing standards or otherwise successfully appeal any determination by the NYSE MKT to delist our common stock for failure to comply with the NYSE MKT’s continued listing standards.

If our common stock is delisted from the NYSE MKT, it will trade in the over-the-counter market and there could be negative consequences including reduced trading liquidity of our common stock, lower demand and market price for our common stock, adverse publicity and a reduced interest in the Company from investor and analysts. Such delisting from the NYSE MKT could also greatly impair our ability to raise additional necessary capital, significantly increase the ownership dilution to shareholders caused by our issuing additional equity and impair our ability to attract and retain employees by means of equity compensation. In addition, our board of directors may issue preferred stock with rights, preferences and privileges that are senior to those of the holders of our common stock. Debt financings could involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens or make investments and may, among other things, preclude us from making distributions to shareholders (either by paying dividends or redeeming stock) and taking other actions beneficial to our shareholders. In addition, investors could impose more one-sided investment terms and conditions on companies that have or are perceived to have limited remaining funds or limited ability to raise additional funds. The lower our cash balance, the more difficult it is likely to be for us to raise additional capital on commercially reasonable terms, or at all.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

[Table of Contents](#)

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Incorporated by reference to Exhibits filed after signature page.

Table of Contents

EXHIBIT INDEX

<u>Exhibit number</u>	<u>Exhibit description</u>	<u>Incorporated by Reference</u>			<u>Filing date</u>	<u>Filed herewith</u>
		<u>Form</u>	<u>File no.</u>	<u>Exhibit</u>		
3.1	<u>Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock</u>	8-K	001-32188	3.1	5/11/17	
4.1	<u>Form of Common Stock Purchase Warrant</u>	8-K	001-32188	4.1	5/11/17	
4.2	<u>Promissory Note dated May 10, 2017</u>	8-K	001-32188	4.2	5/11/17	
9.1	<u>Form of Voting Agreement</u>	8-K	001-32188	9.1	5/11/17	
10.1	<u>Securities Purchase Agreement by and between Orogenics, Inc. and the Purchasers dated May 10, 2017</u>	8-K	001-32188	10.1	5/11/17	
10.2	<u>Form of Registration Rights Agreement</u>	8-K	001-32188	10.2	5/11/17	
10.3	<u>Note Purchase Agreement by and between Orogenics, Inc. and Intrexon Corporation dated May 10, 2017</u>	8-K	001-32188	10.3	5/11/17	
10.4	<u>Exclusive Channel Collaboration Agreement by and between Orogenics, Inc. and Intrexon Corporation dated as of June 9, 2015*</u>	8-K	001-32188	10.1	6/11/15	
10.5	<u>Exclusive Channel Collaboration Agreement Amendment by and between Orogenics, Inc. and Intrexon Corporation dated as of May 10, 2017</u>	8-K	001-32188	10.4	5/11/17	
10.6	<u>Stock Purchase and Issuance Agreement by and between Orogenics, Inc. and Intrexon Corporation dated as of June 9, 2015*</u>	8-K	001-32188	10.2	6/11/15	
10.7	<u>Stock Issuance Agreement Amendment by and between Orogenics, Inc. and Intrexon Corporation dated as of May 10, 2017</u>	8-K	001-32188	10.5	5/11/17	
31.1	<u>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.</u>					X
31.2	<u>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.</u>					X
32.1	<u>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).</u>					X
32.2	<u>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).</u>					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 granted as to certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended, or Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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 31st day of October, 2017.

ORAGENICS, INC.

BY: /s/ Alan F. Joslyn Ph.D.
Alan F. Joslyn Ph.D., President, Chief Executive
Officer and Principal Executive Officer

BY: /s/ Michael Sullivan
Michael Sullivan, Chief Financial Officer and
Principal Accounting Officer

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Alan Joslyn, 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 31st day of October, 2017

By: /s/ Alan F. Joslyn Ph.D.

Alan F. Joslyn Ph.D.

President and Chief Executive Officer

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Michael Sullivan, certify that:

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

Dated this 31st day of October, 2017

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

Certification of Chief Executive Officer

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

In connection with the Quarterly Report on Form 10-Q for the quarter ended June 30, 2017 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Alan Joslyn, 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/ Alan F. Joslyn Ph.D.

Name: Alan F. Joslyn Ph.D.
President and Chief Executive Officer

Date: October 31, 2017

Certification of Chief Financial Officer

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

In connection with the Quarterly Report on Form 10-Q for the quarter ended June 30, 2017 (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

Date: October 31, 2017